

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 259545-1 (S)    **Related reports:** 259545-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	11-Jul-2006	11-Jul-2006	0	14-Jul-2006	14-Jul-2006	DC		13-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Dehydration, Fall, Headache, Hyperventilation, Injection site pain, Muscle spasms, Speech disorder, Syncope, Vision blurred, Vomiting

**Symptom Text:** Immediately after injection complained of severe pain at site. Fell off table and fainted for approximately 10 - 15 seconds. Hyperventilated and cried progressing Chvostek's sign in hands and feet. Rebreathing into a bag progressing to clearing of symptoms. Complained of headache, blurry vision; Vision test was normal. Vomiting x 1 in parking lot and speech was momentarily inarticulate. Sent to ER. At ER neuro exam was normal except for word recall "coffee instead of coughing" "Sired instead of tired." Continued complaint of headache. Vomited x 2. All symptoms spontaneously cleared approximately 6 hours after incident. Overnight hospitalization for observation. Neurological evaluation before discharge was normal. Diagnosis also included dehydration. No fluids were taken from 7/10/2006 PM until IV in ER. Anion gap noted on chemistries and concentration of urine obtained after several hours of hydration. Discharge diagnosis: Dehydration, Vasovagal syncope secondary to shot vs pain at injection site. 7/17/06 Medical records received from reporter/provider which included vax record, office note of 7/11 & neuro consult of 7/15 by MD who also saw her in the hospital on 7/11-12. Neuro report indicates the CT scan of head was WNL & that dx is syncope probably precipitated by pain of vax injection along w/dehydration (no fluid intake since evening of 7/10 until IVF given in ER). As of 7/15 patient continued to have throbbing HA when bending down & also c/o strong heart beats occasionally. PMH: dehydration requiring hospitalization at age 3 yo. Also has hx of mild anxiety. Family hx: patient's mother has Fuch's disease (genetic degenerative corneal disease which her mother also had) & patient's father has depression. There are no siblings. It was noted that she had 3 episodes of emesis following vax along w/ sustaining mild concussion when fell from exam table which was characterized by brief episode of aphasia, slurred speech & possible right facial paresis noted only by patient's mother./ss 10/27/06 Received medic

**Other Meds:** NONE

**Lab Data:** LABS: WBC 11.7, neutros 84, lymphs 9.7.

**History:** Allergic rhinitis, spring pollens/ragweed/dust/mold

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 259545-2      **Related reports:** 259545-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	11-Jul-2006	11-Jul-2006	0	16-Mar-2007	21-Mar-2007	--	WAES0702USA03647	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Amblyopia, Fall, Headache, Pain, Speech disorder, Syncope, Syncope, Vomiting

**Symptom Text:** Information has been received via a company representative regarding an article as reported concerning a 14 year old female. On 11-JUL-2006, the patient was vaccinated with Gardasil (yeast). Immediately following the vaccination, the patient developed severe pain, fell off the examining table and experienced a 10 to 15 second fainting spell. It was reported that the patient ended up at the emergency room with a headache and speech problems. It was further that the patient had developed a syncopal episode combined with amblyopia (poor vision in one eye), abnormal speech and vomiting. At the time of this report, the outcome of the events were unknown. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 260144-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	25-Jul-2006	25-Jul-2006	0	26-Jul-2006	28-Jul-2006	CA		10-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0144F		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyskinesia, Hypertonia, Hypoaesthesia, Hypotonia, Pain, Syncope

**Symptom Text:** Patient received Hep A in right arm. Then received HPV in left arm. C/O pains, numbness. Started walking down hall fainted and had tonic/clonic movement for 15 sec.

**Other Meds:** NONE

**Lab Data:** BP 90/30 90/62 110/70 110/60, BG 114 Pulse OX 99, Strep culture neg.

**History:** NONE

**Prex Illness:** Viral with low grade fever

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 260907-1      **Related reports:** 260907-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	18-Jul-2006	18-Jul-2006	0	01-Aug-2006	02-Aug-2006	TX		02-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Swelling

**Symptom Text:** Swelling immediately after vaccine was administered, also rash. Ice pack was applied for 5 minutes and swelling decreases. Rash was still visible, but cream was applied.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** human papilloma virus, genital warts

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 260907-2      **Related reports:** 260907-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		15-Aug-2006	23-Aug-2006	TX	WAES0607USA04365	19-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Swelling

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on unspecified date was vaccinated with a 0.5 ml of HPV rLI 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced painful swelling " the size of a golf ball". The patient recovered by the "next day". Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** NONE

**History:** Unknown

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 261359-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	13-Jul-2006	Unknown		10-Aug-2006	11-Aug-2006	CA		11-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TD	UNKNOWN MANUFACTURER	C2457AA	5	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Unknown	
	MEN	UNKNOWN MANUFACTURER	U1920AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Lymphadenopathy, Nausea

**Symptom Text:** Dizzy, nauseated, developed axillary lymphadenopathy on side with Menactra inoculation.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 261575-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	12-Jul-2006	12-Jul-2006	0	15-Aug-2006	23-Aug-2006	CA	WAES0607USA041063	25-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 24 year old female with no medical history and no drug allergies who "last week" on approximately 12-JUL-2006 was vaccinated with HPV vaccine rLI 6 11 16 18 VLP vaccine (yeast) (0.5 ml). Concomitant therapy that day included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. The vaccines were administered in different arms. Subsequently, "12 hours after vaccination" the patient developed a rash throughout her whole body that lasted for two days. Unspecified medical attention was sought. The patient recovered two days after injection. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 261576-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	19-Jul-2006	19-Jul-2006	0	15-Aug-2006	23-Aug-2006	TX	WAES0607USA04314	19-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Pain, Swelling

**Symptom Text:** Information has been received from a physician concerning an approximately 16 year old female who on 19-JUL-2006 was vaccinated with HPV rLI 6 11 16 18 VLP vaccine (yeast). It was reported that "immediately after the injection", on 19-JUL-2006, the patient experienced pain and stinging at the injection site that lasted about 2 minutes and radiated the arm. The patient also reported feeling faint following the injection and experienced swelling. It was reported that the swelling went down but the pain persisted. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 261577-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	27-Jul-2006	27-Jul-2006	0	15-Aug-2006	23-Aug-2006	FL	WAES0607USA05727	23-Aug-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Syncope

**Symptom Text:** Information has been received from a registered nurse and a physician concerning a 16 year old female no medical history and no drug allergies who on 27-JUL-2006 was vaccinated intramuscularly in the right deltoid with the first dose of HPV rLI 6 11 16 18 VLP vaccine (yeast) (0.5 ml) (lot#653650/0702F). There were no concomitant medications. At the time of vaccination the patient experienced extreme pain at the injection site and fainted. The nurse reported that "the onset of the pain was immediate and lasted for 1 and a half to 2 minutes and then the patient passed out for 15 to 20 seconds and then was all right". The physician reported that the patient had a vasovagal syncopal episode, was not incontinent, and experienced no post- ictal state. Unspecified medical attention was sought. Subsequently, the same day the patient recovered from the extreme pain at the injection site and vasovagal syncopal episode. The patient did not wish to continue the series as a result of the adverse experience. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 261578-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	27-Jul-2006	27-Jul-2006	0	15-Aug-2006	23-Aug-2006	FL	WAES0607USA05775	23-Aug-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician and registered nurse concerning a 21 year old female with no medical history of drug allergies who on 27-JUL-2006 was vaccinated intramuscularly in the left deltoid with the first dose of HPV rLI 6 11 16 18 VLP vaccine (yeast) (0.5 ml) (lot#653650/0702F). Concomitant therapy included possible hormonal contraceptives (unspecified). On 27-JUL-2006 the patient experienced extreme pain at the injection site. The onset of the pain was immediate and lasted for 5 to 6 minutes and then resolved. Unspecified medical attention was sought. It was reported that the patient does not wish to continue the series of vaccinations. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 261579-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	28-Jul-2006	28-Jul-2006	0	15-Aug-2006	23-Aug-2006	TX	WAES0608USA00186	25-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who on 28-JUL-2006 was vaccinated with HPV rLI 3 11 16 18 VLP vaccine (yeast). Concomitant vaccination on 28-JUL-2006 included diphtheria toxoid (+) pertussis vaccine (unspecified) (+) tetanus toxoid. The patient stated that following vaccination on 28-JUL-2006, she " experienced a great deal of pain at the injection site". Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262070-1      **Related reports:** 262070-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	14-Aug-2006	22-Aug-2006	8	24-Aug-2006	25-Aug-2006	TX		25-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Patient developed a fine, red rash over torso and legs with itching reported on 8/22/2006.

**Other Meds:** OrthoTricyclen-Lo

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262070-2      **Related reports:** 262070-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	14-Aug-2006	19-Aug-2006	5	19-Sep-2006	21-Sep-2006	TX	WAES0608USA05899	05-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0637F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia, Rash

**Symptom Text:** Information has been received from a nurse practitioner concerning a 25 year old female with no pertinent medical history or drug allergies, who on 8/14/06 was vaccinated IM in the right deltoid with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) 0.5ml (lot 653937/0637F). There was no concomitant medication. On 8/19/06 the pt notified her physicians office stating that she had developed a rash on both legs and torso. The pt did not experienced a fever . Unspecified medical attention was sought. Treatment advised was an antihistamine. Subsequently, the pt recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262096-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	14-Aug-2006	14-Aug-2006	0	25-Aug-2006	28-Aug-2006	NY		28-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637C	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Chills, Cyanosis, Dizziness, Pallor, Pyrexia, Visual disturbance

**Symptom Text:** 1 hr after vaccination, pt reported to feel dizzy, weak, vision went black for a few seconds, got pale with purple lips x 1/2hr. Felt better after drinking OJ. Then got temp 101F and chills x 1 day.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262242-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	23-Aug-2006	23-Aug-2006	0	29-Aug-2006	31-Aug-2006	WA		31-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0706R	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fall, Fracture, Syncope vasovagal

**Symptom Text:** Vasovagal syncope shortly after receiving hep A and Gardasil vaccine, fell, hit nose on a drawer, loss of consciousness, sent to ER in transport broke nose.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262243-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	25-Jul-2006	25-Jul-2006	0	29-Aug-2006	31-Aug-2006	WA		31-Aug-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injury, Syncope, Tremor

**Symptom Text:** Vaccine given after physical. Pt fainted, vasovagal, hit head on carpeted cement floor. Loss of consciousness 1 min, had tonic posturing of right hand only some shaking.

**Other Meds:**

**Lab Data:** MRI next AM nl

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262451-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	17-Aug-2006	18-Aug-2006	1	01-Sep-2006	05-Sep-2006	CA	WAES0608USA04945	05-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Information has been received from a physician and a medical assistant concerning an 18 yr old female with no pertinent medical history or allergies, who on 17Aug06 was vaccinated IM with HPV rL1 6 11 16 18 VLP vaccine (yeast) (0.5ml) (lot 653650/0702F). There was no concomitant therapy. Subsequently, on 18Aug06 the pt developed a rash and hives. It was reported that this was not an injection site rash. The pt presented to her physician's office on 18Aug06 with hives all over her body. She was treated with oral diphenhydramine hydrochloride (Benadryl). It was also reported that the pt went to the ER twice on 19Aug06 and 20Aug06 and was treated with intravenous methylprednisolone sodium succinate (Solu Medrol) for the hives and welts all over her body and was released (it was also reported that the pt was given IV saline). The pt was scheduled to have a follow up visit with her physician within a week. At the time of this report, the pt had not recovered. The rash and generalized urticaria were felt to be other important medical events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262482-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	25-Jul-2006	26-Jul-2006	1	31-Aug-2006	01-Sep-2006	RI		01-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Feeling hot, Injection site hypersensitivity, Injection site mass, Injection site pain

**Symptom Text:** Hard painful lump at site of injection, red, site is hot to the touch. Pt states feeling "tired & run down" since injection.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262735-1 (S) **Related reports:** 262735-2; 262735-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	31-Jul-2006	13-Aug-2006	13	07-Sep-2006	08-Sep-2006	MS		22-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	42107AA	0	Gluteous maxima	Intramuscular	
	HPV4	MERCK & CO. INC.	0697F	0	Gluteous maxima	Intramuscular	

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Guillain-Barre syndrome, Hypoaesthesia, Paraesthesia, Proteinuria, Red blood cell sedimentation rate increased

**Symptom Text:** Vaccine was given on July 31 2006. She began having numbness and tingling in her feet and hands on or around August 13th or 14th, which persisted and slightly worsened until she was seen in our office on August 21st. Her neurological examination was normal, she had an elevated sedimentation rate (39), mild proteinuria, otherwise normal labs. MRI of her lumbosacral spine showed a (possibly old, chronic) subarachnoid cyst. She was referred to a neurologist and was seen on August 25th and was found to have weakened severely and was admitted to PICU for suspected Guillain-Barre syndrome which was confirmed by lumbar puncture. She was treated with IVIG with rapid improvement and has gone home. She is slowly improving and has residual weakness. Medical records including neurology received/reviewed. Final diagnosis is GBS. Was treated with IVIG as indicated on VAERS form. Per records pt has residual weakness. 12/19/06-progress notes received for and DC Summary DC DX: GBS.

**Other Meds:**

**Lab Data:** MRI of brain, cervical, thoracic and lumbosacral spine, drug screen, pregnancy test, sed rate, Blood count, blood chemistries, Lumbar Puncture.

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262735-2 (S) **Related reports:** 262735-1; 262735-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	31-Jul-2006	13-Aug-2006	13	15-Dec-2006	29-Dec-2006	MS	200602493	29-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	42107A		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0697F		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Guillain-Barre syndrome, Hypoaesthesia

**Symptom Text:** Initial report received on 22/Sep/2006 from the Centers for Disease Control and Prevention (CDC). A 16 year old female patient had received an intramuscular, first dose injection of Menactra, lot number reported as 42017AA; and an intramuscular, first dose injection of Human Papillomavirus Recombinant Vaccine, lot number 0697F; on 31/Jul/2006. On or around 13/Aug/2006, the patient experienced numbness and tingling in her feet and hands. The symptoms persisted and had slightly worsened at the time of her examination by a physician on 21/Aug/2006. At that time, "neurological examination was normal." She had an elevated sedimentation rate (39), mild proteinuria, and "otherwise normal labs." Other laboratory tests performed, (specific results not provided), included a blood count, blood chemistries, pregnancy test and drug screen. MRI was performed of the brain, cervical, thoracic and lumbosacral spine. MRI of the lumbosacral spine showed a (possibly old, chronic) subarachnoid cyst. The patient was referred to and examined by a neurologist on 25/Aug/2006. During that exam, she was found to have weakened severely. She was admitted to a pediatric intensive care unit for suspected Guillain Barre syndrome which was confirmed by lumbar puncture. Lumbar puncture results were not provided. She was treated with IVIG with rapid improvement; and after five days of hospitalization, was discharged to home. Per the reported, she is slowly improving and had residual weakness. Recovery status was documented as unknown. As per the CDC this case was confirmed by CISA (Clinical Immunization Safety Assessment network) as being Guillain Barre syndrome following Menactra vaccination. Follow-up information received 27/Sep/2006 from the Centers for Disease Control and Prevention. Per the reported, the patient was hospitalized on 25/Aug/2006. The date of discharge was not reported. The patient's Guillain Barre Syndrome was confirmed by lumbar puncture testing.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 21

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262735-3 (S) **Related reports:** 262735-1; 262735-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	31-Jul-2006	13-Aug-2006	13	08-Mar-2007	09-Mar-2007	MS	200602493	09-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	42107A	0	Gluteous maxima	Intramuscular	
	HPV4	MERCK & CO. INC.	0697F	0	Gluteous maxima	Intramuscular	

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Areflexia, Asthenia, Asthenia, Cyst, Guillain-Barre syndrome, Hypoaesthesia, Hypoaesthesia, Laboratory test normal, Lumbar puncture, Muscular weakness, Nerve conduction studies abnormal, Neurological examination normal, Nuclear magnetic resonance imaging abnormal, Occupational therapy, Paraesthesia, Physiotherapy, Pregnancy test, Proteinuria, Red blood cell sedimentation rate increased

**Symptom Text:** Initial report received on 22/Sep/2006. A 16-year-old female patient had received an intramuscular, first dose injection of Menactra, lot number reported as 42107AA (not a valid manufacturer lot number), and intramuscular, first dose injection of Gardasil, lot number 0697F, on 31/Jul/2006. On or around 13/Aug/2006 or 14/Aug/2006, the patient experienced numbness and tingling in her feet and hands. The symptoms persisted and had slightly worsened at the time of her examination by a physician on 21/Aug/2006. At that time, neurological examination was normal. She had an elevated sedimentation rate (39), mild proteinuria, and otherwise normal labs. Other laboratory tests performed, (specific results not provided), included a blood count, blood chemistries, pregnancy test and drug screen. MRI was performed of the brain, cervical, thoracic and lumbosacral spine. MRI of the lumbosacral spine showed a (possibly old, chronic) subarachnoid cyst. The patient was referred to and examined by a neurologist on 25/Aug/2006. During that exam, she was found to have weakened severely. She was admitted to a pediatric intensive care unit for suspected Guillain Barre syndrome which was confirmed by lumbar puncture. Lumbar puncture results were not provided. She was treated with IVIG with rapid improvement, and after five days of hospitalization, was discharged to home. Per the reporter, she is slowly improving and has residual weakness. Recovery status was documented as unknown. This case was confirmed as being Guillain Barre syndrome following Menactra vaccination. Follow-up information received on 27/Sep/2006. Per the reporter, the patient was hospitalized on 25/Aug/2006. The date of discharge was not reported. The patient's Guillain Barre syndrome was confirmed by lumbar puncture testing. Literature citation, update: Guillain Barre syndrome among recipients of Menactra Meningococcal conjugate vaccine June 2005-September 2006. Follow-up information received on 19 October 2006 from a health care professional concerning a publication.

**Other Meds:**

**Lab Data:** Blood chemistries normal, urinalysis Albuminuria, nerve conduction study GBS, MRI of LS spine, brain, Cervical, thoracic possibly old, Chronic subarachnoid cyst, blood drug screen normal, erythrocyte elevated, serum beta human normal, CBC n

**History:** The patient was well on the day of immunization.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262742-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	01-Aug-2006	01-Aug-2006	0	08-Sep-2006	11-Sep-2006	VA	WAES0608USA06904	11-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Convulsion, Injection site pain

**Symptom Text:** Information has been received from a physician concerning a 15 year old female patient who in August 2006, was vaccinated IM with a dose of HPV rL1 6 11 16 18 VLP vaccine. Prior to administration, the patient received the following concomitant therapy: hepatitis A vaccine and meningococcal ACYW conjugate vaccine. The patient had a mild seizure after receiving HPV rL1 6 11 16 18 VLP vaccine injection. She also complained of a great deal of pain at injection site. Medical attention was sought. It was reported that the patient recovered 1 day after the event. Her mother called the physician at home 1 day after the injections to state that the patient was fine. Upon internal review, mild seizure was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262743-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Aug-2006	23-Aug-2006	1	08-Sep-2006	11-Sep-2006	--	WAES0608USA05911	11-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Chest discomfort, Erythema, Oedema peripheral

**Symptom Text:** Information has been received from a nurse concerning her 17 year old daughter with asthma who on 8/22/06 was vaccinated IM with HPV rL1 6 11 16 18 VLP vaccine (0.5ml). On 8/23/06 the patient developed a swollen thumb and her palms became red and hot. The patient later developed a tightness in her chest. The patient was immediately taken to a physician (an allergist who was the mother's employer) who immediately gave the patient a huge dose of cetirizine hydrochloride and acetaminophen as an intervention. The patient was not hospitalized and did not get to the emergency room. It was unknown if the affected site was the same arm that the vaccine was given in. The patient subsequently recovered from the red and hot palms, swollen thumb, and chest tightness on an unspecified date. The red and hot palms, swollen thumb and chest tightness were felt to be other important medical events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262785-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	10-Aug-2006	15-Aug-2006	5	08-Sep-2006	11-Sep-2006	TX		11-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Movement disorder

**Symptom Text:** 09/01/06 pt call with c/o decreased ROM in L arm 5 days after injection administration to current date. Tx with Naproxen x 10 days and Tylenol #3.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262809-1      **Related reports:** 262809-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Aug-2006	27-Aug-2006	4	11-Sep-2006	12-Sep-2006	GA	WAES0608USA06930	13-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0689F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Hypokinesia, Lymphadenopathy, Lymphadenopathy, Skin nodule

**Symptom Text:** Information had been received from a healthcare worker concerning a 17 year old female pt with a sulfonamide allergy who on 8/23/06 was vaccinated IM in left upper arm with a dose of HPV rL1 6 11 16 18 VLP vaccine yeast, lot 653736/089F. There was no concomitant medication. it was reported that 5 days after vaccination, on 8/27/06, the pt developed lymph node swelling in the clavicle area, described as grape size. The pt complained of interference of upper arm movement and felt something was present in the clavicle area. Unspecified blood work was done. On 8/29/06 a CAT scan was performed and lump was described as having 2 smaller and 1 larger lymph nodes involved. On 8/30/06 the pt was scheduled for surgery to have the lymph nodes removed and biopsied. As of the report date, the pt had not recovered. The reporter felt that the lymph node swelling and interference with upper arm movement were other important medical events (OMIC). Additional information has been requested. 10/13/06 Received medical records from hospital which reveal patient seen in ER 8/29/06 for enlarged lymph node left supraclavicular area which was tender to palpation. Final Dx: lymphadenopathy. 8/31/06 surgical biopsy done of left node & several other lymph nodes were palpated & sent to lab.

**Other Meds:** NONE

**Lab Data:** Computed axial 8/29/06 lump having 2 smaller and 1 larger lymph nodes involved. LABS: all WNL. CT of chest/abd/pelvis revealed 14mm circumscribed noe in left supraclavicular node & several less than 1 cm nodes in bilateral axillary areas

**History:** Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262809-2 (S)    **Related reports:** 262809-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Aug-2006	27-Aug-2006	4	13-Sep-2006	18-Sep-2006	GA		19-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Lymphadenopathy

**Symptom Text:** Enlarged nodes in the clavicle area.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262847-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	06-Sep-2006	06-Sep-2006	0	11-Sep-2006	12-Sep-2006	KY		12-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2117AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Joint range of motion decreased, Pain, Pain, Swelling

**Symptom Text:** Patient said right deltoid area, became red, swollen, quarter size hard knot, achy, painful to raise arm. Knot was hot to touch.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** yearly examination

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262872-1      **Related reports:** 262872-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	02-Sep-2006	02-Sep-2006	0	12-Sep-2006	13-Sep-2006	FL		13-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	08007	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope, Tonic clonic movements

**Symptom Text:** Immediately after vaccine administration patient had syncopal episode with tonic posturing fell from table. Responded with gentle stimulation versus normal 5 minutes post regaining full consciousness.

**Other Meds:**

**Lab Data:** vital signs stable

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 262872-2      **Related reports:** 262872-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03649	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fall

**Symptom Text:** Information has been received via a company representative regarding an article concerning a 11 year old female. On an unspecified date, the patient was vaccinated with Gardasil. Subsequently the patient fell from the examining table. At the time of this report, the outcome of the event was unknown. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263024-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.5	M	11-Sep-2006	Unknown		13-Sep-2006	14-Sep-2006	NC		14-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	PNC	LEDERLE LABORATORIES	B08682H	2	Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	DTAP	AVENTIS PASTEUR	U1751AB	3	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Medication error

**Symptom Text:** Wrong vaccine was given Gardasil was given instead of Hep A by mistake.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263032-1 (S) **Related reports:** 263032-2; 263032-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Jul-2006	20-Jul-2006	13	14-Sep-2006	15-Sep-2006	IL		03-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2069AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Dehydration, Gait disturbance, Guillain-Barre syndrome, Paraesthesia, Psychomotor hyperactivity

**Symptom Text:** Guillain Barre. She was well on day of immunization but later said she was weak and several months this was not objectively noticed then, but shortly after the vaccine. 9/28/06 Received medical records from neurologists which reveal patient seen by PCP 7/31/06 with complaint of loss of strength over past 3 mos. Labs were done by PCP & showed mild dehydration & elevated neutrophils, eos were absent. Patient referred to neuro & initial eval on 8/3 reveals patient noted weakness beginning in June which had progressively worsened. Symptoms included tingling sensation at tip of fingers & significant weakness to the point she could not do her own hair. Birth history was WNL & only PMH is of ADD & has been on Adderall for about 1 year as well as BCP. Exam showed definite weakness of all extremities, esp upper extremities, & neck. Reflexes were absent in legs. Gait was normal but had difficulty taking steps w/o support & could not rise from sitting w/o help. Normal CPK made dx difficult & EMG/NCS was done on 8/4 which was strongly positive for GBS & copy of test included with records. Treated with IVIG x 2 days & placed in rehab facility on 8/5/06 for eval & therapy then received home PT. Seen by neuro next on 8/24 which showed improvement but still with weakness especially in the hands. Now able to rise from sitting on floor w/o support. Still no reflexes in legs. Complete but slow recovery was expected at that time/ss 9/28/06 Received medical records from hospital which reveal patient admitted 8/4/-8/6/06 for IVIG & PT./ss

**Other Meds:** Adderall

**Lab Data:**

**History:** Attention deficit disorder.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263032-2 (S) **Related reports:** 263032-1; 263032-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Jul-2006	20-Jul-2006	13	15-Dec-2006	29-Dec-2006	IL	200602494	29-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2069A	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Guillain-Barre syndrome

**Symptom Text:** Initial report received on 22/Sep/2006 from the Centers for Disease Control and Prevention. An "approximately" 16 year old female patient, with a history of attention deficit disorder, had received an intramuscular, first dose injection of Menactra, lot number U2069AA; and an intramuscular, first dose injection of Gardasil, lot number 06373F; on 07/Jul/2006. She had no illness at the time of vaccination. Concomitant medications included Adderall 50mg. Thirteen days post-vaccination, the patient experienced weakness "times several months." Although the report is difficult to read, it appears the reporter had written, "this was not objectively noticed then, but mostly after the vaccine." The event required hospitalization for one day. The patient was examined by a neurologist and treated with IVIG. The event was reported as Guillain Barre syndrome. The patient recovered from the event. As per the CDC this case has not yet been confirmed by CISA (Clinical Immunization Safety Assessment network) as being Guillain Barre syndrome following Menactra vaccination. The onset of symptoms may have been prior to vaccination. Follow up information, received on 27/Sep/2006 from the Centers for Disease Control and Prevention. Per the report, "there is doubt regarding the date of onset. The symptoms may have started in June of 2006 prior to vaccination. The neurologist's history of weakness goes back to late June before immunization. The primary care physician's report on the VAERS form was based on a physician assistant's screening history prior to vaccine administration that was not specific for neurologic symptoms." Per the CDC comments regarding GBS confirmation status, "Unless we get other information from the patient/family to the contrary, the neurologist's consult should stand, and this would not be a post-vaccine Guillain Barre case."

**Other Meds:** Adderall, oral contraceptives

**Lab Data:**

**History:** The patient had a history of attention deficit disorder for which she took Adderall 50mg.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263032-3 (S) **Related reports:** 263032-1; 263032-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Jul-2006	20-Jul-2006	13	21-Feb-2007	22-Feb-2007	IL	200602494	22-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2069AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Asthenia, Dehydration, Gait disturbance, Guillain-Barre syndrome, Hyperkinesia, Paraesthesia

**Symptom Text:** Initial report received on 22/Sep/2006. An "approximately" 16 year old female patient, with a history of attention deficit disorder, had received an intramuscular, first dose injection of Menactra, lot number U2069AA, and in intramuscular, first dose injection of Gardasil, Lot number 0637F, on 07/Jul/2006. She had no illness at the time of vaccination. Concomitant medications included Adderall 50 mg. Thirteen days post vaccination, the patient experienced weakness "times several months." Although the report is difficult to read, it appears the reporter had written, "this was not objectively noticed then, but mostly after the vaccine." The event required hospitalization for one day. The patient was examined by a neurologist and treated with IVIG. The event was reported as Guillain Barre syndrome. The patient recovered from the event. This case has not yet been confirmed by CISA (Clinical immunization safety assessment network) as being Guillain Barre syndrome following Menactra vaccination. The onset of symptoms may have been prior to vaccination. Follow-up information received on 27/Sep/2006. Per the reporter, "there is doubt regarding the date of onset. The symptoms may have started in June of 2006 prior to vaccination. The neurologist's history of weakness goes back to late June before immunization. The primary care physician's report on the VAERS form was based on a physician assistant's screening history prior to vaccine administration that was not specific for neurologic symptoms. Comments regarding GBS confirmation status, "unless we get other information from the patient/family to the contrary, the neurologist's consult should stand, and this would not be a post vaccine Guillain Barre case. Follow up information received on 12 February 2007 from a manufacturer, whose reference number is WAES0702USA00828. This manufacturer received the original report. This manufacturer reported the lot number for Gardasil as being 653937/0637F. The lot number in the case was amended from 0637F to 653937/0637F per this ne

**Other Meds:** Adderall, oral contraceptives

**Lab Data:**

**History:** The patient had a history of attention deficit disorder for which she took Adderall 50 mg.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263185-1      **Related reports:** 263185-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Aug-2006	29-Aug-2006	0	19-Sep-2006	20-Sep-2006	NY		20-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysphagia

**Symptom Text:** 2 hours after Gardasil Administration pt developed inability to swallow. Advised to take Benadryl by covering physician and go to ER. In ER not given EPI but Solumedrol to take for 5 days.

**Other Meds:** Singulair, Allegra, Flovent, Rhinocort

**Lab Data:**

**History:** Asthma, Penicillin allergy.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263185-2      **Related reports:** 263185-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Aug-2006	29-Aug-2006	0	16-Mar-2007	21-Mar-2007	--	WAES0702USA03648	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysphagia

**Symptom Text:** Information has been received via a company representative regarding an article concerning a 15 year old female with asthma. On 29-AUG-2006, the patient was vaccinated with Gardasil. Concomitant therapy included four unspecified therapies for the treatment of asthma. On 29-AUG-2006, two hours post vaccination, the patient developed difficulty swallowing prompting a visit to the emergency room. At the time of this report, the outcome of the event was unknown. No further information is available.

**Other Meds:** Therapy unspecified

**Lab Data:** UNK

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263200-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	25-Jul-2006	25-Jul-2006	0	19-Sep-2006	21-Sep-2006	--	WAES0608USA00410	19-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a pharmacist concerning her daughter who on approximately 25-JUL-2006 was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). On approximately 25-JUL-2006 the patient experienced soreness at the injection site that lasted approximately one week and at the time of this report had not resolved. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263201-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	02-Aug-2006	02-Aug-2006	0	19-Sep-2006	21-Sep-2006	NY	WAES0608USA01129	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female who on 02-AUG-2006 was vaccinated with the first dose of HPV rLi 3 11 16 18 VLP vaccine (yeast). It was reported that the patient fainted "shortly after receiving the vaccination". The nurse did not feel the experience was vaccine related and stated "the patient was very uneasy with the idea of an injection". The patient subsequently recovered "shortly after fainting". Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263202-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	03-Aug-2006	04-Aug-2006	1	19-Sep-2006	21-Sep-2006	CO	WAES0608USA01355	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Rash papular, Skin burning sensation, Skin ulcer

**Symptom Text:** Information has been received from a registered nurse concerning a 14 year old female with seasonal allergies who was exposed to roseola on 25-JUL-2006 and had a fever on 02-AUG-2006. On 03-AUG-2006, the patient was vaccinated intramuscularly with a 0.5 ml dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653937/0637F). Concomitant therapy included loratadine (CLARITIN) and vitamins (unspecified). On 04-AUG-2006, the patient developed an extensive rash. The patient discovered the rash at 7 am on the back of her legs. It was reported that the rash spread to her back and shoulders and had started to spread to her abdomen. The rash consisted of non vesicular papular single lesions that were slightly larger than a pinpoint and too numerous to count. The lesions were described as "burning and itchy". Unspecified medical attention was sought. At the time of the report, the patient's rash persisted. Additional information has been requested.

**Other Meds:** CLARITIN, vitamins (unspecified)

**Lab Data:** NONE

**History:** MEDICAL HISTORY: fever, CONCURRENT CONDITIONS: seasonal allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263203-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	09-Aug-2006	09-Aug-2006	0	19-Sep-2006	21-Sep-2006	TX	WAES0608USA02569	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Influenza like illness, Nausea, Pain, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 29 year old female with no pertinent medical history and no history of drug reactions allergies who on 8/9/06 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653937/0637F) inappropriate schedule of vaccina administration. There was no concomitant medication. On 8/9/06 the pt experienced a fever, nausea, body aches, joint pains and experienced flu like symptoms. Unspecified medical attention was sought. At the time of this report, the pt was recovering from the fever, nausea, body aches, joint pains and flu like symptoms.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263204-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	18-Jul-2006	18-Jul-2006	0	19-Sep-2006	21-Sep-2006	KY	WAES0608USA02804	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0640F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dysarthria, Injection site pain, Musculoskeletal stiffness, Pallor, Shock, Skin papilloma, Syncope

**Symptom Text:** Initial and follow up information has been received from a 21 year old female with breast implants and had a history of abnormal pap test and dysplasia and from a nurse practitioner. On 7/18/06 the pt was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653650/0640F). Concomitant therapy included ethinyl estradiol + norgestimate (Ortho Lo). On 7/18/06, immediately following vaccination, the pt experienced slurred speech for approx 3 to 4 minutes and reported that she felt as if her body went into shock. She noted that her fingers curled into a fist and her fingers and hands stiffened up. She reported that the later symptoms lasted for approx 25 to 30 minutes. Also approx two weeks after receiving the vaccination, she began to have some pain and stiffness in her upper left arm and shoulder in the same arm she had received the injection. Unspecified medical attention was sought. At the time of this report, the pain and stiffness in the left arm and shoulder had not resolved. The pt also reported that although she had never had nay type of genital warts in the past, on approx 8/4/06 she noted she had small genital warts which were confirmed by her health care professional. In follow up th nurse practitioner reported conflicting information that what the pt described was not what she and another nurse witnesses. The nurse practitioner stated that following the injection the pt appeared pale and almost fainted. The pt became woozy and could speak clearly. The pt was attended to by both the nurse practitioner and another nurse. The pt was diagnosed with having a near syncopal episode. The pt was treated with a cool compress and she recovered quickly and was noted as fine afterwards. The pts blood pressure was fine noted at 130/80 mmHg. it was reported that the pt did not experience any drop in hart rate, did not loose consciousness, did not seize and did not experience wheezing. The nurse practitioner did not see what she would describe as any adverse reaction to the vaccines and described th

**Other Meds:** Ortho Tri cyclen Lo

**Lab Data:** Blood pressure 7/18/06 130/80

**History:** Pap smear abnormal, Dysplasia, Breast Prosthesis user.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263205-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Aug-2006	11-Aug-2006	3	19-Sep-2006	21-Sep-2006	--	WAES0608USA02806	05-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a nurse concerning two female pts (WAES0609USA01112) who on approx 8/8/06 were vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast (lot not provided). It was reported that after receiving the vaccinations both pts fainted. Additional information regarding the pts was not provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263206-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	14-Aug-2006	14-Aug-2006	0	19-Sep-2006	21-Sep-2006	TN	WAES0608USA03642	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Myalgia, Nausea, Pyrexia, Vomiting

**Symptom Text:** Information has been received from a physician concerning an 18 year old who on 14-AUG-2006 was vaccinated (yeast). Concomitant therapy included an unspecified therapy ("ESTRASTEP"). On 14-AUG-2006 the patient experienced profuse nausea, vomiting, low grade fever and myalgia. The patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** (therapy unspecified)

**Lab Data:** body temperature 08/14/06 "low grade fever"

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263207-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	08-Aug-2006	Unknown		19-Sep-2006	21-Sep-2006	--	WAES0608USA03841	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female who on 08-AUG-2006 was vaccinated with the first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO TRI CYCLEN). Following the vaccination, on an unspecified date in August 2006, the patient experienced diarrhea. Unspecified medical attention was sought. At the time of this report, the outcome of the diarrhea was unknown. Additional information has been requested.

**Other Meds:** ORTHO TRI CYCLEN

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263208-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		19-Sep-2006	21-Sep-2006	NJ	WAES0608USA03934	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a pt who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast. Subsequently the pt experienced hives. No further details were provided, and at the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263209-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	15-Aug-2006	15-Aug-2006	0	19-Sep-2006	21-Sep-2006	PA	WAES0608USA03961	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a nurse concerning a 19 year old female with no pertinent medical history or drug reactions allergies who on 8/15/06 was vaccinated IM with the first dose of HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653650/0702F). Concomitant therapy included Menactra. On an unspecified date the pt was given tuberculin purified protein derivative. On 8/15/06, 5 minutes after vaccination with HPV rL1 6 11 16 18 VLP vaccine yeast, the pt became faint. The pt was given water and chocolate as treatment. Subsequently, the pt recovered on 8/15/06. Additional information has been requested.

**Other Meds:**

**Lab Data:** Tuberculin skin test

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263210-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	15-Aug-2006	15-Aug-2006	0	19-Sep-2006	26-Sep-2006	PA	WAES0608USA03962	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a 20 year old female with a penicillin allergy, drug hypersensitivity to cefaclor (CECLOR) and no other pertinent medical history reported. On 15-AUG-2006, the patient was vaccinated intramuscularly with HPV rLi 6 11 16 18 VLP vaccine (yeast) (Lot#653650/0702F). Concomitant therapy included paroxetine HCL (PAXIL), bupropion HCL (WELLBUTRIN) and famotidine. It was reported that the patient became faint within 5 minutes of vaccination with HPV rLi 6 11 16 18 VLP vaccine (yeast). The patient was given a soda to drink as treatment. There were no laboratory diagnostic studies performed. On 15-AUG-2006, the patient recovered from the event. Additional information has been requested.

**Other Meds:** WELLBUTRIN, PEPCID, PAXIL

**Lab Data:** NONE

**History:** CONCURRENT CONDITIONS: Penicillin allergy, drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263211-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	11-Aug-2006	12-Aug-2006	1	19-Sep-2006	26-Sep-2006	FL	WAES0608USA03973	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Initial and follow up has been received from a healthcare worker in a physician's office concerning her 19 year old daughter who was a student and an unspecified person at the physician's office. On 11-AUG-2006, at 11:15 am, the patient was vaccinated intramuscularly in the deltoid with the first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (Lot#653650/0702F). Other concomitant therapy included an unspecified therapy ("LO-L"). On 12-AUG-2006 (previously reported as 14-AUG-2006) the patient developed pain in her right arm and ribcage on the same side where the vaccine was administered. On 16-AUG-2006, the patient had recovered from the events. No further information is available.

**Other Meds:** (therapy unspecified)

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263212-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	14-Aug-2006	14-Aug-2006	0	19-Sep-2006	26-Sep-2006	AR	WAES0608USA04253	20-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F		Unknown	Subcutaneously	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Information has been received from a registered nurse concerning a 19 year old female with no pertinent medical history or drug reactions/allergies who on 14-AUG-2006 was vaccinated subcutaneously with "the standard dose" of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653736/0689F). There was no concomitant medication. ON 15-AUG-2006 the patient developed a rash on her face and experienced itching on her face. It was reported that the rash was only on the patient's face and not at the injection site or any other part of her body. The patient was instructed to take diphenhydramine hydrochloride (BENADRYL). On 17-AUG-2006, in the morning, the patient was instructed to take diphenhydramine hydrochloride (BENADRYL). On 17-AUG-2006, in the morning, the patient called her physician's office and reported that "it was responding to diphenhydramine hydrochloride (BENADRYL) but had not fully recovered". The patient was scheduled to be seen by her physician on 17-AUG-2006. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263213-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	17-Aug-2006	17-Aug-2006	0	19-Sep-2006	26-Sep-2006	PA	WAES0608USA04330	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 14 year old female with no pertinent medial history or drug reactions/allergies, who on 17-AUG-2006 was vaccinated intramuscularly with HPV rLI 6 11 16 18 VLP vaccine (yeast) (lot#653650/0702F). There was no concomitant medication. On 17-AUG-2006, 15 minutes after receiving the vaccination, the patient "passed out" in the car on her way home. The patient was driven back to the physician's office, where she "woke up and was given soda and cold compresses". There was no reactions at the injection site and the patient had no additional reactions. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263214-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	16-Aug-2006	16-Aug-2006	0	19-Sep-2006	26-Sep-2006	MA	WAES0608USA04456	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female who on 16-AUG-2006 was vaccinated intramuscularly in the deltoid with HPV rLi 6 11 16 18 VLP vaccine (yeast) (0.5 ml). The patient subsequently experienced severe injection site pain. It was reported that the patient remarked that the injection really hurt and that the pain flew down her arm. The patient rubbed her arm for a few minutes after receiving the injection. The patient subsequently went home and the nurse had not heard back from the patient. The patient was to be followed by her physician's office. The nurse also reported that she had not agitated the syringe prior to injection. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263215-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	10-Aug-2006	10-Aug-2006	0	19-Sep-2006	26-Sep-2006	CA	WAES0608USA04457	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Information has been received from a physician concerning an 18 year old female with no pertinent medical history or drug reactions/allergies, who on 10-AUG-2006 was vaccinated intramuscularly with HPV rLi 6 11 16 18 VLP vaccine (yeast) (0.5 ml) (lot#653650/0702F). Concomitant therapy included ethinyl estradiol/norgestimate (TRINESSA). On 10-AUG-2006 the patient experienced multiple episodes of vomiting. Unspecified medical attention was sought. Subsequently, the patient recovered from the vomiting within 48 hours. Additional information has been requested.

**Other Meds:** TRINESSA

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263216-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	17-Aug-2006	17-Aug-2006	0	19-Sep-2006	26-Sep-2006	CA	WAES0608USA04465	26-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with no pertinent medical history or drug reactions/allergies, who on 17-AUG-2006 was vaccinated intramuscularly with HPV rLi 6 11 16 18 VLP vaccine (yeast) (0.5 ml) (lot#653650/0702F). There was no concomitant medication. On 17-aug-2006 the patient experienced nausea. Unspecified medical attention was sought. At the time of this report, the patient's nausea persisted. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263217-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	18-Aug-2006	18-Aug-2006	0	19-Sep-2006	21-Sep-2006	MA	WAES0608USA04485	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Syncope

**Symptom Text:** Information has been received from a nurse concerning an 18 year old female with no known allergies and no other pertinent medical history reported. On 18-AUG-2006, the patient was vaccinated intramuscularly in the deltoid with a 0.5 ml "single dose prefilled syringe" of HPV rLi 6 11 16 18 VLP vaccine (yeast) (Lot#653650/0702F). There were no concomitant medication reported. On 18-AUG-2006, the patient developed severe injection site pain with HPV rLi 6 11 16 18 VLP vaccine (yeast) injection. The patient remarked that "it hurt and felt that the injection went to her head". The nurse reported that the patient felt faint immediately after the vaccination. The nurse had the patient lay down. It was reported that the patient "got up after 1 minute and said that she was ok.". The nurse reported that the "patient left the office immediately after this and the nurse was following up with the patient later today to make sure that the patient was ok." The nurse reported that she had not agitated the syringe prior to injection. The patient sought unspecified medical attention. There were no laboratory diagnostic studies performed. On 18-AUG-2006, the patient recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263218-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	CA	WAES0608USA04520	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site reaction

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated intramuscularly with the first dose of 0.5 ml of HPV rLi 6 11 16 18 VLP vaccine (yeast). On an unspecified date, the patient developed "burning at the injection site". It was reported that the event improved after medical attention. It was reported that the event improved after "stopping therapy". At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263219-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	CA	WAES0608USA05355	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date, was vaccinated intramuscularly with the first dose of 0.5 ml of HPV rLi 6 11 16 18 VLP vaccine (yeast). The day after receiving HPV rLi 6 11 16 18 VLP vaccine (yeast), the patient developed "flu-like symptoms" (date unknown). The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263220-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	21-Aug-2006	21-Aug-2006	0	19-Sep-2006	21-Sep-2006	IL	WAES0608USA05414	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a 22 year old female with an allergy to meperidine hydrochloride (DEMEROL) who on 21-AUG-2006 was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO TRI CYCLEN). On 21-AUG-2006, following the vaccination, the patient fainted. Unspecified medical attention was sought. At the time of this report, the patient was recovering. Additional information has been requested.

**Other Meds:** ORTHO TRI CYCLEN

**Lab Data:** NONE

**History:** CONCURRENT CONDITIONS: drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263221-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	AZ	WAES0609USA00390	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site vesicles

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who in 2006 was vaccinated with her first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, she was vaccinated with her second dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, she developed a blister at the injection site. Medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263222-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	AZ	WAES0609USA00391	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site vesicles

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who in 2006 was vaccinated with her first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, she was vaccinated with her second dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, she developed a blister at the injection site. Medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263223-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Aug-2006	11-Aug-2006	3	19-Sep-2006	21-Sep-2006	--	WAES0609USA01112	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from a nurse concerning two female patients who on approximately 08-AUG-2006 were vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast).

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263224-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	--	WAES0608USA05808	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a licensed practical nurse concerning female college students 9(exact number of patients unspecified) who were vaccinated intramuscularly with HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently the patients experienced injection site (deltoid) pain. At the time of this report, the outcome of the event was unknown. Further attempts are being made to identify the exact number of patients and identifiers of the patients involved in this report.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263225-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	19-Jul-2006	19-Jul-2006	0	19-Sep-2006	21-Sep-2006	TX	WAES0608USA06029	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Erythema, Injection site pain, Pain

**Symptom Text:** Information has been receiving from a registered nurse concerning a 15 year old female with no medical history who on 19-JUL-2006 was vaccinated in the right deltoid with the first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653937/0637F). Subsequently, on approximately 19-JUL-2006, the patient experienced burning at the injection site that lasted approximately 60 to 90 seconds and her arm became red and painful enough to cause the patient to cry. The patient subsequently recovered from the pain in the extremity, erythema, and injection site irritation. Additional information has been requested. The registered nurse also reported that the patient's sister experienced pain in the extremity, erythema, and injection site irritation following vaccination with HPV rLi 6 11 16 18 VLP vaccine (yeast) (LOT#653937/0637F).

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263226-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	NY	WAES0608USA06089	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 24 year old female patient who in approximately August 2006, was vaccinated with a dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced pain in joints and developed low grade fever. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263227-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	07-Aug-2006	07-Aug-2006	0	19-Sep-2006	21-Sep-2006	MA	WAES0608USA06260	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a 20 year old female patient who on 07-AUG-2006 was vaccinated intramuscularly with her first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653650/0702F). Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). The patient stated that "right after getting the shot" she experienced pain in the upper arm on and off throughout the day. She also stated that the pain "feels like she has a knife in her arm". Unspecified medical attention was sought. The patient was treated with Ibuprofen. As of the report date, she was recovering. Additional information has been requested.

**Other Meds:** YAZ

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263228-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	25-Aug-2006	25-Aug-2006	0	19-Sep-2006	21-Sep-2006	RI	WAES0608USA06297	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Skin burning sensation

**Symptom Text:** Information has been received from a nurse practitioner concerning a 27 year old female who on 25-AUG-2006 was vaccinated with a dose of HPV rLi 6 11 16 18 VLP vaccine (yeast), lot#653650/0702F. During the administration of the vaccine, part of the fluid went into the patient's arm, the patient's arm, the patient pulled away and the remainder went on the skin (no adverse reaction noted). The patient complained of burning during administration. Medical attention was sought. The patient received a repeat dose with no burning noted. Patient's status was reported as recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263229-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	19-Jul-2006	19-Jul-2006	0	19-Sep-2006	21-Sep-2006	TX	WAES0608USA06310	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Erythema, Pain

**Symptom Text:** Information has been received from a registered nurse concerning a 17 year old female with no medical history who on 19-JUL-2006 was vaccinated in the right deltoid with the first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653937/0637F). Subsequently on approximately site that lasted approximately 60 to 90 seconds and her arm became red and painful enough to cause the patient to cry. The patient subsequently recovered from the pain in the extremity, erythema, and injection site irritation. Additional information has been requested. The registered nurse also reported that the patient's sister experienced pain in the extremity, erythema, and injection site irritation following vaccination with HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653937/0637F).

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263230-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		19-Sep-2006	21-Sep-2006	NY	WAES0608USA06470	21-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 19 year old female patient who in approximately August 2006, was vaccinated with a dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced pain in joints and developed low grade fever. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263231-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	M	Unknown	Unknown		19-Sep-2006	21-Sep-2006	NY	WAES0608USA06471	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Pyrexia

**Symptom Text:** Information has been received from a physician concerning an 18 year old male patient who in approximately August 2006, was vaccinated with a dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced pain in joints and developed low grade fever. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263232-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	21-Aug-2006	21-Aug-2006	0	19-Sep-2006	21-Sep-2006	NJ	WAES0608USA06478	21-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from an other health professional concerning a 26 year old female in sales with no pre-existing allergies, birth defects or medical conditions reported. On 21-AUG-2006, in the pm, the patient was vaccinated in the left deltoid with the first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653650/0702F). Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO TRI CYCLEN). There were no illness noted at the time of vaccination. On 21-AUG-2006, in the pm, the patient experienced an unspecified adverse event. The patient went to the emergency room and it was reported that she "went home that day". On 21-AUG-2006, the patient underwent a complete blood count (CBC), comprehensive metabolic panel, estimated glomerular filtration rate (GFR), urine microscopic analysis, urinalysis and an electrocardiogram (EKG). On 21-AUG-2006, the patient's laboratory data revealed an absolute neutrophil count noted as 7.9 K/ul, urine ketones noted as >-80, a urine white blood cell count noted as 30-40/hpf and urine bacteria noted as 4+. On 21-AUG-2006, the patient recovered from the events. Additional information has been requested.

**Other Meds:** ORTHO TRI CYCLEN

**Lab Data:** diagnostic laboratory 08/21/2006 "comprehensive metabolic panel tests", electrocardiogram 08/21/06, absolute neutrophil 08/21/06 7.9 K/ul 2.0-609, total urine ketones 08/21/06 >-80 negative, urine bacteria screen 08/21/2006 4+, urine WBC co

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263233-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	07-Aug-2006	07-Aug-2006	0	19-Sep-2006	22-Sep-2006	--	WAES0608USA06605	22-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0696F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from a 26 year old female licensed practical nurse with no pertinent medical history and no known allergies or adverse drug reactions reported who on 07-AUG-2006 was vaccinated intramuscularly with a 0.5 ml dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (Lot#653650/0696F). There were no concomitant medications reported. The licensed practical nurse reported that she received HPV rLi 6 11 16 18 VLP vaccine (yeast) in her deltoid from a pre-filled syringe. It was reported that when the injection was completed, the nurse administering it "let go of the plunger before taking it out of her arm" and the "spring shot the syringe out of the arm like a dart". It was reported that "some fluid leaked out of her arm". The licensed practical nurse reported that it "stung a little when the vaccine was administered" and then resolved in a few moments. The area of the spill was cleansed with alcohol. The patient sought unspecified medical attention. There were no laboratory diagnostic studies performed. At the time of this report, the patient had recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263234-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		19-Sep-2006	22-Sep-2006	WA	WAES0608USA06614	22-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated intramuscularly with the first dose of 0.5 ml of HPV rLi 6 11 16 18 VLP vaccine (yeast). The patient "fainted after receiving HPV rLi 6 11 16 18 VLP vaccine (yeast)". The patient "fainted after receiving HPV rLi 6 11 16 18 VLP vaccine (yeast)". It was reported that the patient had not eaten anything. The patient sought unspecified medical attention. At the time of this report, the patient was recovering from the event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263235-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	24-Aug-2006	29-Aug-2006	5	19-Sep-2006	22-Sep-2006	NC	WAES0608USA06869	22-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 23 year old female who on approximately 24-AUG-2006 was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). On approximately 29-AUG-2006 (about 5 days after vaccination) the patient developed a rash (site of rash unspecified). Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263236-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Sep-2006	22-Sep-2006	AZ	WAES0608USA06941	22-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site vesicles

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who in 2006 was vaccinated with her first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, she was vaccinated with her second dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, she developed a blister at the injection site. Medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263237-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		19-Sep-2006	22-Sep-2006	RI	WAES0608USA07071	22-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site reaction

**Symptom Text:** Information has been received from a nurse practitioner concerning an unspecified number of patient's who were vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast) and complained of burning during administration. The patient's outcomes were not reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263238-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		19-Sep-2006	26-Sep-2006	WA	WAES0609USA00001	26-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning three patients (age and gender not reported) who on an unspecified date, in the morning, were vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, the patients fainted after receiving HPV rLi 6 11 16 18 VLP vaccine (yeast) (date unknown). It was reported that the patients had not eaten anything. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263239-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		19-Sep-2006	26-Sep-2006	NC	WAES0609USA00041	26-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning 3 patients 9age and gender not reported) who on an unspecified date were vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently the patients developed injection site pain (date unknown). The patients sought unspecified medical attention. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263240-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	30-Aug-2006	30-Aug-2006	0	19-Sep-2006	26-Sep-2006	CA	WAES0609USA00066	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 26 year old female who on 30-AUG-2006 was vaccinated intramuscularly in her right arm with a 0.5 ml dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included ketorolac tromethamine (TORADOL). On 30-aUG-2006, the patient felt "dizzy" after the injection. The patient was then given a ketorolac tromethamine (TORADOL) injection and she "passed out" after receiving that injection (also reported as "dizziness followed by syncope"). It was reported that the patient was seeing the physician or her pain shot. The syncope occurred after her pain injection. The physician believed this was a vaso vagal response. It was reported that "it was not known if the patient was that she was scheduled to receive". The patient sought unspecified medical attention. It was reported that "she did not her second shot yet". On 30-AUG-2006, "a few minutes after", the patient recovered from the events. Additional information has been requested.

**Other Meds:** TORADOL

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263241-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		19-Sep-2006	26-Sep-2006	PA	WAES0609USA00077	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site swelling

**Symptom Text:** Information has been received from a physician concerning a female patient in her early 20's who was vaccinated with her first dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced a high amount of pain and swelling at the injection site. Medical attention was sought. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263242-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		19-Sep-2006	26-Sep-2006	CA	WAES0609USA00264	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Pallor

**Symptom Text:** Information has been received from a physician concerning a 23 year old female. It was reported that it was "not known if the patient was pregnant, if she was taking any other medications or had a history of drug reactions or allergies." On an unspecified date, the patient was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). It was reported that the patient felt "light headed and dizzy" after receiving HPV rLi 6 11 16 18 VLP vaccine (yeast). The patient also "turned very pale", but did not faint. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263243-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		19-Sep-2006	26-Sep-2006	CA	WAES0609USA00265	26-Sep-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse in a physician's office concerning a female patient "in her 20's" who on an unspecified date was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). It was reported that the patient "fainted" after being given HPV rLi 6 11 16 18 VLP vaccine (yeast) (date unknown). At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263244-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		19-Sep-2006	26-Sep-2006	CA	WAES0609USA00266	26-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse in a physician's office concerning a female patient "in her 20's" who on an unspecified date was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). It was reported that the patient "fainted" after being given HPV rLi 6 11 16 18 VLP vaccine (yeast) (date unknown). At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263256-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	29-Aug-2006	31-Aug-2006	2	19-Sep-2006	20-Sep-2006	ME		28-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fungal infection, Pruritus

**Symptom Text:** About 2 days after administration of Gardasil pt reported onset of intense itching under armpit same side, has now been present for about 3 weeks, not improving. Possibly reaction to Gardasil vs fungal infection -avoid any irritants, no creams of soaps or deodorants -fungal cream twice a day -will report this as adverse event to Gardasil -reeval in 1 week Medications Added to Medication List This Visit: 1) Ketoconazole 2 % Crea (Ketoconazole) .... Apply twice a day

**Other Meds:** Celexa 40mg 1 1/2 tabs po q day

**Lab Data:**

**History:** none known

**Prex Illness:** none known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263314-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	28-Aug-2006	29-Aug-2006	1	20-Sep-2006	21-Sep-2006	CA		21-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2557AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia, Rash

**Symptom Text:** On 8/29/06 pt woke up in am to rash on face and fever of 103. Rash not itchy. Treatment Tylenol or Motrin for fever. On 8/30/06 Pt continues with rash on face off and on and also fever continues. Temperature ranging 99.2 - . Also complains of headache.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Allergic rhinitis, RAD

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263332-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	18-Sep-2006	19-Sep-2006	1	20-Sep-2006	21-Sep-2006	WI		21-Sep-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Right arm	Intramuscular	TDAP

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Pain

**Symptom Text:** Right hypothenar eminence (thumb) started aching approximately 24 hours after shot administered, then the right wrist ached badly (i.e arthralgia). No other etiology of pain identified. Anaprox DS (Naproxen) and split provided.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263354-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	06-Sep-2006	06-Sep-2006	0	21-Sep-2006	22-Sep-2006	MA	WAES0609USA02500	22-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Convulsion, Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning a 17 year old female with no other pertinent medical history, adverse drug reactions or allergies reported. On 9/6/06, at 3:30pm, the pt was vaccianted IM with the first dose of 0.5ml of HPV rL1 6 11 16 18 VLP vaccine yeast (lot 654540/0800F). Concomitant therapy included an unspecified hormonal contraceptives (also reported as birth control). On 9/6/06, the pt developed a mild seizure right after receiving HPV rL1 6 11 16 18 VLP vaccine yeast. The pt came to and immediately fainted again. The pt sought unspecified medical attention. It was reported that the pt had not eaten anything all day. After eating, the pt felt better. On 9/6/06, the pt had fully recovered from the events. Upon internal review, the mild seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Hormonal contraceptions.

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263370-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	24-Aug-2006	25-Aug-2006	1	21-Sep-2006	22-Sep-2006	KS		22-Sep-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Gluteous maxima	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Breast disorder female, Tenderness

**Symptom Text:** Extreme Breast tenderness x 4 days.

**Other Meds:** Ortho Tri cyclen LO x 6 years.

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263539-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	22-Sep-2006	22-Sep-2006	0	25-Sep-2006	05-Oct-2006	CA		30-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Pt fainted.

**Other Meds:**

**Lab Data:**

**History:** Seasonal

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263612-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Sep-2006	08-Sep-2006	7	26-Sep-2006	05-Oct-2006	NC		05-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	MNQ

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blister, Erythema, Hypersensitivity, Rash erythematous

**Symptom Text:** Raised erythematous patchy rash of left shoulder (Behind left deltoid muscle) with slight vesicles. Also similar linear rash on left leg (appearance of delayed hypersensitivity) rash began 1 week after injection.

**Other Meds:** Singular, Zyrtec

**Lab Data:** NONE

**History:** Seasonal allergic rhinitis.

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263740-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	01-Sep-2006	08-Sep-2006	7	29-Sep-2006	06-Oct-2006	MO		06-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Itchy bumps, 1 on arm, 1 on breast, 1 on back.

**Other Meds:** Birth Control Seasonal

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263743-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	Unknown	Unknown		29-Sep-2006	06-Oct-2006	MO		20-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Itchy bumps 1 on back, 1 on arm, 1 on leg.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263750-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	14-Sep-2006	21-Sep-2006	7	29-Sep-2006	05-Oct-2006	TX		31-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0641F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Joint range of motion decreased, Pain

**Symptom Text:** One week post injection, complain of achy arm where injection was given, difficult to raise arm, no swelling or redness at injection site.

**Other Meds:** Phentermine 37.5 mg as needed

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263751-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	25-Aug-2006	26-Aug-2006	1	29-Sep-2006	05-Oct-2006	NY		31-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site reaction, Rash

**Symptom Text:** Rash at injection site at 24 hours after administration, then rash on other arm (at corresponding site)

**Other Meds:** Yasmin

**Lab Data:** NONE

**History:** possible polycystic ovary syndrome

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263754-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	25-Sep-2006	25-Sep-2006	0	29-Sep-2006	05-Oct-2006	KY		06-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site warmth, Pruritus, Urticaria

**Symptom Text:** Hives on neck and chest, injection site red, warm to touch, itching at area and on palms of hands.

**Other Meds:** BUSPAR, ATIVAN, CELEXA

**Lab Data:** took two BENADRYL

**History:** Penicillin

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263862-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	28-Sep-2006	29-Sep-2006	1	02-Oct-2006	09-Oct-2006	IL		09-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anorexia, Back pain, Fatigue, Headache, Pyrexia

**Symptom Text:** Fatigue, Headache, Backaches, Temp 103, no appetite, x 3 days then was ok no treatment.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263878-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	02-Oct-2006	02-Oct-2006	0	16-Nov-2006	22-Nov-2006	--	WAES0610USA01135	22-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a consumer concerning her 20 year old daughter who on 02-OCT-2006 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. The patient experienced dizziness for a short period of time after the vaccination. Medical attention was sought. It was reported that the patient has a fear of needles and that may have been a causal factor. No further information is available.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263895-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	25-Sep-2006	25-Sep-2006	0	03-Oct-2006	04-Oct-2006	ME	WAES0609USA06568	05-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Left arm	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Dyspnoea, Injection site swelling, Nasopharyngitis, Swelling face

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female with asthma, polycystic ovaries and no known allergies or adverse drug reactions reported. On 25-SEP-2006, the patient was vaccinated intramuscularly with a 0.5 ml dose of HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653735/0688F). Concomitant therapy included bupropion HCL (WELLBUTRIN XL), lithium carbonate and risperidone (RISPERDAL). That evening, on 25-SEP-2006, the patient developed left arm swelling and difficulty breathing. It was reported that the difficulty breathing could be due to the patient having a cold and being an asthmatic. On 26-SEP-2006 the patient developed facial swelling. The patient sought unspecified medical attention. It was reported that a nurse practitioner and physician were doing an assessment and consultation. At the time of this report, the patient was recovering from th events. The reporter considered the events to be serious as other important medical events. Additional information has been requested. (OMIC)

**Other Meds:** Wellbutrin XL; lithium carbonate; Risperdal

**Lab Data:**

**History:** Asthma; Polycystic ovaries; cold

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 263930-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	28-Sep-2006	28-Sep-2006	0	03-Oct-2006	04-Oct-2006	RI		09-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	08001F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site warmth, Pain, Pyrexia

**Symptom Text:** FEVER, SITE WARM TO TOUCH, PAIN NOTED WITH MOVEMENT OF EXTREMITY.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264066-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	25-Sep-2006	25-Sep-2006	0	06-Oct-2006	10-Oct-2006	WI		10-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2556AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Unknown	
	MNQ	AVENTIS PASTEUR	U2108AA	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site induration, Injection site reaction, Injection site warmth

**Symptom Text:** 2 separate reactions Tdap 6x4 1/2" area hot to touch. Induration of biceps upper arm started day of injection given seen in office 9/28/06, Gardasil 3 1/2 x 3" hot to touch started 3 days after shot for both ice and Ibuprophen.

**Other Meds:** Prozac, Abilify, Lamictal.

**Lab Data:** NONE

**History:** allergies, sinusitis, Bipolar disorder.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264172-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	02-Oct-2006	06-Oct-2006	4	09-Oct-2006	11-Oct-2006	CA		11-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2559BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2114AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Urticaria (hives) developed 4 days after vaccines were given covered torso and extremities, extremely itchy. Pt was given Benadryl Zyrtec, Prednisone orally and took a bath with baking soda.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264204-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	12-Sep-2006	13-Sep-2006	1	10-Oct-2006	13-Oct-2006	MA		13-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Coma, Mental impairment, Urticaria

**Symptom Text:** 09/13/06 pt went to school where she developed hives at 10am. She was sent home, mom came home and found pt unresponsive and called 911. Pt seen at ER. Became responsive and talking well at ER. Exam WNL. DX'd changed mental status sent home.

**Other Meds:** Lithium, Propanolol, Prozac, Seraguel, Clozapine, Ritalin, Aviane, Keflex.

**Lab Data:** At ER 9/13/06 EKG sinus arrhythmia, chest X ray NL, CT head normal, CBC, U/A, Lytes and toxic screen neg NL.

**History:** Bipolar DS, ADHS, left hydronephrosis.

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264209-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	27-Sep-2006	27-Sep-2006	0	10-Oct-2006	13-Oct-2006	--		30-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	AC52B002AA	4	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	B229AA	0	Right arm	Intramuscular	
	IPV	AVENTIS PASTEUR	Y1067	1	Left arm	Intramuscular	
	MMRV	MERCK & CO. INC.	0816F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cellulitis, Injection site reaction

**Symptom Text:** Cellulitis at injection site

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264284-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Sep-2006	29-Sep-2006	0	11-Oct-2006	12-Oct-2006	FR	WAES0610CAN00009	12-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Anaphylactic reaction, Malaise

**Symptom Text:** Information has been received from a consumer concerning her 15 year old daughter with asthma, peanut allergy and allergy to nuts and a history of anaphylaxis (three episodes of anaphylaxis (first at age 8) related to allergy to peanuts/nuts) who on 9/29/06 was vaccinated with first dose of HPV rL1 6 11 16 18 VLP vaccine yeast at approx 16:00. Concomitant therapy included Ventolin (rarely uses it ). The pt stayed in the physicians office for about half an hour with the clinic staff ready for an allergic anaphylactic reaction since she had three episodes of anaphylaxis previously. However she felt fine. On 9/29/06 the pt experienced anaphylactic reaction described as going into shock at approx 20:00 she suddenly felt ill (anaphylactic reaction that could not be traced back to food eaten that day that could have contained nuts). The pt immediately administered on Epi Pen dose. Subsequently the pt was taken to the emergency dept where she received supportive care only as no other medications were needed. Subsequently, the pt recovered from anaphylactic reaction. Upon internal review anaphylactic reaction was considered other important medical event (OMIC). Additional information has been requested.

**Other Meds:** VENTOLIN (ALBUTEROL)

**Lab Data:**

**History:** Anaphylaxis peanut allergy, allergy to nuts Asthma.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264366-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		11-Oct-2006	11-Nov-2006	TX	WAES0609USA00433	13-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Joint range of motion decreased

**Symptom Text:** Information has been received from a physician concerning a 19 year old female who in early August 2006, was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast) (0.5 ml). The physician reported that at the time of vaccination, the patient experienced injection site pain. The patient later experienced decreased range of motion in the arm she received the vaccination. It was reported that the patient's arm hurt when she raised it above her head. At the time of this report, the patient's injection site pain, decreased range of motion in arm pain persisted. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** NONE

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264367-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Sep-2006	Unknown		11-Oct-2006	11-Nov-2006	--	WAES0609USA00663	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0702F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a nurse concerning a female who on 01 Sep 2006 was vaccinated intramuscularly with HPV rLi 6 11 16 18 VLP vaccine (yeast) (lot#653650/0702P). The nurse reported that she was very unhappy with the syringe. The nurse reported that she "had received no instructions, and upon using the syringe for the first time, the safety device activated as soon as she pushed all the way down on the plunger, and it hit the patient in the arm". The nurse also reported that she had not read the product insert prior to administering the vaccine, as it was not available in the carton, and as soon as she administered the full dose of vaccine, she immediately let go of the plunger. She also reported that "it was loud, which scared the patient, and the needle coil sprang out and hurt the patient. The patient was kept in the office longer than normal since the coil hit the patient against her arm and hurt her. Unspecified medical attention was sought. The nurse was able to administer the entire dose of vaccine. On 05-Sep-2006 the patient had recovered.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264368-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	31-Aug-2006	31-Aug-2006	0	11-Oct-2006	13-Nov-2006	OR	WAES0609USA00688	06-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injury, Medication error

**Symptom Text:** Information has been received from a medical assistant concerning a 23 year old female with no pertinent medical history or drug reaction/allergies, who on 8/31/06 was vaccinated IM with a pre filled syringe HPV rL1 6 11 16 18 VLP vaccine yeast (lot 654540/0800F). There was no concomitant therapy. The medical assistant reported that the spring action activated so forceful the needle and spring popped out of the clients left arm and scratched her. It was reported that all the vaccine was administered and that the pts left arm was washed with soap and water. She also reported that the pt did not bleed. No further details were provided. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264369-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Aug-2006	23-Aug-2006	1	11-Oct-2006	13-Nov-2006	--	WAES0609USA00704	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a registered nurse concerning a female pt (age not provided) who on approx 8/22/06 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast (lot not provided). The nurse reported that a day and half after receiving the vaccine, on approx 8/23/06 the pt developed what appeared to be hives. Unspecified medical attention was sought. Subsequently, the p0t recovered from the hives. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264370-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		11-Oct-2006	13-Nov-2006	WI	WAES0609USA01030	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with the first dose of 0.5 ml of HPV rL1 6 11 16 18 VLP vaccine yeast. It was reported that the pt fainted after the injection (date unk). The pt sought unspecified medical attention. AT the time of this report, the pt had recovered from the event (date unk). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264371-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	16-Aug-2006	16-Aug-2006	0	11-Oct-2006	13-Nov-2006	TX	WAES0609USA01051	13-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician concerning her 13 year old daughter who on approx 8/16/06, (also reported as within the past 2-3 weeks) was vaccinated with a 0.5ml dose of HPV rL1 6 11 16 18 VLP vaccine yeast. the physician reported that her daughter experienced soreness at injection site for a couple of days after receiving HPV vaccine. The pt sought unspecified medical attention. At the time of this report, the outcome of the event was unk. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264372-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
28.0	F	07-Sep-2006	07-Sep-2006	0	11-Oct-2006	13-Nov-2006	MT	WAES0609USA01437	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0689F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysgeusia, Hyperhidrosis, Nausea

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 27 year old female with no pertinent medical history or drug reactions. allergies, who on 9/7/06 was vaccinated IM with HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653736/0689F). Concomitant therapy included ethinyl Estradiol norgestimate (Ortho Tri Cyclen). On 9/7/06, immediately after receiving the vaccine, the pt experienced a metallic taste in her mouth, nausea and sweating. The nurse had the pt lay down for a little while and the pt started to feel better. No further details were provided. At the time of this report, the pt was recovering. Additional information has been requested.

**Other Meds:** Ortho Tri Cyclen

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264373-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		11-Oct-2006	13-Nov-2006	CA	WAES0609USA01470	13-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia, Rash, Rash macular

**Symptom Text:** Information has been received from a physician concerning a female who on an unspecified date was vaccinated IM with HPV rL1 6 11 16 18 VLP vaccine yeast (0.5ml). Concomitant therapy included Dtap. The day after vaccination with HPV the pt developed a blotchy rash which lasted for three days (site of rash not specified). It was also reported that the pt experienced a fever with a temp between 99 and 103 degrees during the same three day period. Unspecified medical attention was sought. At the time of this report, the pt was recovering from the rash and fever. Additional information has been requested.

**Other Meds:**

**Lab Data:** Body temp between 99 and 103 degrees.

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264374-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		11-Oct-2006	13-Nov-2006	WA	WAES0609USA01524	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Hypoxia

**Symptom Text:** Initial and follow up information has been received from a physician concerning a female pt (age not reported) who on an unspecified date, in the morning, was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast (date unknown). It was reported that the pt felt dizzy and was administered oxygen. The pt was observed for 30 minutes (previously reported that the pt had not eaten anything. At the time of this report, the pt had recovered from the events (date unk). The physician assessed the events as non serious and reported that she was unsure of the causality of the events. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264375-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		11-Oct-2006	13-Nov-2006	WA	WAES0609USA01525	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Syncope

**Symptom Text:** Initial and follow up information has been received from a physician concerning a female pt (age not reported) who on an unspecified date, in the morning, was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast. Subsequently, the pt fainted after receiving HPV vaccine (date unk). It was reported that the pt felt dizzy and was kept for observation (previously reported that the pt had no eaten anything). At the time of this report, the pt had recovered from the events (date unk). The physician assessed the events as non serious and reported that she was unsure of the causality of the events. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264376-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	30-Aug-2006	02-Sep-2006	3	11-Oct-2006	13-Nov-2006	AZ	WAES0609USA01979	13-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Aphthous stomatitis, Herpes simplex, Malaise, Myalgia, Nausea, Pharyngolaryngeal pain, Pyrexia, Skin ulcer, Vomiting

**Symptom Text:** Information has been received from a physician concerning a 22 year old female with no pertinent medical history and no allergies, who on 8/30/06 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast. On 9/2/06 the pt developed a canker sore on her lip and sore throat. On 9/6/06 she experienced nausea, vomiting, malaise, a temperature of 102F and developed a herpetic ulcerative ring on her left ring finger. It was also reported that the pt experienced myalgia. Unspecified medical attention was sought/ Subsequently, it was reported on 9/8/06 that the symptoms were subsiding, the lesion on the pts lip had crusted and her temp was 98.9F.

**Other Meds:** UNK

**Lab Data:** Body temp 9/6/06 102F, body temp 9/8/06 98.9F.

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264377-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	05-Sep-2006	06-Sep-2006	1	11-Oct-2006	13-Nov-2006	MO	WAES0609USA02094	13-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Skin discolouration, Sunburn

**Symptom Text:** Information has been received from a certified medical assistant concerning a 19 year old female with no pertinent medical history and no known allergies or adverse drug reactions reported. On 9/5/06, the pt was vaccinated IM with one dose of HPV rL1 6 11 16 18 VLP vaccine yeast. Concomitant therapy included Ortho Tri Cyclen. It was reported that the pt woke up the next morning and her skin was pink from head to toe. There was no rash, no pain, no itching, no swelling and no hives. It was reported that her only symptom was a sunburn like appearance to her skin. the pt sought unspecified medical attention. On 9/7/06 in the evening, the color began to subside. As of 9/8/06 her skin was reported as looks better and the pt was noted as recovering. Additional information has been requested.

**Other Meds:** Ortho Tri Cyclen

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264556-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	05-Oct-2006	05-Oct-2006	0	16-Oct-2006	20-Oct-2006	IN		20-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Unknown	
	HEP	MERCK & CO. INC.	0223F	1	Left arm	Unknown	
	FLU	AVENTIS PASTEUR	U2239AA	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Pain in right upper arm from time of administration of vaccine and continuing 8 days.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264585-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	10-Oct-2006	10-Oct-2006	0	16-Oct-2006	20-Oct-2006	KY		20-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hyperhidrosis, Nausea, Pallor, Peripheral coldness

**Symptom Text:** Pt experienced paleness, sweating, cold hands, nausea, dizziness and lightheadedness.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264674-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	14-Sep-2006	14-Sep-2006	0	17-Oct-2006	18-Oct-2006	TX	WAES0610USA04329	18-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Dyspnoea, Pyrexia

**Symptom Text:** Information has been received from a physician concerning an 18 year old female who on 14-SEP-2006 was vaccinated intramuscularly with a first 0.5 ml dose of HPV rLi 6 11 16 18 VLP vaccine (yeast). About an hour after receiving the vaccine, the patient developed shortness of breath and a fever. The patient was directed to the emergency room. It was noted that the patient's symptoms improved "on therapy" (unspecified). No product quality complaint was involved. Shortness of breath and fever were considered to be other important medical events. Additional information has been requested. (OMIC)

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264675-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		17-Oct-2006	18-Oct-2006	TX	WAES0610USA05710	30-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Abdominal pain, Hepatitis

**Symptom Text:** Information has been received from a physician concerning a pt who was vaccinated with a dose of HPV vaccine yeast. Subsequently the pt experienced a recurrence of hepatitis and abdominal pain. The physicians office manager reported that the pt tested positive for hepatitis after receiving the vaccine. The pts outcome was not reported. Recurrence of hepatitis and abdominal pain were considered to be other important medical events (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264684-1 (S)    **Related reports:** 264684-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
0.2	M	02-Oct-2006	04-Oct-2006	2	17-Oct-2006	18-Oct-2006	GA	WAES0610USA06268	18-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	ROTHB5	MERCK & CO. INC.	NULL	0	Unknown	By Mouth	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Acidosis, Dehydration, Diarrhoea, Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning a 9 week old male, with no medical history and no allergies, who on 02-OCT-2006 was vaccinated with a first oral dose of rotavirus G1 G2 G3 G4 P1 reassortant vaccine live (human-bovine). There was no concomitant medication. On 04-OCT-2006 the patient developed vomiting. He was seen at the physician's office on 06-OCT-2006 and by then was experiencing vomiting and loose stools. He was admitted to the hospital on 09-OCT-2006 for vomiting, diarrhea, and acidotic dehydration. He was being given intravenous fluids. At the time of the report the patient had not recovered. Vomiting, diarrhea, and acidotic dehydration were considered to disabling, life threatening, and other important medical events by the reporter. Additional information has been requested. (OMIC)

**Other Meds:** NONE

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 119

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264684-2 (S) **Related reports:** 264684-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
0.2	M	02-Oct-2006	09-Oct-2006	7	02-Jan-2007	03-Jan-2007	GA	200603514	03-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	PNC	LEDERLE LABORATORIES	C086910	0	Right leg	Unknown	
	IPV	AVENTIS PASTEUR	Z0240	0	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0607F	0	Unknown	By Mouth	
	DTAP	AVENTIS PASTEUR	C2489AA	0	Left leg	Unknown	
	HBHEPB	MERCK & CO. INC.	0269F	0	Right leg	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Acidosis, Bacterial infection, Blood urine, Chromaturia, Decreased appetite, Dehydration, Diarrhoea, Enteritis, Faeces discoloured, Gastroenteritis, Haematochezia, Intussusception, Malaise, Pyrexia, Viral infection, Vomiting

**Symptom Text:** Initial report received on 15 December 2006 from an other manufacturer, report number WAES0610USA06268, who received the original report from a health care professional. This report is a follow up report to previously submitted reports by the other manufacturer on 13 October 2006, 30 October 2006, and 11 December 2006. Information has been received by the other manufacturer, from a registered nurse concerning a 9 week old male, with no concurrent illnesses, no medical history, and no allergies, who on 02 October 2006, at 13:00pm, was vaccinated with a first dose, left leg (route not reported) administration of IPOL, lot number Z0240, a first dose, left leg (route not reported) administration of Tripedia, lot number C2489AA, a first dose, right leg 9route not reported0 administration of Comvax, lot number 654538/0269T, a first dose, right leg (route not reported) administration of Prevnar, lot number B086910, and a first 2.0ml oral dose of Rotateq, lot number 654422/0607F. Reportedly, there were no adverse events following prior vaccinations. On 04 October 2006, the patient vomited one time and decreased appetite. He again vomited one time on 05 October 2006. He was seen in the physician's office the following day, on 06 October 2006, and had experienced loose stools two times that morning, with one episode of vomiting. Reportedly, two days later, on 08 October 2006, the patient presented with a four day history of diarrheal stool which looked rusty colored. It was noted that the patients mother could not exclude blood in the stool and the patient was admitted to the hospital. The following day, on 09 October 2006, the patient had ad differential diagnosis of viral illness (possibly from the Rotateq vaccine), bacterial enteritis, and intussusception. Diagnostic urinalysis showed pH 5.0 SP GR 1010, trace protein, no glucose, ketones, leukocytes, blood NHT, no culture. Laboratory work showed lymphocyte 37.0, serum blood urea 24, serum granulocytes 7.66, segmented neutrophil 47.0, CSF monocyte count 11.0. The patien

**Other Meds:**

**Lab Data:** 09 October 2006 abdominal X ray no evidence of obstruction. Diagnostic urinalysis pH 5.0 SP GR 1010, trace protein, no glucose. Laboratory work showed Lymphocyte 37.0, Serum blood urea 24, serum granulocytes 7.6, segmented neutrophil 47.0,

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264688-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	03-Oct-2006	04-Oct-2006	1	17-Oct-2006	18-Oct-2006	FL	WAES0610USA03769	18-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Dyspnoea, Myalgia, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 16 year old female who on 10/3/06 was vaccinated with 0.5ml of HPV. On 10/4/06, the pt developed muscle aches, fever and shortness of breath. The pt went to the ER. It was unknown if the pt was hospitalized. At the time of this report, the outcome of the event was unknown. The physician considered the events to be serious as other important medical events (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264695-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	30-Aug-2006	Unknown		17-Oct-2006	19-Oct-2006	NJ	WAES0609USA02204	19-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician assistant concerning an 18 year old female with on 8/30/06 was vaccinated with the first dose of HPV (lot 653650/0702F). The physician assistant reported that the pt received the first dose of HPV, about 12 days ago, and she still experiencing injection site pain. The pt sought unspecified medical attention. It was reported that the pt was being treated with ibuprofen (Advil). At the time of this report, the pt had not recovered from the event. The reporter considered the event to be serious as an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264696-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	27-Sep-2006	27-Sep-2006	0	17-Oct-2006	19-Oct-2006	NH	WAES0609USA07424	30-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Injection site pain, Medication error

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) with on known allergies or adverse drug reactions reported. On 9/27/06, the pt was vaccinated IM in the left deltoid with 1 ml (2 vials) of HPV vaccine (lot 0B37F). Concomitant therapy included a tetanus toxoid shot in the other arm. Subsequently, the pt experienced arm hurting. The registered nurse confirmed that the pain was at the injection site. The pt has not mentioned any other symptoms. The pt sought unspecified medical attention. The intervention to prevent serious criteria was 800 mg, of Motrin. The registered nurse reported that she did not know if the event would have worsened or improved without the intervention of Motrin. On 9/28/06, the pt returned to the physicians office and was fine, however her arm still hurt. At the time of this report, the pt had not recovered from the event. The reporter considered the event to be serious as an other important medical event (OMIC). Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264703-1      **Related reports:** 264703-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	11-Oct-2006	12-Oct-2006	1	17-Oct-2006	20-Oct-2006	MA		20-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Acne, Rash

**Symptom Text:** Rash/Pimple like on fact and neck.

**Other Meds:** Ortho tricylen

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264703-2      **Related reports:** 264703-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	11-Oct-2006	11-Oct-2006	0	16-Nov-2006	22-Nov-2006	MA	WAES0610USA10680	22-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	635978/0955F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Rash

**Symptom Text:** Information has been received from a health professional concerning a 21 year old Caucasian female with no known allergies who on 11-OCT-2006 at 9:00 was vaccinated with a first dose of HPV rL1 6 11 15 18 VLP vaccine (yeast), intramuscularly in the deltoid. Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO TRI-CYCLEN). On 11-OCT-2006 at 9:00 a.m. the patient experienced "face/neck rash, pimple like stinging." It was reported to be unknown if the patient recovered.

**Other Meds:** ORTHO TRI-CYCLEN

**Lab Data:** None

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264738-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		17-Oct-2006	15-Nov-2006	TX	WAES0609USA01527	15-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Initial and follow up information has been received from a physician and a registered nurse in the physicians office concerning a pt (age and gender not reported) who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast. The physician reported that the pt experienced soreness, pain at injection site after receiving HPV. The registered nurse reported that she had spoken with the physician who felt that the soreness was not really a reaction or a problem. It was reported that the physician did not feel it was an adverse effect, just soreness at the injection site. At the time of this report, the outcome of the event was unk. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264739-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	30-Aug-2006	09-Sep-2006	10	17-Oct-2006	15-Nov-2006	NY	WAES0609USA02200	15-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0637F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fungal infection, Pruritus genital, Vaginal infection

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 13 year old female with diabetes and no known adverse drug reactions or allergies reported. On 8/30/06, the pt was vaccinated IM with a 0.5ml dose of HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653937/0637F). Concomitant therapy included insulin. On 9/9/06 the pt developed a yeast infection. It was reported that the pt had vaginal itching since receiving HPV It was reported that the pt underwent a vaginal swab which came back positive for yeast. The pt was being treated with Monistat. the pt was treated with the over the counter medication and was not required to follow up with the physician at this time. According to the licensed practical nurse, the physician did not feel that HPV was the cause of the yeast infection and that it was the pts mother who inquired about the event. At the time of this report, the pt had recovered from the yeast infection (date unk). No further information is available.

**Other Meds:** Insulin

**Lab Data:** Vaginal gram stain vaginal swab came back positive for yeast.

**History:** Diabetes

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 127

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264740-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
42.0	F	05-Sep-2006	05-Sep-2006	0	17-Oct-2006	15-Nov-2006	CA	WAES0609USA02222	15-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Infection, Injection site mass, Injection site reaction, Pruritus

**Symptom Text:** Information has been received from a 42 year old female with hypersensitivity to SOMA and a history of two pregnancies, and two unspecified abortions who on 9/5/06 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine yeast (0.5ml). Concomitant therapy included Lasix and Wellbutrin. The pt reported that on 9/5/06 she developed an injection site reaction. The pt reported that the reaction was like straph infection and described the reaction as looking like and itching like a big mosquito bite. The pt had not yet contacted her physician. At the time of this report, the pt had not yet recovered from the injection site reaction. No further information is expected.

**Other Meds:** Wellbutrin, Lasix

**Lab Data:** NONE

**History:** Abortion, Pregnancy, Drug hypersensitivity.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264741-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	15-Nov-2006	ND	WAES0609USA02251	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site pain, Pain, Paraesthesia

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female pt who on an unspecified date was vaccinated IM with HPV rL1 6 11 16 18 VLP vaccine yeast. Subsequently the pt experienced pain, numbness, and at tingly feeling all the way down to her fingertips. The events occurred in the arm in which the pt received the vaccination. Unspecified medical attention was sought. The pt subsequently recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264742-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	12-Sep-2006	12-Sep-2006	0	17-Oct-2006	15-Nov-2006	MD	WAES0609USA02498	15-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a physician concerning a 22 year old female pt who on 9/12/06 was vaccinated IM into the upper left buttock with a dose of HPV rL1 6 11 16 18 VLP vaccine yeast, lot 653650/0702F. there was no concomitant medication. Approx one hour post vaccination the pt experienced numbness and tingling on the right side of her face. medial attention was sought. No other symptoms were noted. As of the report date, the pt was recovering. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264743-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	11-Sep-2006	12-Sep-2006	1	17-Oct-2006	15-Nov-2006	PA	WAES0609USA02502	15-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling abnormal, Headache, Malaise, Mydriasis

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female with syncope, anxiety and no known allergies reported. On 9/11/06, the pt was vaccinated IM with the first dose of HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653650/0702F). Concomitant therapy included Lexapro, Wellbutrin, Klonopin, Nicomide, and Zithromax. On 9/12/06 when the pt woke up, she complained of her pupils being dilated, a headache, light headed and reported that she feels like something in not quite right. It was reported that it was unknown if the pt had eaten that day. The pt sought unspecified medical attention. At the time of this report, the pt had not recovered from the events. Additional information has been requested.

**Other Meds:** Zithromax, Wellbutrin, Klonopin, Lexapro, Nicomide, Minocycline.

**Lab Data:** UNK

**History:** Syncope, Anxiety.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264744-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	12-Sep-2006	12-Sep-2006	0	17-Oct-2006	15-Nov-2006	--	WAES0609USA02785	15-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Information has been received from a pharmacy intern concerning a female who on 9/12/06 the pt experienced nausea and vomiting. Unspecified medical attention was sought. At the time of this report, the outcome of the events was unk. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264745-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	31-Aug-2006	06-Sep-2006	6	17-Oct-2006	15-Nov-2006	ME	WAES0609USA02871	15-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Unintended pregnancy, Viral infection

**Symptom Text:** Information has been received through the pregnancy registry from a nurse practitioner concerning a 15 year old female with no known drug allergies, and with depression who on 8/31/06 at 3:00pm was vaccinated IM in the right deltoid with the first dose of HPV rL1 6 11 16 18 VLP vaccine yeast (lot 653937/0637F). Illnesses at the time of vaccination included flu symptoms and a breast lump. Concomitant therapy included sertraline HCL (Zoloft). Other vaccinations given on 9/6/06 included diphtheria toxoid + pertussis acellular vaccine (unspecified) + tetanus toxoid. On 9/6/06 the pt was seen at her physician with a complaint of continued viral illness. It was reported that the pt was aware that she was pregnant but did not disclose this information to her health care provider until after vaccination. A urine pregnancy test was performed and found to be positive. The pt was advised no to receive the second dose of HPV. At the time of this report, the outcome of the viral illness and vaccine exposure during pregnancy was not known. Additional information has been requested.

**Other Meds:** Zoloft

**Lab Data:** Urine beta human 09/06/06 positive.

**History:** Pregnancy, breast lump, flu symptoms. depression.

**Prex Illness:** Breast lump, Flu symptoms

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264746-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	11-Sep-2006	11-Sep-2006	0	17-Oct-2006	21-Nov-2006	PA	WAES0609USA03257	21-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash maculo-papular

**Symptom Text:** Information has been received from a physician concerning a female patient who on 11-SEP-2006 was vaccinated with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The physician reported that within 24 hours of receiving the vaccine the patient developed a maculo papular rash all over the body. Medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264747-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		17-Oct-2006	21-Nov-2006	--	WAES0609USA03270	21-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a nurse practitioner concerning her 20 year old daughter who on an unspecified date was vaccinated with 0.5 mL of HPV rL1 6111618 VLP vaccine (yeast). It was reported that "right after she got it", the patient developed severe arm pain (date unknown). The patient sought unspecified medical attention. At the time of this report, the patient was recovering from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264748-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	12-Sep-2006	13-Sep-2006	1	17-Oct-2006	21-Nov-2006	IN	WAES0609USA03694	21-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0641F	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Pyrexia

**Symptom Text:** Initial and follow up information has been received from a physician concerning a 20 year old female patient with sulfonamide allergy who on 12-SEP-2006 at 13:45 p.m. was vaccinated IM in the left deltoid with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), lot #653650/0641. Concomitant therapy included ethinyl estradiol (+) ferrous fumarate (+) norethindrone acetate (MICROGESTIN FE). On the early morning of 13-SEP-2006 the patient developed a fever to 103.6 degrees F, and generalized body aches. Medical attention was sought. On 18-SEP-2006, the patient recovered. Additional information is not expected.

**Other Meds:** MICROGESTIN FE

**Lab Data:** Body temp 09/13/06 103.6 degr

**History:** Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264749-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	21-Nov-2006	--	WAES0609USA04154	21-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Malaise, Syncope

**Symptom Text:** Information has been received from a nurse practioner concerning a female patient (age not reported) who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently, the patient fainted post vaccination. She stated that it "felt like the medicine traveled through my system at time of injection". Subsequently, the patient recovered from the syncope and abnormal feeling. The nurse reported that the patient was not disoriented, was very aware and her blood pressure (actual BP not reported) was within normal limits. The patient was offered a sugar drink (soda) after the event and recovered from the event. The nurse practitioner noted that the patient had eaten before coming in for the vaccination. Additional has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264750-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
28.0	F	18-Sep-2006	18-Sep-2006	0	17-Oct-2006	22-Nov-2006	NY	WAES0609USA04248	22-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Headache, Nausea

**Symptom Text:** Information has been received from a 28 year old female patient with epilepsy, asthma and an allergy to carbamazepine (TEGRETOL) who on 18-SEP-2006 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included escitalopram oxalate (LEXAPRO), lorazepam, "Iomectol," zolpidem tartrate (AMBIEN), and fluticasone propionate (FLOVENT). The patient stated that since her vaccination she has been experiencing dizzy, tired, has headaches and felt nauseous. No medical attention was sought. As of the report date the patient has not recovered. Additional information has been requested.

**Other Meds:** (therapy unspecified), LEXAPRO, FLOVENT, lorazepam, AMBIEN

**Lab Data:** NONE

**History:** Concurrent conditions: epilepsy, asthma, drug hypersensitivity.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264751-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
9.0	F	Unknown	Unknown		17-Oct-2006	22-Nov-2006	PA	WAES0609USA04418	22-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female patient with sulfonamide allergy who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced a fever for four days. Unspecified medical attention was sought. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Concurrent conditions: sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264753-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	11-Sep-2006	12-Sep-2006	1	17-Oct-2006	22-Nov-2006	PA	WAES0609USA04898	22-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	653735/0688F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia, Rash vesicular

**Symptom Text:** Information has been received from a physician concerning a 17 year old female with no history of varicella virus vaccine live vaccination and an unknown history of varicella, who on 11-SEP-2006 was vaccinated intramuscularly with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. The physician reported that on 12-SEP-2006 "the next day, the patient developed a low grade fever and a vesicular rash on her neck and shoulders of about 15-20 lesions." The patient was treated with acetaminophen (TYLENOL). All of her symptoms resolved within 3-4 days (approximately 15-SEP-2006). Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264754-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		17-Oct-2006	28-Nov-2006	MD	WAES0609USA04922	28-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a female patient between the age of 15 to 18 who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient complained of stinging. It was noted that the stinging was only for a moment and resolved quickly. The reporter felt that the stinging could be from the vaccine being cold. No other problems were noted with the administration. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264755-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	20-Sep-2006	21-Sep-2006	1	17-Oct-2006	27-Nov-2006	--	WAES0609USA05006	27-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0702F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Information has been received from a medical assistant concerning a 25 year old female with connective tissue disorder, thrombocytopenia, depression and allergy to ZITHROMAX who on 20-SEP-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) IM in the deltoid described as "pre-filled syringe one time." Concomitant therapy included escitalopram oxalate (LEXAPRO) and methylphenidate HCl (RITALIN). On 21-SEP-2006 the patient experienced fever of 100 degrees F. The patient sought unspecified medical attention. The patient's fever of 100 degrees F. persisted. Additional information has been requested.

**Other Meds:** LEXAPRO, RITALIN

**Lab Data:** NONE

**History:** Concurrent conditions: connective tissue disorder, thrombocytopenia, depression, drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264756-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	28-Nov-2006	--	WAES0609USA05009	28-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site reaction

**Symptom Text:** Information has been received from a nurse practitioner concerning a female who on 18-SEP-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced injection site reaction. The patient sought unspecified medical attention. Injection site reaction persists. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264757-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	01-Sep-2006	08-Sep-2006	7	17-Oct-2006	28-Nov-2006	MO	WAES0609USA05017	28-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	653937/0637F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash

**Symptom Text:** Information has been received from a physician and a registered nurse concerning a 25 year old female who on 01-SEP-2006 was vaccinated IM with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included hormonal contraceptives (unspecified). On approximately 08-SEP-2006, one week after vaccination, the patient developed "small bumps under her skin" at the injection site. The patient sought unspecified medical attention. Subsequently, the patient fully recovered.

**Other Meds:** hormonal contraception

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264758-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NC	WAES0609USA05491	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash pruritic, Rash vesicular

**Symptom Text:** Information has been received from a pharmacist concerning a female patient (age not reported) a physician mentioned who was vaccinated on an unspecified date with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient developed a poison ivy-like rash on her shoulder behind the area where she was administered the vaccine. The rash was reported to be itchy, vesicular and the size of a grapefruit. The patient sought unspecified medical attention. At the time of this report the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264759-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	FL	WAES0609USA05508	02-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oedema peripheral

**Symptom Text:** Information has been received from a physician concerning a 21 year old female who on an unknown date was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # not provided). Subsequently, the patient developed "swelling feet" for an unspecified amount of time after receiving the injection. At the time of this report the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264760-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NC	WAES0609USA05516	02-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site inflammation, Injection site pain

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # not provided). Subsequently, the patient experienced burning and pain at the injection site. Unspecified medical attention was sought. It was unknown at the time of the report if the patient had recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264761-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	--	WAES0609USA05927	29-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a physician concerning his "around 18" year old daughter who was vaccinated IM with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included a dose of diphtheria toxoid (+) pertussis acellular 3-component vaccine (+) tetanus toxoid (BOOSTRIX). Subsequently, the patient experienced numbness in her arms and lower extremities. Unspecified medical attention was sought. On an unspecified date, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264762-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	25-Sep-2006	25-Sep-2006	0	17-Oct-2006	29-Nov-2006	--	WAES0609USA05955	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 26 year old female with a penicillin allergy who on 25-SEP-2006 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Immediately post-vaccination, the patient experienced hives. The patient was treated with oral diphenhydramine hydrochloride (BENADRYL) and symptoms lessened. No diagnostic studies were performed. At the time of this report, the patient was recovering. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** Concurrent conditions: penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264763-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Sep-2006	22-Sep-2006	0	17-Oct-2006	29-Nov-2006	IN	WAES0609USA07045	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site swelling, Lymphadenopathy, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 17 year old female patient who on 22-SEP-2006 was vaccinated IM with a first 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. On 22-SEP-2006 the patient developed swollen lymph nodes in the neck and groin, swelling at injection site and low grade fever. The patient sought unspecified medical attention. It was reported that the patient was recovering. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264764-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
28.0	F	26-Aug-2006	27-Aug-2006	1	17-Oct-2006	29-Nov-2006	FL	WAES0609USA07241	02-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Gluteous maxima	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site mass

**Symptom Text:** Information has been received from a 28 year old female who on approximately 26-AUG-2006 was vaccinated intramuscularly in her right buttocks with HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # not provided). On approximately 27-AUG-2006 the patient developed a painful lump in the area of her injection site. She stated "there is a ball inside my skin and it still occasionally hurts." Subsequently, unspecified medical attention was sought. At the time of this report the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264765-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	WY	WAES0609USA07284	29-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0696F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female between the ages of 14 to 21 years old who was vaccinated IM into the deltoid region with a first 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced extreme pain during injection. No medical attention was sought. About 15 to 20 minutes after injection, the patient was improving. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264766-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	MD	WAES0609USA07368	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a female patient between the age of 15 to 18 who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient complained of stinging. It was noted that the stinging was only for a moment and resolved quickly. The reporter felt that the stinging could be from the vaccine being cold. No other problems were noted with the administration. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264767-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	MD	WAES0609USA07369	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a female patient between the age of 15 to 18 who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient complained of stinging. It was noted that the stinging was only for a moment and resolved quickly. The reporter felt that the stinging could be from the vaccine being cold. No other problems were noted with the administration. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264768-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	MD	WAES0609USA07370	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a female patient between the age of 15 to 18 who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient complained of stinging. It was noted that the stinging was only for a moment and resolved quickly. The reporter felt that the stinging could be from the vaccine being cold. No other problems were noted with the administration. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264769-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	MD	WAES0609USA07371	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a female patient between the age of 15 to 18 who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient complained of stinging. It was noted that the stinging was only for a moment and resolved quickly. The reporter felt that the stinging could be from the vaccine being cold. No other problems were noted with the administration. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264770-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	MD	WAES0609USA07372	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a female patient between the age of 15 to 18 who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient complained of stinging. It was noted that the stinging was only for a moment and resolved quickly. The reporter felt that the stinging could be from the vaccine being cold. No other problems were noted with the administration. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264771-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	--	WAES0609USA07427	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician's office concerning a female patient was vaccinated IM with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The reporter indicated that using the prefilled syringe was "painful and startling" to the patient. Her outcome was not reported. A product quality complaint was not involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264772-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	27-Sep-2006	28-Sep-2006	1	17-Oct-2006	29-Nov-2006	PA	WAES0609USA08050	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral, Pruritus

**Symptom Text:** Information has been received from a 27 year old female with no other pertinent medical history and no known allergies or adverse drug reactions reported. On 27-SEP-2006, the patient was vaccinated with 0.5 mL of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included unspecified hormonal contraceptives (reported as "birth control"). On 28-SEP-2006, the patient developed red, itchy and swollen hands and feet. The patient sought unspecified medical attention. At the time of this report the patient was recovering from the events. Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264773-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	25-Sep-2006	25-Sep-2006	0	17-Oct-2006	29-Nov-2006	PA	WAES0609USA08058	02-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Nausea, Pain

**Symptom Text:** Information has been received from the mother of a female patient in her "early 20's" with no relevant medical history who on 25-SEP-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) (0.5 mL). There was no concomitant medication. On 25-SEP-2006, the patient experienced "a lot of pain and nausea." The pain was described as a stinging feeling when the medication was being injected. The patient subsequently recovered from the pain and nausea one hour after vaccination. Medical attention was not sought. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264774-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	26-Sep-2006	26-Sep-2006	0	17-Oct-2006	29-Nov-2006	NY	WAES0609USA08128	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Medication error, Pain

**Symptom Text:** Information has been received from a nurse practitioner concerning a 23 year old female with mild cervical dysplasia with colposcopy and no known allergies or adverse drug reactions reported. On 26-SEP-2006, the patient was vaccinated with the first dose of 0.5 mL of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication reported. It was reported that the pre-filled syringe had been stored at 34F. On 26-SEP-2006 the patient developed severe pain during administration with lightheadedness and dizziness. The patient was laid on the exam table and given ibuprofen (MOTRIN) for pain. The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Concurrent conditions: cervical dysplasia, colposcopy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264775-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	CO	WAES0609USA08561	29-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Medication error, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a 25 year old female who in 2006 (date not reported) was vaccinated with a 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The nurse reported having "the syringe jam and could not administer the vaccine." The vaccine was given using a second syringe. The nurse also reported that the patient experienced "muscle pain in her arm, the arm of the jammed syringe." At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264776-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Sep-2006	01-Sep-2006	0	17-Oct-2006	29-Nov-2006	MO	WAES0610USA00329	29-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Pyrexia

**Symptom Text:** Information has been received from a physician concerning an 18 year old female patient who in September 2006 was vaccinated IM with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently in September 2006 the patient developed 102 degree temperature and chills. Medical attention was sought. The patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Body temp, 09/??/2006, 102 degrees F

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264777-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	TX	WAES0610USA00388	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from an LPN concerning a female patient who was vaccinated IM with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced pain in her arm in excess of 5 days. There was no swelling or rash, only the pain. Medical attention was sought. The pain was reported to have improved on therapy. It was unknown whether this was an injection site reaction. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264778-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	ND	WAES0610USA00698	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site pain, Paraesthesia

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female patient who on an unspecified date was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced pain, numbness, and a tingly feeling all the way down to her fingertips. The events occurred in the arm in which the patient received the vaccination. Unspecified medical attention was sought. The patient subsequently recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264779-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	ND	WAES0610USA000699	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain, Paraesthesia

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female patient who on an unspecified date was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced pain, numbness and a tingly feeling all the way down to her fingertips. The events occurred in the arm in which the patient received the vaccination. Unspecified medical attention was sought. The patient subsequently recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264780-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	ND	WAES0610USA00700	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain, Paraesthesia

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female patient who on an unspecified date was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced pain, numbness, and a tingly feeling all the way down to her fingertips. The events occurred in the arm in which the patient received the vaccination. Unspecified medical attention was sought. The patient subsequently recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264781-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	ND	WAES0610USA00701	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain, Paraesthesia

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female patient who on an unspecified date was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced pain, numbness, and a tingly feeling all the way down to her fingertips. The events occurred in the arm in which the patient received the vaccination. Unspecified medical attention was sought. The patient subsequently recovered from the events. Additional information has been sought.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264782-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NJ	WAES0610USA00860	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a female patient "between the ages of 11 and 16 years old" who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Within 1 to 2 days after receiving HPV rL1 6 11 16 18 VLP vaccine (yeast), the patient developed a fever and headache (date unknown). At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264783-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NJ	WAES0610USA01164	29-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Information has been received from a physician concerning an 11 year old female patient who on an unspecified date was vaccinated IM with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Within one to two days after administration, the patient developed headache and fever. No medical attention was sought. Her outcome was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264784-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NJ	WAES0610USA01349	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a female patient "between the ages of 11 and 16 years old" who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Within 1 to 2 days after receiving HPV rL1 6 11 16 18 VLP vaccine (yeast), the patient developed a fever and headache (date unknown). At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264785-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NJ	WAES0610USA01350	29-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a female patient "between the ages of 11 and 16 years old" who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Within 1 to 2 days after receiving HPV rL1 6 11 16 18 VLP vaccine (yeast), the patient developed a fever and headache (date unknown). At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264786-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	01-Sep-2006	08-Sep-2006	7	17-Oct-2006	29-Nov-2006	MO	WAES0610USA03087	30-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653937/0637F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site reaction

**Symptom Text:** Information has been received from a physician and a registered nurse concerning a 25 year old female who on 01-SEP-2006 was vaccinated IM with a 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included hormonal contraceptives (unspecified). On approximately 08-SEP-2006, one week after vaccination, the patient developed "small bumps under her skin" at the injection site. The patient sought unspecified medical attention. Subsequently, the patient fully recovered. Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264787-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NJ	WAES0610USA03614	30-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 13 year old female patient who on an unspecified date was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient developed headache and fever. Her outcome was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264788-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	NJ	WAES0610USA03615	30-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 16 year old female patient who on an unspecified date was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient developed headache and fever. Her outcome was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264789-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	WY	WAES0610USA03622	30-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0696F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a registered nurse concerning a female between the ages of 14 to 21 years old who was vaccinated IM into the deltoid region with a first 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced extreme pain during injection. The patient had to lie down for a short time period until the pain subsided. No medical attention was sought. About 15 to 20 minutes after injection, the patient was improving. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264790-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	WY	WAES0610USA03624	30-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0696F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a registered nurse concerning a female between the ages of 14 to 21 years old who was vaccinated IM into the deltoid region with a first 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient experienced extreme pain during injection. No medical attention was sought. About 15 to 20 minutes after injection, the patient was improving. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264791-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	--	WAES0610USA03816	30-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Malaise, Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning a female patient (age not reported) who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient fainted post vaccination. She stated that it "felt like the medicine traveled through my system at time of injection." Subsequently, the patient recovered from the syncope and abnormal feeling. The nurse reported that the patient was not disoriented, was very aware and her blood pressure (actual BP not reported) was within normal limits. The patient was offered a sugar drink (soda) after the event and recovered from the event. The nurse practitioner noted that the patient had eaten before coming in for the vaccination. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264792-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	--	WAES0610USA03817	30-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning a female patient (age not reported) who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient fainted post vaccination. Subsequently, the patient recovered from the syncope. The nurse reported that the patient was not disoriented, was very aware and her blood pressure (actual BP not reported) was within normal limits. The patient was offered a sugar drink (soda) after the event and recovered from the event. The nurse practitioner noted that the patient had eaten before coming in for the vaccination. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264793-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Oct-2006	29-Nov-2006	--	WAES0610USA03818	30-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning a female patient (age not reported) who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient fainted post vaccination. Subsequently, the patient recovered from the syncope. The nurse reported that the patient was not disoriented, was very aware and her blood pressure (actual BP not reported) was within normal limits. The patient was offered a sugar drink (soda) after the event and recovered from the event. The nurse practitioner noted that the patient had eaten before coming in for the vaccination. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264950-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
57.0	F	19-Sep-2006	03-Oct-2006	14	19-Oct-2006	25-Oct-2006	WI		25-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MMR	MERCK & CO. INC.	0296R		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0039F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain, Hypoaesthesia, Lymphadenopathy

**Symptom Text:** 09/19/2006 MMR and HBV adm 1, 10/03/2006 swollen glands, numbness and tingling of arm and legs bilat. Pt called hotline and states she was told this was from the MMR. 10/15/06 chest pain. Pt wonders if this is related to immunizations.

**Other Meds:**

**Lab Data:**

**History:** Valve Proplase in distant past, neg heart cath 2 yrs ago.

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264959-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	16-Oct-2006	16-Oct-2006	0	19-Oct-2006	25-Oct-2006	CT		18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0741F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bradycardia, Coma, Heart rate irregular, Musculoskeletal stiffness, Pallor, Syncope, Urinary incontinence

**Symptom Text:** Administr4ed Vaqta, then Gardasil, immediately after Gardasil child became unresponsive, stiff, pale about 30 sec. Child lost bladder control, pulse 46-55 after event, child alert and aware after events. 11/27/06 Received medical records from provider/reporter which reveal patient had LOC, tonic/clonic movements & loss of bladder control after received 2nd Gardasil vax. HR was 46-55. This was the 3rd episode of LOC within a year (1st after tetanus shot, 2nd after finding a tick & 3rd after 2nd dose of Gardasil). PCP recommended cardiac & neuro w/u. Received cardiac consultation which revealed final dx: probable fainting. Holter monitor was WNL. Awaiting neuro consult.

**Other Meds:**

**Lab Data:** Scheduled for cardiac and Neuro follow up. LABS: IgG was only positive for Lyme dx which was considered negative.

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264992-1      **Related reports:** 264992-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	16-Oct-2006	18-Oct-2006	2	19-Oct-2006	25-Oct-2006	CA		25-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2572AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0637F		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blister, Face oedema

**Symptom Text:** Received Tdap and HPV vaccine on 10/16/2006 noticed some blisters at the corner of mouth and swelling of lower lip on the evening of 10/18/2006 and facial swelling around eyes on 10/19/06. No fever, headache, dizziness or any GI symptoms.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 264992-2      **Related reports:** 264992-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	16-Oct-2006	16-Oct-2006	0	16-Nov-2006	04-Dec-2006	CA	WAES0610USA12143	25-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653937/0637F		Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypersensitivity, Hypersensitivity, Swelling

**Symptom Text:** Information has been received from a business manager in a physicians office concerning a 15 year old female who on 16 Oct 2006 was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine. Concomitant therapy that day included diphtheria toxoid + pertussis acellular vaccine + tetanus toxoid. Subsequently, the patient experienced an allergic reaction, her face and body began to swell. The physician recommended the patient take an unspecified dose of diphenhydramine hydrochloride (Benadryl). After taking diphenhydramine hydrochloride the patients face and body swelling "went down". On 20 Oct 2006 it was reported that "the swelling became worse again". At the time of this report the patient had not recovered from the event. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265013-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	09-Oct-2006	16-Oct-2006	7	20-Oct-2006	26-Oct-2006	KY		26-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Injection site reaction, Pruritus, Thermal burn

**Symptom Text:** Localized reaction at injection site right del itching and burning beginning 7 day post injection, also headache. Txd symptoms with Benadryl, Tylenol, Hydrocortisone cream.

**Other Meds:** Lexapro, Effexor, Yasmin, HCTZ, Elmiron, Parida Plus, Claritin.

**Lab Data:**

**History:** Sulfa Allergy, Hypertension, Intestinal cystitis.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265107-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	19-Oct-2006	19-Oct-2006	0	23-Oct-2006	25-Oct-2006	--		25-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Asthenia, Dizziness, Hyperhidrosis

**Symptom Text:** After receiving Gardasil vaccine #1 pt immediately became lightheaded, weak and sweaty. SX lasted approx 5 minutes. (OMIC).

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265305-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	16-Oct-2006	16-Oct-2006	0	24-Oct-2006	25-Oct-2006	FL		25-Oct-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		UNKNOWN	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Difficulty in walking, Muscle rigidity, Syncope

**Symptom Text:** According to my daughter, the following happened: 1. Shot was given between 1100-1115 am 2. Proceed to wait a few minutes with doctor in room and then went to check out 3. Between 1120-1125 am...she passed out in doctors office. 4. Day 2-4: tightness in muscles especially around lower legs. Also tightness in arms, but not as bad as legs. 5. Hard time walking after first waking up in morning and gradually loosens up after she starts moving around. 6. I suggested to her to take a Tylenol to help with muscle tightness and to massage calves prior to getting out of bed to help loosen them up.

**Other Meds:** Ortho-tricyclene Low

**Lab Data:** N/A

**History:** None

**Prex Illness:** None.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265338-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.0	M	13-Oct-2006	Unknown		25-Oct-2006	01-Nov-2006	MI		01-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	PNC	LEDERLE LABORATORIES	B22930D	3	Left leg	Intramuscular	
	FLU	AVENTIS PASTEUR	V2175HA	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB099CB	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	
	HIBV	MERCK & CO. INC.	0212R	3	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT:** Unevaluable event

**Symptom Text:** None Stated

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265357-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	13-Oct-2006	20-Oct-2006	7	25-Oct-2006	26-Oct-2006	KY		26-Oct-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0660F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pain, Injection site swelling

**Symptom Text:** Approximately 7 days after HPV IM, L deltoid became very sore, painful to abduct. Nosig soreness at 24 hours after IM. On exam is tender deep in muscle and is enlarged. No surface redness. No induration.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265372-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	06-Oct-2006	06-Oct-2006	0	26-Oct-2006	27-Oct-2006	CA	WAES0610USA09738	27-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Eye swelling, Pruritus, Vision blurred

**Symptom Text:** Information has been received from a physician concerning a 24 year old female pt with no known allergies or reportable medical history who on 10/6/06 was vaccinated IM with a 0.5ml dose of HPV. Several hours later, on 10/6/06 the pt called the office with complaints of swollen puffy eyes, some itching but no rash and blurry vision. The pt was seen in the office that evening on 10/6/06 and was given a dose of Benadryl and was sent home. The pt took a nap for the blurry vision and upon awakening the next morning the pt fully recovered. Blurry vision was considered to be disabling according to the physician since the pt was unable to perform her normal task. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265384-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	23-Oct-2006	23-Oct-2006	0	26-Oct-2006	30-Oct-2006	--		31-Oct-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0966P		Unknown	Intramuscular	

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Asthenia, Dizziness, Hyperhidrosis, Syncope vasovagal

**Symptom Text:** Few minutes after receiving Gardasil vaccine patient had vaso vagal type reaction, weak, dizzy, hot, sweaty. Felt like she was going to faint.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265435-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	17-Oct-2006	17-Oct-2006	0	26-Oct-2006	02-Nov-2006	PA		03-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0641F	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Acne

**Symptom Text:** Papules used BENADRYL and cortisone.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265676-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	17-Oct-2006	22-Oct-2006	5	31-Oct-2006	09-Nov-2006	NC		09-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Cough, Hypersensitivity, Hypoaesthesia, Psychomotor hyperactivity, Pyrexia

**Symptom Text:** Fever, cough, numb, and tingling all over, acted hyperactive loopy, taking OTC cold remedies, MD suggested Claritin and nasal spray for allergies, may need anti anxiety and anti depressant for ADHD, anxiety.

**Other Meds:**

**Lab Data:** Thyroid, Potassium levels done. Given flu vaccine 10/27/06

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265756-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	01-Aug-2006	03-Aug-2006	2	01-Nov-2006	02-Nov-2006	MO		18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Patient complained of Left arm numbness after receiving injection. Lasted less than 48 hours.

**Other Meds:** Doxycycline,Zoloft,Yasmin

**Lab Data:**

**History:** Depression & Anxiety, Migraine Headaches, Acne, Exzema, Seasonal Allergies.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265801-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	25-Oct-2006	25-Oct-2006	0	01-Nov-2006	14-Nov-2006	WA		14-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Patient reports she vomited 1 time approximately 4 hours following injection of Gardasil. Patient's mother reports that the patient vomited following the first injection in series.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265808-1      **Related reports:** 265808-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	06-Oct-2006	07-Oct-2006	1	01-Nov-2006	14-Nov-2006	MD		15-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Nausea, Pyrexia, Vomiting

**Symptom Text:** Nausea and vomiting, fever 99 degrees F- 100 degrees F, chills for 3 days.

**Other Meds:** Estrostep

**Lab Data:**

**History:** allergic to Penicillin.

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265808-2      **Related reports:** 265808-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	06-Oct-2006	07-Oct-2006	1	16-Nov-2006	29-Nov-2006	MD	WAES0610USA12543	29-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	654540/0800F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Information has been received from a physician concerning a 21 year old female with an allergy to penicillin who was receiving contraceptive therapy, who on 06-OCT-2006 was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (0.5 mL). Concomitant therapy included ethinyl estradiol/norethindrone acetate (ESTROSTEP). On 07-OCT-2006 or 08-OCT-2006 the patient experienced nausea and vomiting. Unspecified medical attention was sought. Subsequently, the patient recovered from the nausea and vomiting. Additional information has been requested.

**Other Meds:** ESTROSTEP

**Lab Data:** NONE

**History:** Concurrent conditions: penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265839-1 (S)    **Related reports:** 265839-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	09-Oct-2006		02-Nov-2006	03-Nov-2006	OH	WAES0610USA11542	19-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Guillain-Barre syndrome, Hypoaesthesia

**Symptom Text:** Information has been received from a physician concerning a 16 year old female who on an unspecified date was vaccinated with the first dose of HPV vaccine. subsequently the pt developed lower extremity weakness and was hospitalized for two days with Guillain Barre. The pt received treatment with gamma globulin during her hospitalization. At the time of this report, the pt was back to school and was 99% recovered having only some area of numbness to her lower extremities. The physician did not believe that the pt was on any other medications at the time and had no further details to provide. Additional information has been requested. Mild Guillane Barre Syndrome. EMG study on 10/10/2006: nerve conduction studies of right peroneal and tibial nerves were normal. F wave latencies were normal but some blocking was present. Conclusion: study consistent with mild Guillain Barre Syndrome.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265839-2      **Related reports:** 265839-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Nov-2006	16-Nov-2006	OH	WAES0611USA01036	16-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Guillain-Barre syndrome, Neuropathy, Pain

**Symptom Text:** Information has been received from a neurologist concerning a female pt who was vaccinated with one dose of HPV vaccine. Subsequently the pt developed neuropathy and pain in the legs. The pt was diagnosed with Guillain Barre syndrome. The pts Guillain Barre syndrome persisted. Upon internal review, Guillain Barre syndrome was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265930-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	23-Sep-2006	07-Oct-2006	14	03-Nov-2006	06-Nov-2006	FR	WAES0610CAN00210	19-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Encephalitis

**Symptom Text:** Information has been received from a physician concerning a female who on approximately 9/23/06 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). On 10/7/06, the patient experienced acute disseminated encephalomyelitis and was hospitalized in a neurology ward of a children's hospital. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 265955-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	21-Oct-2006	21-Oct-2006	0	03-Nov-2006	15-Nov-2006	CA		15-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site pain, Syncope

**Symptom Text:** Per pt arm where Gardasil was administered felt painful then numb and then pt fainted for a few seconds.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266325-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	30-Aug-2006	30-Aug-2006	0	08-Nov-2006	05-Dec-2006	WV		05-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0696F	0	Right arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Complaints of pain in right arm initially after 1st Gardasil injection. States right arm hurt for 1 month after shot was given.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266371-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	03-Oct-2006	06-Oct-2006	3	09-Nov-2006	10-Nov-2006	CA	WAES0610USA14679	10-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Information has been received from a physician and the mother of a 15 year old female with a history of hypersensitivity reactions to allergens. On 10/3/06, the pt was vaccinated IM with the first dose of 0.5ml of HPV vaccine (lot 653650/0702F. Concomitant therapy included Ortho Tri Cyclen LO started on 10/6/06. On 10/06/06, the pt developed widespread itching and hives of both upper and lower extremities. The pt did not experience respiratory symptoms. The pt was self treated with Benadryl with only mild improvement. A nurse in the local ER was consulted by phone but the pt did not require hospitalization. The symptoms resolved after one week and the pt had not experienced further problems. On 10/13/06 the pt had recovered from the event. The physician considered the event to be serious as disabling. Additional information has been requested.

**Other Meds:** Ortho Tri Cyclen LO

**Lab Data:**

**History:** Hypersensitivity.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266497-1      **Related reports:** 266497-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	30-Oct-2006	30-Oct-2006	0	10-Nov-2006	13-Nov-2006	IN		12-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Disorientation, Dizziness, Dyspnoea, Nausea, Syncope

**Symptom Text:** Patient fainted in waiting area less than five minutes after receiving Gardasil injection. Patient disoriented and c/o difficulty breathing when roused. C/O nausea, dizziness. Sent to ER & diagnosed as vasovagal syncope. Patient c/o sores in genital area 3 days post vaccination. Upon visit to doctor, diagnosed with Condyloma.

**Other Meds:** Advil, Benadryl, Tylenol

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266497-2      **Related reports:** 266497-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	30-Oct-2006	30-Oct-2006	0	18-Dec-2006	19-Dec-2006	--	WAES0611USA02498	19-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** Information has been received from a registered nurse concerning a 17 year old white female (121 pounds, 61.5 inches) who on 30 Oct 2006 was vaccinated with Gardasil (lot number 653978/0955F) intramuscularly. On 30 Oct 2006, after the injection , the patient left the examination room and arrived in the lobby (noted as less than 2 minutes) when the nurse was called to the lobby. The patient's mother stated the patient "passed out" for a few seconds. It was also noted that the patient was "faint" with a duration of less than 1 minute, had dizziness which lasted approximately 1.5 hours, had nausea for approximately 15 minutes, and her skin was clammy. The patients blood pressure and pulse were within normal limits. A cold wash cloth was applied to the patients neck. The patient was taken by wheelchair to the Emergency Department. The patient's mother reported that the Emergency Department visit was quick and the physician stated that the patient had a vasovagal response. On 31 Oct 2006, the patient was considered recovered from vasovagal response. Additional information is not available.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266541-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	13-Sep-2006	14-Sep-2006	1	10-Nov-2006	20-Nov-2006	KY		20-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702P	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Angioneurotic oedema, Face oedema

**Symptom Text:** Angioedema lips for one month by history from pt.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266568-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	25-Oct-2006	25-Oct-2006	0	13-Nov-2006	27-Nov-2006	WV		27-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Irritability, Rash

**Symptom Text:** Fussy body rash X 24 hours following vaccination. Cleared spontaneously.

**Other Meds:** NONE

**Lab Data:** NONE

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266581-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	13-Oct-2006	13-Oct-2006	0	13-Nov-2006	22-Nov-2006	VA		18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2165CA	2	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Bradycardia, Heart rate irregular

**Symptom Text:** Vasovagal RXN. Pt HR decreased to 50 and BP decreased.

**Other Meds:** Allegra, Nasolcrom, Acne meds, Bactrim

**Lab Data:** Skin prick tested for allergies.

**History:** Acne, allergies to raw peaches, carrot, potatoes, kiwi, apples, cherries.

**Prex Illness:** NONE

**Prex Vax Illns:** Fever~DTP (unknown mfr)~1~1~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266592-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	31-Oct-2006	01-Nov-2006	1	13-Nov-2006	12-Dec-2006	PA		12-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B011CA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2199AA	4	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Rash, Rash papular

**Symptom Text:** Fine red, papular, pruritic rash on 1st and 2nd digits both hands and dorsum both feet.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266639-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Nov-2006	08-Nov-2006	0	13-Nov-2006	12-Dec-2006	ME		12-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1808AA	0	Left arm	Unknown	FLU
	HPV4	MERCK & CO. INC.	0688F	0	Right arm	Unknown	HEPA

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Swelling, Tenderness

**Symptom Text:** 10.4 cm X 7.0 cm area of redness. Swelling and tenderness. Complains of burning at site left deltoid.

**Other Meds:** CONCERTA 54mg

**Lab Data:**

**History:** Attention-deficit Hyperactivity disorder

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266717-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	25-Sep-2006	30-Sep-2006	5	14-Nov-2006	18-Dec-2006	IL		18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Developed rash all over body gradually subsided after few days.

**Other Meds:** Ovcon

**Lab Data:** NONE

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266734-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	03-Oct-2006	06-Oct-2006	3	14-Nov-2006	18-Dec-2006	CA		18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives all over 3 days after injection. No treatment.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266774-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	12-Oct-2006	19-Oct-2006	7	14-Nov-2006	15-Nov-2006	LA		19-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	08668F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Shoulder pain

**Symptom Text:** Patient developed left shoulder pain at the deltoid corresponding to the site of injection. This began about 1 week after injection and has lasted for 3 weeks. It is 7/10 in severity and requires anti-inflammatories.

**Other Meds:** Yaz, Zolof, Bactrim DS

**Lab Data:** none

**History:** Depression

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266788-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	13-Nov-2006	13-Nov-2006	0	14-Nov-2006	15-Nov-2006	OR		19-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Panic reaction

**Symptom Text:** Patient c/o: dizziness, lightheaded, feels as if she is going to have a panic attack, very fatigued.

**Other Meds:** Advair

**Lab Data:** n/a

**History:**

**Prex Illness:** odd cough & migranes per patient history

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 214

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 266889-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	25-Oct-2006	26-Oct-2006	1	16-Nov-2006	17-Nov-2006	MI		07-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B012AA	0	Unknown	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1948AA	0	Unknown	Intramuscular	
	FLU	AVENTIS PASTEUR	U2256AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Dehydration, Hypersensitivity, Muscle spasms, Pyrexia

**Symptom Text:** Pt received injections 10/25/06. Flu and HPV in one thigh. Tdap and Menactra in other thigh unk which thigh each given. Pt then went to allergist and received allergy injection in each arm. Admitted 10/26/06 for fever 103, dehydration and muscle cramping, sent home 10/27/06. DC DX: allergic reaction. 2 day history of fever. On same day as immunizations she received routine allergy shots. Immunizations received in thighs and allergy injections in arms. Complained of arms puffed and welted evening prior to admission, became painful. Also blotchiness on legs. Complained of pain in legs. Headache since immunizations, myalgias and arthralgias especially to shoulder area. Neck pain, prickly sensaton in feet. Previous immunization reacion 3 weeks ago with pain and symptomatic problems. PMH: environmental allergens. Eczema. Roavirus at age 2 months. PE: Extremities, there is injection site visible. No rash, erythema or exudate noted around the injection sites. No other rashes.

**Other Meds:** Nasocort, Zyrtec, Allergy injections.

**Lab Data:** Labs: Glucose 118, CO2 21, C-reactive protein 1.8.

**History:** Allergic Rhinitis. PMH: environmental allergens. Eczema. Roavirus at age 2 months.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267030-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	15-Nov-2006	15-Nov-2006	0	16-Nov-2006	17-Nov-2006	PA		19-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Disorientation, Dyskinesia, Eye movement disorder, Pallor, Syncope

**Symptom Text:** Within a minute of giving injection in rt deltoid, pt experienced pallor, syncope, rolling back of the eyes followed by jerky movements of upper & lower extremities. After 5 seconds, she became responsive, but disoriented to place. Pt stated that she had not eaten much all day.

**Other Meds:** Adderall XL 30mg q day Depo Provera 150mg q 3 months

**Lab Data:** none

**History:** NKA none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267080-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	31-Aug-2006	03-Oct-2006	33	17-Nov-2006	20-Nov-2006	FL	WAES0611USA02762	20-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, HOSPITALIZED, OMIC, SERIOUS

**MedDRA PT** Abdominal pain, Feeling cold, Haemorrhage, Hot flush, Nausea, Pyrexia

**Symptom Text:** concerning a 19 year old female with diabetes and hypothyroidism on 8/31/06 was vaccainted IM with a first dose of HPV vaccine. Concomitant therapy included an insulin pump, Levothyroxine (Synthroid) and (Loworval). On 10/3/06 (also reported as a month later), the pt experienced hot flushes and cold flashed, nausea, a temp less than 100F and abnormal bleeding. On 11/4/06, the pt experienced right lower quadrant abdominal pain and was hospitalized. She has had a CAT scan, MRI, laparoscopy and a few ultrasounds of the area but all have been neg. The pt was treated wit IV fluids. At the time of this report, the pt had not recovered. No product quality complaint was involved. Right lower quadrant abdominal pain was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Insulin, Synthroid

**Lab Data:**

**History:** Diabetes, Hypothyroidism.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267100-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	08-Nov-2006	08-Nov-2006	0	17-Nov-2006	27-Nov-2006	MN		27-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Pt received vaccination early in AM. Called later that afternoon and was itching all over. took Benadryl which helped.

**Other Meds:** Nuvaring, Allegra D, Albuterol, Nasonex

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267171-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	10-Nov-2006	11-Nov-2006	1	17-Nov-2006	20-Nov-2006	MN		19-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	08668F	0	Right arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2244AA	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy, Hypoaesthesia, Pain, Paralysis

**Symptom Text:** INfluenza vaccine and Human Papilloma Virus vaccines given November 10 about 11:45 AM. Patient woke up with numbness on right side of face on November 11. Presented to Emergency Room on November 12 with Bells Palsy of right side of face. Unable to move right side of face. Unable to close right eye. Previously healthy, no symptoms on day of vaccine administration. Received MR from pediatrician revealing a healthy 12 year old in for well-child exam. 24 hours after Flu and Gardasil vax. child developed numbness, pain, and inability to move the right side of face. Assessment: Facial Nerve Palsy-unclear etiology. Child was sent by car to Minneapolis Children's ER to be evaluated. ER report received: DX: Bell's Palsy

**Other Meds:** NONE

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267197-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	13-Nov-2006	14-Nov-2006	1	17-Nov-2006	13-Dec-2006	WI		11-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy

**Symptom Text:** Bell's Palsy right occurred 24 hours after injection of Gardasil. Previously healthy. MR received revealing an 18 yr. old in for well-woman exam with only c/o some discomfort in the mastoid area behind her right ear x2 days. The following day she presented with right-sided facial droop. HPI: Pt awoke morning following Gardasil vax. and had difficulty with spitting out her toothpaste. No pain or visual loss. No extremity weakness or paresthesias. Most obvious upon smiling. Able to wrinkle forehead and puff cheeks. Good sensation. Txd with Famvir, Solu-medrol and Refresh Tears. Assessment: Bell's Palsy.

**Other Meds:** ortho tricyclic Meds-Ortho Tri-Cyclen

**Lab Data:** Lymes, CBC, CRP, CMP, Sed rate. Labs and Diagnostics: All normal.

**History:** None PMH: None noted except for dysmenorrhea. NKA.

**Prex Illness:** Well woman exam. C/o some discomfort in the mastoid area behind her right ear x2 days.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 220

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267288-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	29-Sep-2006	30-Sep-2006	1	20-Nov-2006	21-Nov-2006	MD	WAES0611USA03232	21-Nov-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Unknown			

**Seriousness:** ER VISIT, LIFE THREATENING, OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Throat tightness, Tongue oedema, Urticaria

**Symptom Text:** Information has been received from a physicians assistant concerning a 25 year old female who on 9/29/06 was vaccinated with a first dose of HPV vaccine. Concomitant suspect therapy initiated a few days prior included nitrofurantoin (Macrobid) for the treatment of a urinary tract infection (dose not reported). Other concomitant therapy included drospirenone + ethinyl Estradiol (Yasmin). On 9/20/06 the pt called the physicians office to state that she had developed hives. The physicians office referred her to the ER where she was placed on methylprednisolone (Medrol Dosepak). The pt was not hospitalized. On 10/2/06 the pt called the physicians office to report that her tongue was swelling and her throat was closing. The pt was immediately referred to the ER where she was given epinephrine (Epi Pen). The pt was not hospitalized. On 1/04/06 the pt recovered. Hives, tongue swelling and throat closing were considered to be disabling, immediately life threatening and other important medical events (OMIC). The physicians assistant reported that they were not sure if the reactions was to the HPV or the Macrobid. Additional information has been requested.

**Other Meds:** Yasmin, Macrobid

**Lab Data:**

**History:**

**Prex Illness:** Urinary tract infection

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267319-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	29-Sep-2006	08-Oct-2006	9	20-Nov-2006	29-Nov-2006	GA		29-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Pruritus - rash began on lower extremities 1.5 weeks following the first vaccine for HPV. The rash then spread to trunk, back and arms over the next week. Rash began as singular lesions which coalesced it places.

**Other Meds:**

**Lab Data:** Biopsy done on 11/9/06.

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267409-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	18-Sep-2006	18-Sep-2006	0	16-Nov-2006	18-Dec-2006	WA	WAES0609USA07330	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0637F	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Medication error

**Symptom Text:** Initial and follow up information has been received from a nurse practitioner concerning a 25 year old female customer service representative. On 9/18/06, the pt was vaccinated in the right deltoid with the first dose of 0.5ml of HPV vaccine (lot 653937/0637F). There were no other illnesses noted at the time of vaccination. The nurse practitioner reported that the pt was severely obese and when she received the HPV vaccine, the medication dribbled down her arm. It was report that upon removal of the needle, blood tinged fluid flowed from the injection site. The nurse practitioner was unable to estimate the amount but assumed the pt received less than the full dose. The plan was to re inject the pt with a full dose. At the time of this report, the outcome of the events were unk. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** Obesity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267410-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	19-Jul-2006	19-Jul-2006	0	16-Nov-2006	15-Dec-2006	FL	WAES0610USA01137	15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0697F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fatigue, Malaise, Mood swings

**Symptom Text:** Information has been received from a nurse concerning a 21 year old female with asthma, unspecified drug reaction to Penicillin and Amoxicillin and might have been exposed to papilloma viral infection. On 7/19/06, the pt was vaccinated IM with the first dose of HPV vaccine (lot 653650/0697F). Concomitant therapy included unspecified hormonal contraceptives. Subsequently, the pt experienced fatigue, was sick and had mood swings for two months. It was reported that the pt felt rotten after receiving HPV vaccine. (date unk). The pt sought unspecified medical attention. The pt underwent a test for mononucleosis that came back neg (date unk). It was reported that the pt felt better two weeks before the second dose of HPV was due to be administered (date unk). It was reported that the pt does not want to receive the second and third dose of HPV vaccine. At the time of this report, the pt had recovered from the events (date unk). Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:** Serum Epstein Barr neg

**History:** Papilloma viral infection, Penicillin allergy, Asthma.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267411-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	02-Oct-2006	02-Oct-2006	0	16-Nov-2006	15-Dec-2006	--	WAES0610USA01138	15-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 17 year old female pt with on past medical history who on 10/2/06 was vaccainted with a dose of HPV vaccine, lot 653735/0688F. Concomitant therapy included an unspecified flu shot. It was reported that after receiving HPV vaccine, the pt passed out. Medical attention was sought. the pt recovered the same day. No further information is available.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267412-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	26-Sep-2006	26-Sep-2006	0	16-Nov-2006	15-Dec-2006	--	WAES0610USA01157	15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from physician concerning a 17 year old female with no other pertinent medical history reported and no known allergies or adverse drug reactions reported. On 9/26/06 the pt was vaccainted with HPV vaccine (lot 653735/0688F). There were no concomitant medications reported. Subsequently, the pt passed out after receiving the vaccine. The pt sought unspecified medical attention. On 9/26/06, the pt had recovered from the event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267413-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA01483	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning an adult pt who was vaccinated with a dose of HPV vaccine. The pt complained of pain while being injected using the pre filled syringe. The nurse reported that another pt did not complain of pain when a normal syringe was used. The nurse suggested the pre filled needles may be dull causing pain during injection. The pts outcome was not reported. A product quality complaint was involved. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267414-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	14-Sep-2006	14-Sep-2006	0	16-Nov-2006	18-Dec-2006	TX	WAES0610USA01561	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Lymphadenopathy, Pyrexia

**Symptom Text:** Information has been received from a healthcare professional concerning a 15 year old female student who on 9/14/06 at 3:00 pm was vaccinated in the right hip with her first dose of HPV vaccine, lot 654540/0800F. On 9/18/06 the pt developed low grade fever and swollen glands. Her outcome was unk. The reporter indicated the pt would be evaluated at her next vaccination. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 228

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267415-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	02-Oct-2006	02-Oct-2006	0	16-Nov-2006	18-Dec-2006	WA	WAES0610USA02296	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus

**Symptom Text:** Information has been received from a registered nurse and a medical assistant concerning a 27 year old female with seasonal allergies, a possible penicillin allergy and had a history of an abnormal Papanicolaou smear and loop electrosurgical excision procedure. On 8/2/06, the pt was vaccinated IM in the arm with the first 0.5ml pre filled syringe dose of HPV Vaccine (lot 653650/0640F). Concomitant therapy included unspecified hormonal contraceptive (reported as birth control pills). Following the first vaccination, the pt did not experience any adverse reactions. On 10/2/06, the pt was vaccinated with the second dose of HPV vaccine. On 10/2/06, 12 hours after the vaccination, the pt woke up in the middle of the night with right red, itchy hands and feet (also reported as soaked them in ice). It was reported that the symptoms were better the afternoon of the vaccination. On 10/3/06, the pt took Benadryl. The pt sought unspecified medical attention. On 10/4/06, the registered nurse spoke with the pt in the afternoon and all symptoms had resolved. The medical assistant note that the pt had no immediate severe symptoms. The medical assistant reported that there was no mention of seriousness of events in the pts chart and reported that the events did not look like they were serious. The registered nurse further reported that she would not classify the events as serious. Additional information has been requested.

**Other Meds:** Hormonal Contraceptives

**Lab Data:** NONE

**History:** Pap Smear abnormal, Loop electrosurgical excision procedure, seasonal allergy, penicillin allergy.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267416-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Oct-2006	02-Oct-2006	1	16-Nov-2006	18-Dec-2006	--	WAES0610USA03498	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Information has been received from a physician concerning her 18 year old daughter who on 10/01/2006 was vaccinated with HPV vaccine IM in right deltoid. On 10/2/06, within 24 hours, the pt experienced itchy rash on her elbows, feet, buttocks and back. She was given Benadryl and topical steroid cream to treat the symptoms. The pts itchy rash on her elbows, feet, buttocks and back persisted. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267417-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CA	WAES0610USA03730	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a health professional concerning a female patient who was not pregnant and who was vaccinated with a first 0.5 ml dose of HPV (lot # 653735/0688F). Initially the patient experienced numbness at the injection site immediately after administration of the vaccine which was followed by "tingling or prickly feeling" on arm of the injection site. The patient sought unspecified medical attention. The tingling or prickly feeling lasted for a period of 2 to 5 minutes and then totally went away. It was also reported that the patient recovered from numbness at the injection site. It was reported that 3 other female patient's had the same experience (WAES #'s 0610USA04384, 0610USA04385 and 0610USA04386). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 231

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267418-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	01-Sep-2003	29-Sep-2006	1124	16-Nov-2006	15-Dec-2006	NY	WAES0610USA04009	15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug ineffective

**Symptom Text:** Information has been received spontaneously from a gynecologist concerning a 22 year old female patient who had participated in an HPV study. On 29-SEP-2006 the patient tested positive for high risk HPV. The patient's outcome was unknown. Upon internal request, the patient was unblinded on 25-OCT-2006, she received her first dose of HPV on 06-FEB-2003, her second dose in March 2003, and her third dose in September 2003. She showed strong conversion to all 4 vaccine types. At baseline the patient had been seronegative and polymerase chain reaction test (PCR) negative to all 4 vaccine types. In October 2003 she had been PCR negative to all 4 vaccine types. An April 2005 PCR result from a biopsy was negative for the 4 vaccine types. Additional study results: 07-DEC-2004: "ASC-H". 04-APR-2005 colposcopy biopsy negative for lesion, discrepancy noted - biopsy was of less severity than the Papanicolaou (PAP) test result and repeat colposcopy, PAP, and endocervical curettage (ECC) (among other choices) were needed per protocol. 21-SEP-2005 low grade squamous intraepithelial lesions (LSIL). 13-OCT-2005 colposcopy cervical intraepithelial neoplasia (CIN) -1. 25-JAN-2006 atypical squamous cell of undetermined significance (ASCUS) (HPV+). 30-MAR-2006 CIN-2. 12-MAY-2006 loop electrosurgical excision procedure (LEEP) = CIN-1 overall. 24-JUL-2006 PAP negative. At this point the patient had completed the study. She went to her own doctor and had another abnormal pap positive HR HPV test. The specific cytological diagnosis and the PCR test reports as positive for high risk type but did not indicate which specific HPV type. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** 07-DEC-2004: "ASC-H". 04-APR-2005 colposcopy biopsy negative for lesion, discrepancy noted - biopsy was of less severity than the Papanicolaou (PAP) test result and repeat colposcopy, PAP, and endocervical curettage (ECC) (among other choic

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267419-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CA	WAES0610USA04384	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a health professional concerning a female patient who was not pregnant and who was vaccinated with a first 0.5 ml dose of HPV (lot # 653735/0688F). Initially the patient experienced numbness at the injection site immediately after administration of the vaccine which was followed by "tingling or prickly feeling" on arm of the injection site. The patient sought unspecified medical attention. The tingling or prickly feeling lasted for a period of 2 to 5 minutes and then totally went away. It was also reported that the patient recovered from numbness at the injection site. It was reported that 3 other female patient's had the same experience (WAES #'s 0610USA04385, 0610USA04386 and 0610USA03730). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267420-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CA	WAES0610USA04385	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a health professional concerning a female patient who was not pregnant and who was vaccinated with a first 0.5ml dose of HPV (lot # 653735/0688F). Initially the patient experienced numbness at the injection site immediately after administration of the vaccine which was followed by "tingling or prickly feeling" on arm of the injection site. The patient sought unspecified medical attention. The tingling or prickly feeling lasted for a period of 2 to 5 minutes and then totally went away. It was also reported that the patient recovered from numbness at the injection site. It was reported that 3 other female patient's had the same experiences (WAES #'s 0610USA04384, 0610USA04386 and 0610USA03730). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267421-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CA	WAES0610USA04386	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site anaesthesia, Paraesthesia

**Symptom Text:** Information has been received from a health professional concerning a female patient who was not pregnant and who was vaccinated with a first 0.5 mL dose of GARDADIL (lot #653735/0688F). Initially the patient experienced numbness at the injection site immediately after administration of the vaccine which was followed by "tingling or prickly feeling" on arm of the injection site. The patient sought unspecified medical attention. The tingling or prickly feeling lasted for a period of 2 to 5 minutes and then totally went away. It was also reported that the patient recovered from numbness at the injection site. It was reported that 3 other female patients had the same experience (WAES0620USA04384, WAES0610USA04385 and WAES0610USA03730). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267422-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	27-Sep-2006	27-Sep-2006	0	16-Nov-2006	15-Dec-2006	FL	WAES0610USA04983	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Contusion, Injection site pain, Pain, Pyrexia

**Symptom Text:** Information has been received from a 26 year old female medical assistant (not CMA) with migraines, sulfonamide allergy and drug hypersensitivity to over the counter cold medications, who on 27-SEP-2006, was vaccinated IM with a 0.5ml dose of HPV (lot # 653735/0688F). Concomitant therapy included ethinyl estradiol/norethindrone (OVCON 35), netaxalone (SKELAXIN) and acetaminophen/hydrocodone bitartrate (VICODIN TABLETS). On 27-SEP-2006, the patient experienced severe pain at the injection site while the medication was being injected. The medical assistant also reported the pain as a sore bruised feeling that lasted for 4 to 5 days. On approximately 27-SEP-2006, the patient also experienced slight fever for 4 to 5 days. On 04-OCT-2006, she had physical therapy and the sore bruised feeling came back. Subsequently, the medical assistant recovered, however it was unknown if she recovered from the sore bruised feeling that came back on 04-OCT-2006. There was no product quality complaint involved. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** VICODIN TABLETS; OVCON 35; SKELAXIN

**Lab Data:** NONE

**History:** Migraine; Sulfonamide allergy; Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267423-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	06-Oct-2006	06-Oct-2006	0	16-Nov-2006	15-Dec-2006	TN	WAES0610USA05062	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Hypoaesthesia

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on 06-OCT-2006 was vaccinated in the right arm with the first dose of HPV (lot # not provided). On 06-OCT-2006, the patient experienced lightheadedness and numbness in her left arm. Unspecified medical attention was sought. Subsequently, that same day the patient recovered from lightheadedness and numbness in her left arm and was able to leave the office. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 237

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267424-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	05-Oct-2006	05-Oct-2006	0	16-Nov-2006	15-Dec-2006	CA	WAES0610USA06133	12-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Muscle spasms, Pain

**Symptom Text:** Information has been received from a physician concerning a 14 year old female patient who on 05-OCT-2006 was vaccinated IM with a dose of HPV. Concomitant therapy included hepatitis A virus vaccine (unspecified), administered at the same time and in the same arm. The physician reported that the patient was experiencing "severe spasmodic pain in her arm", and that the muscle would tense up for a 5 to 10 minute time frame. An hour later the pain would subside. Medical attention was sought. The patient recovered the next day, 06-OCT-2006. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267425-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	02-Oct-2006	02-Oct-2006	0	16-Nov-2006	15-Dec-2006	PA	WAES0610USA06154	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 25 year old female with anxiety, depression and a lump in her vagina who on 02-OCT-2006 was vaccinated with IM in the upper arm with a 0.5 mL first dose of HPV (lot 653978/0955F). Concomitant therapy included bupropion HCl (WELLBUTRIN XL), diclofenac potassium (CATAFLAM) and paroxetine HCl (PAXIL). On 02-OCT-2006, ten minutes post vaccination, the patient passed out for a few seconds. The patient received unspecified medical attention. Subsequently, on 02-OCT-2006, the patient recovered. Additional information has been requested.

**Other Meds:** WELLBUTRIN XL; CATAFLAM; PAXIL

**Lab Data:** UNK

**History:**

**Prex Illness:** Anxiety; Depression; Mass

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267426-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA06214	15-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning her 15 year old daughter who was vaccinated with HPV. Subsequently, the patient experienced red dots/rashes on her ankles, elbows, and buttocks. Subsequently, the patient recovered from red dots/rashes on ankles, elbows, and buttocks. Therapy with HPV was not re-introduced. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267427-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	30-Sep-2006	01-Oct-2006	1	16-Nov-2006	15-Dec-2006	TX	WAES0610USA08291	12-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F		Unknown	Unknown	
	FLUN	MEDIMMUNE, INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy

**Symptom Text:** Information has been received from a physician concerning an 11 year old female who was the daughter of a nurse that works in his office. On 30-SEP-2006 the patient was vaccinated with a 0.5 ml dose of GARDASIL (lot #654540/0800F). At that same time, the patient received a second dose of FLUMIST. On 01-OCT-2006 the patient had a "funny feeling in her face." By 03-OCT-2006 "her face was crooked on one side and becoming paralyzed." The patient was treated with an unspecified steroid medication and was reported to be "feeling better," but the symptoms were not totally gone. The patient was seen by a neurologist and was diagnosed with Bell's Palsy. The physician reported that one year ago, the patient was given FLUMIST and had no adverse reactions. At the time of this report, the patient was recovering from the events. The physician reported that it was his opinion that "Bells Palsy was caused by FLUMIST and not GARDASIL." Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267428-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	21-Sep-2006	21-Sep-2006	0	16-Nov-2006	15-Dec-2006	DE	WAES0610USA08303	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a nurse concerning a 21 year old female with a history of an allergic reaction to penicillin and sulfonamide who on 21-SEP-2006 was vaccinated with HPV. On 21-SEP-2006, following vaccination, the patient broke out in hives all over her upper body particularly in the face, chest, and arms. Unspecified medical attention was sought. Subsequently, the patient recovered on 26- SEP-2006. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Hypersensitivity reaction

**Prex Illness:** Penicillin allergy; Sulfonamide allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267429-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	05-Oct-2006	05-Oct-2006	0	16-Nov-2006	15-Dec-2006	FL	WAES0610USA08337	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Hypoaesthesia, Injection site erythema, Injection site mass, Malaise, Pruritus, Pyrexia, Thermal burn

**Symptom Text:** Information has been received from a physician and a 22 year old white female certified medical assistant with latex allergy, drug hypersensitivity to pertussis and iodine allergy and a history of unspecified adverse reaction after first dose of diphtheria toxoid (+) pertussis vaccine (unspecified) (+) tetanus toxoid (at less than 1 year of age. On 05-OCT-2006, at 4:00 PM, the patient was vaccinated, into the right arm, with a first dose of HPV (lot # 653978/0955F). On 05-OCT-2006, at 4:00 PM, the patient experienced burning "as if the arm was cut with razor blade and alcohol was poured on cut," and it "hurt really bad." The patient also developed dizziness, numbness in her lower arm, fever, fatigue, and malaise. She reported that her arm swelled up 2 times the normal size and was red. She developed a dime size lump and redness at the injection site that was itchy when touched or pressed on. Unspecified medical attention was sought. At the time of the report, the dime size lump, redness and itching at the injection site persisted. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Vaccination adverse reaction

**Prex Illness:** Latex allergy; Drug hypersensitivity; Iodine allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267430-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	05-Oct-2006	06-Oct-2006	1	16-Nov-2006	15-Dec-2006	FL	WAES0610USA08344	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Dysuria, Vaginal pain

**Symptom Text:** Information has been received from a certified medical assistant concerning a 16 year old female who on 05-OCT-2006 was vaccinated with a first dose of HPV (lot # 653735/0688F). There was no concomitant medication. on 06-OCT-2006 the patient experienced sharp pain around the abdomen area and vaginal area and intense pain during urination. It was reported that the pain was on and off. It was reported that the patient was going to go to the physician's office to be evaluated. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267431-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	04-Oct-2006	04-Oct-2006	0	16-Nov-2006	18-Dec-2006	CA	WAES0610USA08391	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a 12 year old female with no past medical history who on approximately 10/4/06 was vaccinated, into the arm, with a 0.5ml dose of HPV vaccine. Concomitant therapy included a dose of Hep A vaccine. It was reported that the nurse rubbed the child's arm after the vaccination and the child passed out. The physician thought that it was a vasovagal reaction and revived her with ammonia. On approximately 10/04/06, the pt recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267432-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	11-Oct-2006	11-Oct-2006	0	16-Nov-2006	18-Dec-2006	CA	WAES0610USA09277	04-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site reaction

**Symptom Text:** Information has been received from a physician concerning a 12 year old female with asthma and Advair allergy who on 10/11/06 was vaccinated with HVP vaccine. Concomitant therapy that day included varicella virus vaccine and influenza vaccine. On 10/11/06 the pt experienced numbing at injection site and around arm. The pt recovered. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** Asthma, drug Hypersensitivity.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267433-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA09299	15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Flushing

**Symptom Text:** Information has been received from a nurse concerning her 15 year old niece who was vaccinated with HPV rL1 6 11 18 VLP vaccine (yeast) (0.5 ml). Subsequently, "soon after having injections", the patient experienced dizziness and flushing "about ten minutes after her injections". It was reported that the patient received HPV rL1 6 11 16 18 VLP vaccine (yeast) with "other shots" and blood work. The patient recovered ;about 15 minutes after injections". Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** (therapy unspecified)

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267435-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	11-Oct-2006	12-Oct-2006	1	16-Nov-2006	15-Dec-2006	MA	WAES0610USA09303	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 22 year old female who on 11-Oct-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot#653978/0955F) (0.5ml), intramuscularly. Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO TRI-CYCLEN). On 12-Oct-2006 the patient experienced "rash on her face and neck". Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** ORTHO TRI-CYCLEN

**Lab Data:** UNK

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267436-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	05-Oct-2006	06-Oct-2006	1	16-Nov-2006	15-Dec-2006	CA	WAES0610USA09554	15-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscle spasms, Myalgia

**Symptom Text:** Information has been received from a physician concerning a 14 year old female student who on 05-Oct-2006 was vaccinated IM with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot#653735/0688F). Concomitant therapy given at the same time in the same arm included a dose of hepatitis A virus vaccine (unspecified). On 06-Oct-2006, the patient experienced extremely severe cramping pain in arm at the vaccine site intermittently over about 16 hours following vaccination. The episodes lasted about 30 minutes each and were incapacitating. During the time between episodes the patient was completely pain free. The episodes continued through the night with the same intensity. The episodes stopped abruptly the next morning and there was no reoccurrence. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267437-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA10123	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with HPV rLi 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced numbness at the injection site and numbness around the arm. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267438-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	09-Oct-2006	16-Oct-2006	7	16-Nov-2006	15-Dec-2006	--	WAES0610USA10767	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site mass, Injection site warmth

**Symptom Text:** Information has been received from a health professional concerning a 22 year old female with hypertension and "an interstitial problem" NOS who on 09-Oct-2006 was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Concomitant therapy included unspecified therapy. On 16-Oct-2006 the patient developed a "quarter size knot at the injection site that was warm to touch". Medical attention was sought and the patient was treated with diphenhydramine hydrochloride (BENADRYL). It was reported that the patient will discontinue the vaccination series. At the time of this report the patient had not recovered from the event. Additional information has been requested.

**Other Meds:** (therapy unspecified)

**Lab Data:**

**History:** CONCURRENT CONDITIONS: Hypertension; General symptom

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267439-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CA	WAES0610USA10773	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). The physician reported that the patient "was administered the shot and then fainted/passed out". Unspecified medical attention was sought. The physician reported that the patient recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267440-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	VA	WAES0610USA11270	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, following the vaccination, the patient fainted. Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267441-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
42.0	F	18-Oct-2006	18-Oct-2006	0	16-Nov-2006	15-Dec-2006	OK	WAES0610USA11279	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0640F		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema

**Symptom Text:** Information has been received from an office manager and a 42 year old female medical assistant with a Penicillin allergy who on 18-Oct-2006 went to place the needle on the HPV rL1 6 11 16 18 VLP vaccine (yeast0 (Lot#653650/0640F) pre-filled syringe and the medication squirted "out of the syringe" into the air. Concomitant therapy included bupropion HCl (WELLBUTRIN SR), Clarithromycin (BIAXIN), acetaminophen/hydrocodone bitartrate (LORTAB) and Trazodone HCl. The medication did get on her hands and she was experiencing burning and had redness on her index finger. It was warm to touch. At the time of this report, the patient was recovering from the events and the redness was decreasing. Additional information has been requested.

**Other Meds:** LORTAB, WELLBUTRIN SR, BIAXIN, trazodone hydrochloride

**Lab Data:** UNK

**History:** CONCURRENT CONDITIONS: Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 254

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267442-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	10-Oct-2006	11-Oct-2006	1	16-Nov-2006	15-Dec-2006	NY	WAES0610USA11390	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Initial and follow up information has been received from a physician concerning a 17 year old white female student with no pre-existing medical conditions. On 10-Oct2006, at 4 PM, the patient was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#654540/0800F). Concomitant therapy included an unspecified therapy (reported as "over-the-counter acne medication"). There were no illnesses noted at the time of vaccination. The physician reported that when the patient left the office she was fine. That same day, the patient had been given desloratadine (CLARINEX) without positive result, by her mother and without physician consultation. On 11-Oct-2006, at 4 PM, the patient developed a rash which appeared on the ear tips, face, elbows, knee caps and around the belly button area. On 14-Oct-2006, the patient went to the emergency room (ER) but was not admitted for an overnight stay. The patient was treated with prednisone. The physician reported that she did not see the patient. The physician reported that the patient "had hives" and was given the steroids in the emergency room which she considered to be routine. At the time of this report, the patient had not recovered from the event. The physician considered the event to be non-serious. Additional information is expected.

**Other Meds:** (therapy unspecified), CLARINEX

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267443-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	03-Oct-2006	03-Oct-2006	0	16-Nov-2006	15-Dec-2006	TX	WAES0610USA11404	15-Dec-2006
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Loss of consciousness, Muscle contractions involuntary

**Symptom Text:** Information has been received from a 23 year old female who on 03-OCT-2006 was vaccinated with a 0.5 mL dose of GARDASIL. The patient reported that the vaccine was given in the front part of the thigh muscle. Subsequently, the muscle contracted and the patient passed out due to pain. Unspecified medical attention was sought. When the patient woke up, she reported that she "felt fine." On 03-OCT-2006, the patient recovered from the events. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267444-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
30.0	F	11-Sep-2006	11-Sep-2006	0	16-Nov-2006	15-Dec-2006	CA	WAES0610USA11829	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from an LPN concerning a 30 year old female patient with anxiety who on 11-Sep-2006 was vaccinated IM with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), lot#654540/0800F. Concomitant therapy included ethinyl estradiol/norgestrel (LO/OVRAL). After receiving the vaccination on 11-Sep-2006, the patient complained of a lot of pain under the arm pit and also on the left arm (injection arm). The arm hurt on and off, especially during workouts and while sleeping. the pain wakes up the patient in the middle of the night. She sought medical attention and was told to take Ibuprofen, apply ice to the area, and no upper body exercises. The nurse stated the patient was still having moderate pain 4 weeks after the injection, and that she probably would not receive further doses. At the time of the report, the patient had not recovered. There was no product quality complaint involved. Additional information has been requested.

**Other Meds:** LO/OVRAL

**Lab Data:** NONE

**History:** CONCURRENT CONDITIONS: Anxiety

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267445-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	--	WAES0610USA11832	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Upper respiratory tract infection

**Symptom Text:** Information has been received from a nurse practitioner concerning a female (age not reported) who on an unspecified date was vaccinated with a 0.5 ml dose of HPV vaccine. Subsequently the pt developed an upper respiratory infection. The pt sought unspecified medical attention. The nurse practitioner stated that she told the pt when the pt called the office that she did not feel the upper respiratory infection was caused by the HPV vaccine. No further information was provided at the time of this report. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267446-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	16-Oct-2006	16-Oct-2006	0	16-Nov-2006	18-Dec-2006	--	WAES0610USA11838	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Condition aggravated, Diarrhoea, Irritable bowel syndrome, Loss of consciousness, Nausea, Pain, Vomiting

**Symptom Text:** Information has been received from the mother of a 24 year old female with irritable bowel syndrome and food allergies to 28 different foods, including yeast and corn who on 10/16/06 was vaccinated with HPV Vaccine. Concomitant therapy included Hormonal contraceptives (unspecified) and dermatologic (unspecified). On 10/16/06 the pt experienced nausea, diarrhea, aches, and vomiting which continued for three days without changes. On 10/19/06, it was reported that the pts irritable bowel syndrome was also triggered by the above events. On 10/19/06 the pt underwent a blood test (usually very well tolerated), however following the blood test on 10/19/06, the pt passed out and vomited, Unspecified medical attention was sought. The pts mother stated that she would be contacting her daughters physician with the listed allergies. At the time of this report, the pt was recovering from the events. Additional information is not expected.

**Other Meds:** Dermatologic Unsp, Hormonal contraceptives.

**Lab Data:** Diagnostic lab 10/19/06

**History:** Food allergy, Irritable bowel syndrome.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267447-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	CT	WAES0610USA11954	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Influenza like illness, Malaise

**Symptom Text:** Information has been received from a nurse concerning a female pt who on an unspecified date was vaccinated IM with HPV vaccine (it was reported that it was uncertain whether this was the pts first dose). Subsequently, the day after vaccination, the pt experienced flu-like symptoms, felt horrible and felt very sick for a few days. At the time of this report, the pt had no more flu-like symptoms. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267448-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	22-Aug-2006	22-Aug-2006	0	16-Nov-2006	18-Dec-2006	FR	WAES0610USA12079	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a 38 year old female pt who on 8/22/06 was vaccainted IM with a dose of HPV vaccine. The reporter stated that on 8/22/06 I had pain for two months after the injection. Medical attention was sought. The pt was recovering. A product quality complaint was not involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267449-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	01-Sep-2006	Unknown		16-Nov-2006	15-Dec-2006	CO	WAES0610USA12091	15-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy, Swelling

**Symptom Text:** Information has been received from a physician concerning a 21 year old female who in approximately September 2006 was vaccinated with the first dose of GARDASIL (lot # not provided). On an unspecified date in approximately September the patient developed swelling in her lymph nodes and groin. Unspecified medical attention was sought. At the time of this report it was unknown if the patient had recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267450-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	03-Oct-2006	12-Oct-2006	9	16-Nov-2006	18-Dec-2006	CA	WAES0610USA12097	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a physician concerning a 27 year old female who on 10/3/06 was vaccinated with the first dose of HPV Vaccine (lot not provided). On 10/12/06 the pt experienced a very sore arm. The physician advised the pt to take Advil and apply ice to the area. At the time of the report it was unk if the pt had recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267451-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	MO	WAES0610USA12132	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who was vaccainted with the first dose of HPV vaccine (lot # not provided). Subsequently the pt experienced low grade fever. The physician reported that the pt received Tylenol and felt better. Subsequently, the pt recovered from the low grade fever. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267452-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	16-Oct-2006	17-Oct-2006	1	16-Nov-2006	18-Dec-2006	MO	WAES0610USA12445	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who on 10/16/06 was vaccinated with an IM HVP vaccine (lot 653978/0955F). On 10/17/06 the pt was sent home from school because she developed a fever of 102F and nausea. the physician reported that after 12 hours the pt recovered and returned to school the next day symptoms free. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267453-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CT	WAES 0610USA12537	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced dizziness and nausea within a few minutes post vaccination. Unspecified medical attention was sought. It was reported that the symptoms lasted only a few minutes. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 266

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267454-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Sep-2006	23-Sep-2006	1	16-Nov-2006	15-Dec-2006	IA	WAES0610USA12643	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0702F		Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	DTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Information has been received from a physician concerning a female in her 20's with intermittent problems with asthma and no known drug allergies, who on 22-SEPT-2006 was vaccinated into the left deltoid with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). (Lot #653650/0702F). Concomitant therapy given that day included a dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid and a dose of hepatitis A virus vaccine inactivated (+) hepatitis B virus vaccine rHBsAg (yeast) (Twinrix). It was noted that the vaccines were administered at different anatomical sites. Within 24 hours, the patient experienced intense itching all over her body. Unspecified medical attention was sought. The patient self medicated with diphenhydramine hydrochloride(Benadryl). No diagnostic laboratory tests were performed. One week later, the patient fully recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** Unknown

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267455-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	28-Sep-2006	29-Sep-2006	1	16-Nov-2006	15-Dec-2006	FM	WAES0610USA12794	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653978/0955F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a registered nurse concerning a 12 year old white female with no know drug allergies, who on 28-SEP-2006 at 14:30 was vaccinated IM into the right deltoid with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). (Lot #653978/0955F). On 29-SEP-2006 at 08:00 the patient experienced a "large red rash area near the injection site, 1x1cm red around injection site and 3x2cm spot in the superior lateral site area, and red raised spot inferior and lateral to the injection site." No diagnostic laboratory studies were performed. The patient was treated with cool compresses, ibuprofen (Advil) or ibuprofen (Motrin) and cetirizine hydrochloride (Zyrtec) every 6 to 8 hours. The patient was told to go to the emergency room if her condition worsened. Subsequently, the patient recovered as there was no more follow up phone calls to the office. Additional information is not expected.

**Other Meds:** Unknown

**Lab Data:** None

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267456-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	20-Oct-2006	20-Oct-2006	0	16-Nov-2006	15-Dec-2006	OH	WAES0610USA13009	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician concerning a female patient who on 20-OCT-2006 was vaccinated with the first dose of GARDASIL. Subsequently the patient developed severe arm pain at the injection site. At the time of this report, the outcome of the event was unknown. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267457-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA13029	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Swelling

**Symptom Text:** Information has been received from a midwife registered nurse concerning a female with genital warts who "within the last few weeks" was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included imiquimod (Aldara). Subsequently "within the last few weeks" the patient experienced "swelling in genital warts". At the time of the report the patient was recovering. Unspecified medical attention was sought. Other information has been requested.

**Other Meds:** Aldara

**Lab Data:** Unknown

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267458-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	24-Oct-2006	24-Oct-2006	0	16-Nov-2006	15-Dec-2006	NY	WAES0610USA13156	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Medication error, Post vaccination syndrome

**Symptom Text:** Information has been received from a registered nurse concerning a female who on 24 Oct 2006 was vaccinated with Gardasil (Lot #654540/0800F). The nurse reported that on 24 Oct 2006 the pre-filled syringe while she was withdrawing the syringe and the patient received an incomplete dose of the vaccine. She thought most of the dose was administered. The patient also stated that "the vaccination hurt." Unspecified medical attention was sought. At the time of this report the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267459-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	17-Oct-2006	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA13171	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy, Pelvic pain

**Symptom Text:** Information has been received from a triage nurse concerning a female (age unknown) with no other pertinent medical history reported. On approximately 17 Oct 2006, the patient was vaccinated with a 0.5mL dose of Gardisal. There were no concomitant medications reported. On an unspecified date, the patient contacted the nurse complaining about pain and swelling of the lymph nodes, in the groin area on her right side. Unspecified medical attention was sought. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267460-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	OH	WAES0610USA13175	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness, Malaise, Myositis

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated IM with a 0.5ml first dose of Gardisal. Approximately 3 to 4 days after the vaccination, the patient experienced "myacitis", malaise and flu like symptoms and went to the emergency room. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267461-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	20-Aug-2006	20-Aug-2006	0	16-Nov-2006	15-Dec-2006	NY	WAES0610USA13556	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Pyrexia, Vomiting

**Symptom Text:** Information has been received from a health professional concerning a 17 year old female with no medical history or allergies, who on 20 Aug 2006 and 20 Oct 2006 was vaccinated IM with a first and second 0.5mL dose of Gardisal, respectively (first dose lot # 654540/0800F and second dose lot # 653736/0868F). There was no concomitant medication. On 20 Aug 2006, the patient experienced nausea and emesis. On 20 Oct 2006, the patient again experienced immediate nausea and vomiting. On 21 Oct 2006 the patient experienced low grade fever. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. Subsequently, the patient recovered from emesis. At the time of this report, the patient's low grade fever persisted and the outcome of nausea was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267462-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA14105	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a Registered Nurse concerning an adult patient who was vaccinated with a dose of Gardisal. The patient complained of pain while being injected using the prefilled syringe. The nurse reported that another patient did not complain of pain when a "normal" syringe was used. The nurse suggested the pre-filled needles may be dull causing pain during injection. The patient's out come was not reported. A product quality complaint was involved. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267463-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA14150	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** Information has been received from a nurse practitioner concerning a female who was vaccinated intramuscularly with a dose of Gardasil. The nurse practitioner reported that the patient "experienced a vasovagal reaction and felt woozy and fainted within 5 minutes of the injection." Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267464-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	11-Oct-2006	21-Oct-2006	10	16-Nov-2006	15-Dec-2006	TX	WAES0610USA14291	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site induration, Injection site pain

**Symptom Text:** Information has been received from a physician concerning a 12 year old female who on 11 Oct 2006 was vaccinated with the first dose of 0.5mL of Gardisil (Lot # 653937/0637F). On 21 Oct 2006, the patient developed a know on the arm with no rash and no redness. On 24 Oct 2006, the patient developed throbbing pain around the arm that the injection was administered. The patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267465-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Aug-2006	28-Aug-2006	0	16-Nov-2006	15-Dec-2006	--	WAES0610USA14316	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Information has been received from a physician concerning a 16 year old female patient who on 28 Aug 2006 was vaccinated with a first dose of Gardasil. On 28 Aug 2006 the patient experienced vomiting within four hours of receiving the vaccination. Outcome was not reported. On 25 Oct 2006, the patient was vaccinated with a second dose of Gardasil. On 25 Oct 2006 the patient experienced vomiting within four hours of receiving the vaccination. On 25 Oct 2006, the patient recovered from vomiting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 278

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267466-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	28-Aug-2006	22-Sep-2006	25	16-Nov-2006	15-Dec-2006	AL	WAES0610USA14581	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Headache, Herpes simplex, Insomnia, Pain, Pyrexia, Rhinorrhoea

**Symptom Text:** Information has been received from a Certified Medical Assistant concerning a 21 year old female patient with a history of bacterial vaginosis and yeast infections who on 28 Aug 2006 was vaccinated IM in left deltoid with her first dose of Gardasil vaccine (yeast) lot #653736/0689F. Concomitant therapy included ethinyl estradiol/norgestimate (Ortho Tri-Cyclen). ON 22 Sep 2006 the patient developed fever, which she reported was "off and on". She described the fever as spiking at night after 6-7pm. Her fevers would reach 101-103 F and they resolved with rest plus the use of acetaminophen (Tylenol). After " a couple days or so", the fevers would reappear. Other symptoms included headache, hot and cold chill, body aches, waking in the night. The CMA stated that the patient reported these symptoms to the physician's office on 23 Oct 2006. Laboratory tests performed on that date included HSV(herpes simplex virus) IGG type 1 (positive); HSV IGG type 2 (negative); and EBV(Epstein-Barr virus) (negative). It was reported "EBN was positive". Also reported was "sed rate and CBC=white blood cell count was normal". The patient was to be seen the following week to determine whether the fevers continued. Follow up information indicated that when the patient was seen on 30 Oct 2006 she received a second dose of Gardasil. The CMA noted that the patient was fine "so far". Additional information has been requested.

**Other Meds:** Ortho Tri Cyclen

**Lab Data:** body temp 101-103F; clinical seriology test, 10/23/06, positive; serum Epstein Barr 10/23/2006 negative, serum herpes simplex 10/23/06 positive; serum herpes simplex negative; WBC count normal

**History:** Medical History: Vaginosis bacterial, yeast infection

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267467-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	26-Oct-2006	26-Oct-2006	0	16-Nov-2006	15-Dec-2006	NY	WAES0610USA14848	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blister, Oral mucosal blistering, Swelling

**Symptom Text:** Information has been received from a physician concerning a female patient who on 26-OCT-2006 was vaccinated IM with a first dose of GARDASIL. On 26-OCT-2006 the patient experienced swelling as well as blisters in mouth and on the neck. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267468-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CA	WAES0610USA14937	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female teenager who was vaccinated IM with a first dose of Gardasil. The patient "passed out" when she received the injection. The physician is planning to give the doses as recommended. Unspecified medical attention was sought. Shortly after vaccination, the patient recovered. No product quality complaint was involved. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267469-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	23-Oct-2006	23-Oct-2006	0	16-Nov-2006	15-Dec-2006	CA	WAES0610USA14943	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Pain, Pyrexia

**Symptom Text:** Information has been received from a physician concerning an 18 year old female who on 23 Oct 2006 was vaccinated with 0.5mL of Gardasil (yeast). There were no concomitant medications reported. On 23 Oct 2006, the patient developed a high fever of 102 degrees after receiving shot of Gardasil. The temperature continued for three days and was now noted at 100 degrees. The patient also developed achy legs. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** body temp 10/23/06 102, body temp 10/26/06 100.

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267470-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
30.0	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	--	WAES0610USA14944	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Amenorrhoea, Incorrect dose administered

**Symptom Text:** Information has been received from a physician assistant in her "late thirties" who on an unspecified date was vaccinated intramuscularly with the first dose of Gardasil vaccine (yeast). The physician assistant reported that she did not get her period the first month after the Gardasil vaccine. It was unknown if the patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown as " the patient was not due yet for her next menstrual cycle". Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267471-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Nov-2006	18-Dec-2006	--	WAES0610USA14972	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** Information has been received from a nurse practitioner concerning a patient who was vaccinated with a dose of Gardasil vaccine (yeast). The nurse practitioner reported that the patient "experienced a vasovagal reaction and felt woozy and fainted within 5 minutes of the injection." At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267472-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	25-Oct-2006	27-Oct-2006	2	16-Nov-2006	15-Dec-2006	MN	WAES0610USA15118	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a "15 or 16 year old" female who on approximately 25 Oct 2006 or 26 Oct 2006 was vaccinated intramuscularly in the deltoid with Gardasil. On approximately 27 Oct 2006, the patient developed a low grade fever of about 99 and dizziness. The patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** body temp 10/27/06 -about 99

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267473-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	31-Oct-2006	31-Oct-2006	0	16-Nov-2006	15-Dec-2006	IL	WAES0610USA15293	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vaccination complication

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) with no other pertinent medical history and no known allergies or adverse drug reactions reported. On 31-OCT-2006, the patient was vaccinated intramuscularly with GARDASIL. There were no concomitant medications reported. Subsequently, the patient experienced a cut which was less than 1/4 inch when the syringe was pulled out from the patient. It was reported that the patient had received the full dose. The patient sought unspecified medical attention. The registered nurse reported that the cut was very minor. At the time of this report, the patient was recovering from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267474-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	PA	WAES0610USA15327	15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Tension, Throat tightness

**Symptom Text:** Information has been received from a physician concerning a female age "14 or 15 years old" who on an unspecified date was vaccinated with the first dose of 0.5 ml of GARDASIL. After vaccination, the patient felt faint. It was reported that the patient felt dizzy, had difficulty breathing (also reported as "had a short of breath feeling"), felt like her throat was closing and looked tense. Her lungs were clear, there was no wheezing, no signs or symptoms of swelling, no facial or eye swelling and her blood pressure was stable. The physician reported that she thought this looked like a "slight reaction." The patient was given diphenhydramine hydrochloride (BENADRYL) as a precaution. The physician reported that the events were resolving that same day. It was reported that the patient "experienced similar symptoms not relating to vaccines and felt the symptoms may have been more panic driven than anything else." At the time of this report, the patient had recovered from the events (date unknown). The physician reported that she did not feel that the treatment with diphenhydramine hydrochloride (BENADRYL) was needed to prevent serious criteria and did not feel that this experience was life-threatening to the patient. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** Adverse event

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267475-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	24-Oct-2006	25-Oct-2006	1	16-Nov-2006	15-Dec-2006	NY	WAES0611USA00528	15-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL	2	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vision blurred

**Symptom Text:** Initial and follow-up information has been received from a physician concerning a 26 year old female with no other pertinent medical history and no known allergies or adverse drug reactions reported. On 24-OCT-2006 the patient was vaccinated intramuscularly in the deltoid with the first "1 vial" dose of GARDASIL (lot #653938/0954F). Concomitant therapy included azithromycin (ZITHROMAX). It was reported that on 24-OCT-2006, the patient had been vaccinated with the third dose of TWINRIX. On 25-OCT-2006, "within a day after immunization," the patient experienced blurry vision in both eyes. The patient sought unspecified medical attention. The patient was told by the physician to come to the office to be evaluated but had not. As of 02-NOV-2006, nine days after receiving GARDASIL, the physician reported that the blurred vision was "getting much better." Additional information has been requested.

**Other Meds:** ZITHROMAX

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267476-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	30-Oct-2006	30-Oct-2006	0	16-Nov-2006	15-Dec-2006	OH	WAES0611USA00600	15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female who on 30-OCT-2006 was vaccinated with GARDASIL. Subsequently, the patient experienced redness in her face and had vomited. The patient sought unspecified medical attention. At the time of this report, the patient was recovering from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267477-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	30-Oct-2006	30-Oct-2006	0	16-Nov-2006	15-Dec-2006	IN	WAES0611USA00613	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning an 18 year old female patient who on 30-OCT-2006 was vaccinated IM with her first dose of GARDASIL, lot #653978/0955F. Immediately after receiving the vaccination the patient fainted. She was sent to the emergency room, where it was determined she had fainted "due to nervousness over the needle." The patient recovered "a few hours" after the vaccination. There was no product quality complaint involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267478-1      **Related reports:** 267478-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	30-Oct-2006	30-Oct-2006	0	16-Nov-2006	15-Dec-2006	NC	WAES0611USA00698	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** Information has been received from a physician concerning a 21 year old female who on 30 Oct 2006 was vaccinated with 0.5mL of Gardasil (Lot# 653736/0689F). On 30 Oct 2006, the patient developed a vasovagal reaction and passed out within one minute post vaccination. The patient was revived with an ammonia inhalant. No other symptoms were noted. Unspecified medical attention was sought. At the time of this report, the patient had recovered from the events (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267478-2      **Related reports:** 267478-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	30-Oct-2006	30-Oct-2006	0	16-Nov-2006	18-Dec-2006	NC	WAES0611USA02239	18-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fall, Loss of consciousness, Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female with no pre existing allergies, birth defects or medical conditions and reportedly was not ill at the time of vaccination. On 10/30/06, when the pt checked into the physicians office her blood pressure was 80/50. On 10/30/06, at 12:30pm, the pt was vaccinated IM into the left deltoid muscle with HPV vaccine (lot # 653736/0689F). Concomitant therapy included Ortho Tri Cyclen Lo), Claritin and Celexa. After the pt received the vaccination, she passed out and was unconscious, she hit her head when she fell forward out of her chair. The pt had a neurological check up per in internal medical physician. The pt was checked by two physicians and they considered the pt had a vasovagal reaction. The pt left the office ambulatory, alert, recovered and in satisfactory condition. Additional information has been requested.

**Other Meds:** Celexa, Ortho Tri Cyclen Lo, Claritin

**Lab Data:** Blood pressure 10/30/06 80/50

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267479-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	01-Oct-2006	01-Oct-2006	0	16-Nov-2006	18-Dec-2006	CA	WAES0611USA00701	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0689F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Information has been received from a certified medical assistant and a physician concerning a 25 year old female with a history of hives due to orange juice who in approximately Oct 2006, a couple of weeks ago, was vaccinated with a 0.5ml first dose of HPV vaccine (lot 653736/0689F). There was no concomitant medication. Approximately 30 minutes after the vaccination, the pt experienced severe itching all over her body. It was reported that there was no rash. Unspecified medical attention was sought. Subsequently, the pt recovered after approximately 2 days. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Hives, food allergies.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267480-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	31-Aug-2006	Unknown		16-Nov-2006	18-Dec-2006	--	WAES0611USA00721	18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Viral infection

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 15 year old female with migraines and no known allergies or adverse drug reactions reported. On approx 8/31/06, the pt was vaccinated with the first dose of HPV vaccine. On an unspecified date, the pt was noted to be positive for an unknown number of high risk human papilloma virus types. The pt underwent a pap test (date and results not reported). The pt sought unspecified medical attention. a colposcopy was planned for the pt. At the time of this report, the pt had not recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Pap Test

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267481-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Oct-2006	01-Oct-2006	0	16-Nov-2006	18-Dec-2006	NY	WAES0611USA00728	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Hyperhidrosis, Pallor

**Symptom Text:** Information has been received from a nurse practitioner concerning a female pt who in Oct 2006, was vaccinated IM with a dose of HPV Vaccine. Subsequently in Oct 2006, she experienced lightheadedness, weakness, pallor, and sweating, No medical attention was sought. The nurse practitioner indicated the pt was doing fine. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267482-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Oct-2006	01-Oct-2006	0	16-Nov-2006	18-Dec-2006	NY	WAES0611USA00729	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Hyperhidrosis, Pallor

**Symptom Text:** Information has been received from a nurse practitioner concerning a female pt who in Oct 2006, was vaccinated IM with a dose of HVP vaccine. Subsequently in Oct 2006 she experienced lightheadedness, weakness, pallor and sweating. No medical attention was sought. The nurse practitioner indicated the pt was doing fine. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267483-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	30-Oct-2006	30-Oct-2006	0	16-Nov-2006	15-Dec-2006	CA	WAES0611USA00732	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Ocular hyperaemia, Pruritus, Rash

**Symptom Text:** Information has been received from a nurse concerning an 18 year old female who on 30-OCT-2006 was vaccinated with the first dose of GARDASIL. On 30-OCT-2006 the patient developed a "rash on the palm of her hand and also red, itchy eyes." The patient sought unspecified medical attention. The nurse reported that the patient had recently purchased new eye makeup. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267484-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	30-Oct-2006	30-Oct-2006	0	16-Nov-2006	18-Dec-2006	OH	WAES0611USA00924	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who on 10/30/06 was vaccinated with HPV vaccine. Subsequently, the pt experienced redness in her face and had vomited. The pt sought unspecified medical attention. At the time of this report, the pt was recovering from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267486-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CT	WAES0611USA02365	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with GARDASIL. Subsequently the patient experienced dizziness and nausea within a few minutes post-vaccination. Unspecified medical attention was sought. It was reported that the symptoms lasted only a few minutes. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267487-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	15-Dec-2006	CT	WAES0611USA02366	15-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with GARDASIL. Subsequently, the patient experienced dizziness and nausea within a few minutes post-vaccination. Unspecified medical attention was sought. It was reported that the symptoms lasted only a few minutes. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267488-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	CT	WAES0611USA02367	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning a female pt who on an unspecified date was vaccinated with HPV vaccine. Subsequently the pt experienced dizziness and nausea within a few minutes post vaccination. Unspecified medical attention was sought. It was reported that the symptoms lasted only a few minutes. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267489-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	CT	WAES0611USA02368	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning a female pt who on an unspecified date was vaccinated with HPV vaccine. Subsequently the pt experienced dizziness and nausea within a few minutes post vaccination. Unspecified medical attention was sought. It was reported that the symptoms lasted only a few minutes. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267490-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	VA	WAES0611USA02471	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female pt who on an unspecified date was vaccinated with HPV vaccine. Subsequently, following the vaccination, the pt fainted. At the time of this report, the outcome of the event was unk. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267491-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Nov-2006	18-Dec-2006	VA	WAES0611USA02472	18-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female pt who on an unspecified date was vaccinated with HPV vaccine. Subsequently, following the vaccination, the pt fainted. At the time of this report, the outcome of the event was unk. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267524-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	01-Nov-2006	01-Nov-2006	0	21-Nov-2006	30-Nov-2006	PA		30-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Total body itching

**Other Meds:** Coumadin

**Lab Data:**

**History:** Von Willebrands, MRSA

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267525-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Nov-2006	01-Nov-2006	0	21-Nov-2006	30-Nov-2006	PA		30-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Total body itching.

**Other Meds:** Allegra D

**Lab Data:**

**History:** Seasonal Allergies

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267726-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	06-Nov-2006	06-Nov-2006	0	27-Nov-2006	28-Nov-2006	CA	WAES0611USA03470	28-Nov-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Condition aggravated, Convulsion, Fall, Syncope

**Symptom Text:** Information has been received from a physician and a medical assistant concerning a 14 year old female with a history of a prior seizure (on an unk date about a year ago during a hair cut) who on 11/6/06 was vaccinated IM in the deltoid with the second dose of HPV vaccine (lot not provided). It was reported that the pt had no difficulties when the first dose of the vaccine was administered on an unspecified date. On 11/6/06 the medical assistant administered the vaccine, then turned to discard the needle. The pt fainted, fell from the exam table, hit her head on the floor and had a seizure. Paramedics were called, a cervical collar was placed on the pt and she was transported to the ER. The pt was evaluated in the ER, a CT scan was performed which was reported as normal. The pt was discharged to home from the ER and instructed to follow up with neurology. The medical assistant stated that the physician felt that the pt had a vasovagal response after receiving the vaccine and that the seizure was a result of the head trauma which the pt suffered from the fall off the exam table. It was reported that the physician felt that the seizure was related to the head trauma and not related to the vaccine. The medical assistant also reported that the physician felt the pt had recovered from the event. Upon internal medical review the seizure was felt to be an important medical event (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** Convulsion

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267782-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	13-Nov-2006	13-Nov-2006	0	27-Nov-2006	07-Dec-2006	AL		07-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Overall fine body rash for past 2 days. Pt has a concomitant tonsillitis onset 2 days ago - negative strep

**Other Meds:** Effexor XR

**Lab Data:**

**History:** NKDA

**Prex Illness:** Dyspnea; Tonsillitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267795-1      **Related reports:** 267795-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	09-Nov-2006	09-Nov-2006	0	27-Nov-2006	28-Nov-2006	CA	200603096	28-Nov-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2119AA		Gluteous maxima	Unknown	
	HPV4	MERCK & CO. INC.	0688F		Right arm	Unknown	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Agitation, Anger, Crying, Depression, Pain, Suicide attempt

**Symptom Text:** Seriousness criteria other medically significant (OMIC). Initial report received from the pts mother via a health care professional, on 11/14/06. A 14 year old female pt, received on 11/9/06, Menactra (lot number U2119AA), into the right deltoid (dose and route of administration not reported). The pt received on the same day (11/9/06) Gardasil (lot number 0688F) into the left deltoid, as concomitant vaccination (dose and route of administration not reported). The pt had no history of depression. At the eve of vaccination, 11/9/06, the pt had arm soreness (the reporter was unsure which arm). The pt also became very depressed, frustrated, angered, crying and attempted to cut her wrists with scissors. The wrist site described as scratch by the reporter. At the time of this report, 11/14/06, there had been no ER or medical doctor MD visits for the pt and the pts outcome was unk. No corrective treatment was reported.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267795-2      **Related reports:** 267795-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	09-Nov-2006	09-Nov-2006	0	30-Nov-2006	01-Dec-2006	CA	WAES0611USA04351	16-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Agitation, Crying, Crying, Depression, Depression suicidal, Injury, Suicide attempt

**Symptom Text:** Information has been received from a physician concerning a 14 year old female with no history of depression or suicidal ideation who on 09-NOV-2006 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) concomitantly with a dose of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). Later that day, the pt became depressed. The pts mother reported that the pt became weepy and crying and stated I wish I were dead. On 10-NOV-2006, the pt stated that she wished she were dead and later made some superficial cuts on her arm. The physician reported that she was informed of the event 4 days later it occurred and saw the pt 6 days post vaccination. At that time, the pts physical examination was normal and there were no injection site reactions. The pt was not hospitalized and did not receive treatment for the event. The physician considered the pt recovered from the event. The physician considered the pts suicide attempt and depression were considered to be other important medical events (OMIC).

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267822-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	14-Nov-2006	15-Nov-2006	1	27-Nov-2006	07-Dec-2006	IL		07-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Malaise, Pruritus, Swelling face, Throat tightness

**Symptom Text:** Pt suddenly did not feel well at 9:30 am 11/15 went to bathroom, noticed face very red, followed by intense itching - presented to clinic 1 hr after sxs started, developed swollen lips, edema around eyes and throat constriction. Epi 0.05 ml SQ immediately. 3 min later, pt improved.

**Other Meds:** Benzaclin, Minocin, Orthotricyclen, Prozac

**Lab Data:**

**History:** Acne, Anxiety, depression, TSS (11/05)

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267926-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Nov-2006	22-Nov-2006	0	29-Nov-2006	08-Dec-2006	CA		08-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Patient fainted after administration of vaccine.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267957-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	18-Sep-2006	02-Oct-2006	14	29-Nov-2006	08-Dec-2006	NY		08-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Hypoaesthesia, Injection site pain, Pain

**Symptom Text:** Left arm pain, numbness from elbow to entire hand, started about 2 week safer receiving Gardasil in that arm. Pain is intermittent and 5-10 in intensity. She dose have other symptoms of abdominal pain, and right arm pain, so it is unclear whether vaccine is a factor.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Mild Pulmonary Valve stenosis, stable.

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267995-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	20-Nov-2006	24-Nov-2006	4	30-Nov-2006	08-Dec-2006	MO		08-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Swelling face

**Symptom Text:** 2nd dose Patient medicine on 11-20-06 and complain of swelling in lips, hands, and feet.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267996-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	U	20-Nov-2006	Unknown		30-Nov-2006	08-Dec-2006	MO		08-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** 2nd dose Patient complain of pain.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267997-1 (S)    **Related reports:** 267997-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Sep-2006	23-Sep-2006	1	29-Nov-2006	30-Nov-2006	NJ		25-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F	0	Left arm	Unknown		

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Confusional state, Disorientation, Dysmorphism, Grand mal convulsion, Hypoglycaemia, Mental status changes

**Symptom Text:** Patient awoke morning after vaccination with grand mal seizure. Her mother took her to a local hospital and she was transferred to another hospital and then to another. MR received from 1st ER visit which reveals a 15 yr old brought in by her mother with c/o confusion, disorientation, and facial distortion on the morning following her Gardasil vax. PE: Significant for confusion and disorientation, otherwise normal. Patient was transferred to another hospital to be followed by a pediatric neurologist, Clinical impression : Altered mental status. MR received from 2nd hospital. Pt. transferred to PICU with a diagnosis of altered mental status. Still somewhat confused but improving upon admission. Improvement in mental status over the next 24 hours and she was transferred to a regular pediatric floor, oriented x3 and with no focal deficits. Discharge DX: New onset seizures (probably 2' to hypoglycemia per face sheet).

**Other Meds:** Insulin Meds: Lantus insulin and Novolog.

**Lab Data:** Labs and Diagnostics: EKG shows sinus arrhythmia, Drug and pregnancy screens (-), other labs WNL including serum glucose, CXR-normal, head CT(-). Labs and Diagnostics: UA significant for >1000mg/dl glucose and 40 ketones. HgbA1C 8.8, oth

**History:** Type 1 Diabetes. NKDA

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 267997-2 (S)    **Related reports:** 267997-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Sep-2006	23-Sep-2006	1	11-Dec-2006	12-Dec-2006	NJ	WAES0611USA07576	12-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Unknown	

**Seriousness:** EXTENDED HOSPITAL STAY, HOSPITALIZED, OMIC, SERIOUS

**MedDRA PT** Grand mal convulsion

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with type 1 diabetes mellitus who on 9/22/2006 was vaccinated by injection with her first dose of HPV vaccine (lot 654540/0800F). Concomitant therapy included insulin. On 9/23/06, the day after receiving the HPV vaccine, the pt experienced a Grand mal seizure. the physician reported the pt was hospitalized for 3 days. The pt had the following lab diagnostic studied. spinal tap, MRI, EEG, blood work and urine. The physician stated the pt returned to the office to received the second dose of HPV vaccine, but the physician decided not to reintroduce the HPV vaccine. At the time of the report, the pt had recovered. The physician considered the pts Grand Mal Seizure to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Insulin

**Lab Data:**

**History:** Type I Diabetes Mellitus.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268017-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		30-Nov-2006	08-Dec-2006	TN		08-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyskinesia

**Symptom Text:** Patient developed jerking in upper extremity a few hours after administration of vaccine. Patient was medicated with VALIUM which led to resolution of symptoms.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268036-1 (S) **Related reports:** 268036-2; 268036-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	28-Nov-2006	28-Nov-2006	0	30-Nov-2006	01-Dec-2006	IA		16-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Abdominal pain, Abdominal pain lower, Gastrointestinal disorder, Vomiting

**Symptom Text:** Less than 3 hours following the vaccination she developed severe abdominal cramps and vomited. Subsequently had persistent abdominal pain that eventually localized to the right lower quadrant. A CT of the abdomen was performed the evening of 11/29/06 which revealed appendicitis. A surgical consultation was requested and days of hospitalization are unknown yet at this time. Student health office note of 11/28/06 recording administration of Gardasil #1 on this date. Hospital record received revealing a 20 year old woman who developed crampy abdominal pain centered in the right lower quadrant 1 day following her Gardasil vax. Patient had appendectomy and was discharged home the following day. DX: Appendicitis.

**Other Meds:** Ortho Tri-Cyclen Lo

**Lab Data:** Labs and Diagnostics: WBC's 11.0, Abdominal CT shows a thickened appendix at the base of the cecum with surrounding inflammation c/w acute appendicitis.

**History:** PMH: none Allergies: none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

<b>Vaers Id:</b> 268036-2		<b>Related reports:</b> 268036-1; 268036-3							
<b>Age</b>	<b>Gender</b>	<b>Vaccine Date</b>	<b>Onset Date</b>	<b>Days</b>	<b>Received Date</b>	<b>Status Date</b>	<b>State</b>	<b>Mfr Report Id</b>	<b>Last Edit Date</b>
20.0	F	28-Nov-2006	28-Nov-2006	0	18-Dec-2006	08-Jan-2007	--	WAES0612USA00241	08-Jan-2007
<b>VAX Detail:</b>	<b>Type</b>	<b>Manufacturer</b>		<b>Lot</b>	<b>Prev Doses</b>	<b>Site</b>	<b>Route</b>	<b>Other Vaccine</b>	
	HPV4	MERCK & CO. INC.		0955F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Insomnia

**Symptom Text:** Information has been received from a health professional concerning a 20 year old female patient who on 28-NOV-2006 was vaccinated IM with a 0.5 ml dose of GARDASIL (lot # 653978/0955F). On 28-NOV-2006 three hours after vaccination the patient developed right-sided abdominal cramping, inability to sleep and "appendicitis symptoms." On 29-NOV-2006 the patient returned to the health center with and was referred to the emergency room for a CT scan and abdominal ultrasound. She is being referred to a specialist to rule out appendicitis. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** abdominal ultrasound, 11/29?/2006, computer axial, 11/29?/2006

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268036-3 (S)    **Related reports:** 268036-1; 268036-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	28-Nov-2006	28-Nov-2006	0	20-Dec-2006	22-Dec-2006	IA		22-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Abdominal pain, Vomiting

**Symptom Text:** Shot was given on Nov 28th Tues within 2 hours pt vomiting and abd pain. then worsened to not being able to lay supine. Wed Nov 29th tried to wait SX out but went to student health where Dr asked her to go to hospital for CBC and ABD CT scan. As 0.02% appendicitis from Gardasil. She then proceeded to have appendectomy.

**Other Meds:** Ortho Tricycline LO

**Lab Data:** Increase CBC and ABD CT abnormal. APPY.

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 321

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268143-1 (S) **Related reports:** 268143-2; 268143-3; 268143-4

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	22-Nov-2006	30-Nov-2006	8	03-Dec-2006	04-Dec-2006	AK		22-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	PPV

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT**

Autonomic nervous system imbalance, Autonomic nervous system imbalance, Back pain, Extubation, Fall, Gait disturbance, Guillain-Barre syndrome, Hypertension, Hypoaesthesia, Hypoaesthesia, Hyporeflexia, Intubation, Muscular weakness, Muscular weakness, Neuralgia, Pneumonia haemophilus, Respiratory failure, Staphylococcal infection, Tachycardia, Tracheostomy, Upper respiratory tract infection, Urinary retention, Vital capacity decreased

**Symptom Text:**

Pt admitted to hospital on 12/1/06 with chief complaint of ascending weakness bilaterally, upper and lower extremities. Neuro consult diagnosed Guillain-Barre syndrome. Pt received the Gardasil vaccine on 11/22/06. Resident MD asked pharmacist to write up possible ADR of Guillain-Barre from this vaccine. 02/21/2007 records received and reviewed for DOS:12/1/06-02/06/2007 DC DX:Severe form of Guillain-Barre syndrome after HPV vaccine and possible URI. Respiratory failure with prolonged mechanical ventilation and tracheostomy tube placement. Haemophilus influenzae, left lower lobe pneumonia, coag negative staph UTI. Hypertension. Tachycardia associated with dysautonomia now resolved. Presented to PCP with URI around Thanksgiving with associated sinus infection. Began having numbness and tingling in hands days of admission as well as back pain, headache and greater problems walking and began falling over. Able to wiggle her toes but with great difficulty. Pneumococcal vaccine in September/October. HPV vaccine on 11/22/06. Mother has possible MS and possible lupus. Neuro exam:Weakness of deltoid bilaterally, weakness of lower extremities with grade 4/5 weakness at hip flexor, 4/5 hip extension, 4/5 knee flexion, 4+/5 knee extension and 3+/5 plantar flexion. Deep tendon reflexes absent in all extremities even with augmentation. Plantar responses downgoing. Gait abnormal some degree of pelvic girdle weakness and foot drop bilaterally.Began IVIG. On day 2 began developing post void residuals. Vital capacity deteriorated on day 3 to 2.2 increasing difficulties with secretions as her gag and cough diminished. Able to move only jaw and eyes. Intubated and placed on fentanyl and versed. Developed HTN. Developed neuropathic pain. At discharge able to stand with assistance. Off vent on 1/26/07. Tachycardia and hypertension associated with autonomic dysfunction now resolved at discharge.

**Other Meds:**

Zyrtec prn, guaifenesin prn, tylenol prn

**Lab Data:**

Elevated protein in CSF; clinical symptoms suggestive of Guillain-Barre syndrome (primarily motor weakness, some altered sensation) Head CT normal except for sinusitis. Coag negative staph UTI. CSF: protein 64, glucose 57 and 7WBC. EMG on

**History:**

None that I'm aware of

**Prex Illness:**

I don't have this info

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 322

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268143-2 (S) **Related reports:** 268143-1; 268143-3; 268143-4

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	21-Nov-2006	30-Nov-2006	9	05-Dec-2006	06-Dec-2006	WA		06-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Guillain-Barre syndrome

**Symptom Text:** Cannot walk. This is a previously well 13-year old female who yesterday noticed some numbness and tingling of her toes and feet. Today it is extended a little higher, and she has noticed her hands and fingers being somewhat numb. In addition, today she has difficulties feeling her legs and needs to walk with assistance because she claims she has no sensation in her legs. Six days ago, she had symptoms of a headache, nausea, and some nasal discharge. She was seen at the Fairchild Air Force Base clinic and given Zithromax for otitis media. The next day she developed hives and was instructed to stop Zithromax and given Benadryl. The hives diminished and she was given amoxicillin to start the following day. Two days ago, her eyes became somewhat injected and had some mattering. In addition, patient is complaining of some hip and back pain, and her face feels "bruised". She has had emesis twice today but no fever. She has had a facial rash on her right cheek and behind her right ear. Likely early Guillain Barre.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268143-3 (S) **Related reports:** 268143-1; 268143-2; 268143-4

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	22-Nov-2006	Unknown		19-Dec-2006	20-Dec-2006	WA	WAES0612USA01082	20-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

**MedDRA PT** Guillain-Barre syndrome, Urticaria

**Symptom Text:** Information has been received from a physician concerning a 13 year old female who on 22-Nov-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). A few days later she had cold symptoms and was prescribed azithromycin (ZITHROMAX). A few days after that the patient developed hives and was prescribed amoxicillin. A few days later the patient was hospitalized and diagnosed on 01-Dec-2006 with Guillian-Barre Syndrome. The patient sought unspecified medical attention. At the time of the report, it was unknown if the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268143-4 (S) **Related reports:** 268143-1; 268143-2; 268143-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	15-Aug-2006	30-Nov-2006	107	14-Mar-2007	21-Mar-2007	AK	200603448	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	MNQ	AVENTIS PASTEUR	U2114AA		Unknown	Unknown			

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** CSF protein increased, Guillain-Barre syndrome, Muscular weakness, Paraesthesia

**Symptom Text:** Initial report received on 11 December 2006, who originally received the report from a health care professional. A 13-year-old female patient, who was taking Zyrtec, Guaifenesin, and Tylenol, had received a dose of Menactra log number U2114AA, on 15 August 2006. The route and site of administration were not reported. The patient subsequently received a first dose, intramuscular injection (site unknown) of Gardasil, (lot number not reported), and a Pneumococcal 23-valent vaccine, manufacturer unknown, (lot number, route and site of administration not reported) on 22 November 2006. The patient developed Guillain Barre syndrome on 30 November 2006, 107 days post immunization with Menactra, and eight days post immunization with the Gardasil and Pneumococcal 23 valent vaccine. The patient was admitted to the hospital on 01 Dec 2006 with chief complaint of ascending weakness bilaterally, in the upper and lower extremities. Clinical symptoms suggested Guillain Barre Syndrome with primarily motor weakness and some altered sensation. A neurology consult was made, and the patient was diagnosed with Guillain Barre Syndrome. The CSF fluid showed elevated protein. At the time of this report, the recovery status of the patient was unknown.

**Other Meds:** Zyrtec, Guaifenesin, Tylenol

**Lab Data:**

**History:** The patient was taking Zyrtec prn, Guaifenesin prn, and Tylenol prn at the time of the vaccination on 22 November 2006.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268146-1 (S) **Related reports:** 268146-2; 268146-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	27-Nov-2006	28-Nov-2006	1	01-Dec-2006	06-Dec-2006	IL		08-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Dizziness, Vaccination complication, Vertigo, Vomiting

**Symptom Text:** Gardasil administered 11/27/06, dizziness 11/28/06, severe vertigo 11/29/06, hospitalized 11/29/06-12/01/06. MR received for ER admit for c/o dizziness, vertigo, and vomiting x2 days beginning within 24 hours of Gardasil vax. PE: WNL and in no distress as long as she holds still. Txd with IV fluids, Valium and Antivert. D/Cd home on Meclizine after 48 hours. Discharge DX: Acute vertigo, possible adverse reaction to Gardasil vaccine. 02/05/2007 Tag-2 received. No new codes.

**Other Meds:** Ortho-Evra patch

**Lab Data:** Labs and Diagnostics: significant for a serum glucose of 146 (after IV with dextrose) and K+ of 3.3. UA showed 2+blood, 5-10 WBCs. UC showed mixed urogenital flora. HCG (-). CT of brain (-).

**History:** Previous abnormal pap. PMH: abnormal PAP smear, otherwise healthy. Allergies: NKA.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268146-2 (S) **Related reports:** 268146-1; 268146-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	27-Nov-2006	29-Nov-2006	2	02-Feb-2007	05-Feb-2007	IL		05-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Computerised tomogram normal, Dizziness, Feeling drunk, Gait disturbance, Stress, Vertigo

**Symptom Text:** 2-1-07 Patient states she felt lightheaded the day after her injection. States she felt this was related to stress of school. 2nd day after injection felt "drunk". Terrible walking health center sent her to hospital by ambulance. Admit times 2 days. Diagnosis vertigo, CT Brain WNL was changed with prescription. Medicine - never filled per patient. Too busy with school at finals. No sign of reaction on right deltoid.

**Other Meds:**

**Lab Data:** Contact hospital mentioned to request information

**History:** Denies

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 327

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268146-3 (S) **Related reports:** 268146-1; 268146-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	27-Nov-2006	29-Nov-2006	2	07-Mar-2007	08-Mar-2007	IL	WAES0702USA04507	08-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Dizziness, Feeling drunk, Gait disturbance, Malaise, Vertigo

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 22 year old female student who on 27-NOV-2006 was vaccinated 0.5 ml IM in right deltoid with her first of Gardasil, lot #653938/0954F. The day after the vaccination, the patient felt lightheaded. She stated that she felt it was related to the stress of school. The second day after the vaccination she stated that she felt "drunk" and had trouble walking. The student health center sent her to the hospital by ambulance and she was admitted for two days. She had a head computed axial tomography (CT scan) performed which was within normal limits. Her diagnosis was vertigo (onset date reported as 29-NOV-2006). She was discharged with a prescription of meclizine. It was reported that she never filled the prescription because she was too busy with school and finals. There was no signs of reaction on right deltoid noted. No further information is available.

**Other Meds:** UNK

**Lab Data:** head computed axial 11/29?/06 - WNL

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268161-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	M	16-Nov-2006	17-Nov-2006	1	04-Dec-2006	05-Dec-2006	CO	WAES0611USA05427	05-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Abasia, Gait disturbance, Headache, Muscular weakness, Pyrexia, Sensation of heaviness

**Symptom Text:** Information has been received from an investigator concerning a 12 year old male with migraine headaches who entered a study. On approx 6/16/06 and 8/16/06 and on 11/16/06 at 16:15 the pt was vaccinated with a first, second and third dose of HPV vaccine. On 11/17/06 the pt woke up at 6:40 and went to the bathroom and he reported that he had trouble walking. He returned to bed. The pts father woke him up at 7:45 and noted that he had a fever of 101.3F. the pt stated that his arms and legs were heavy feeling and he didn't think he could walk. the pt experienced muscle weakness. The pts parents call the physician and were advised to take the pt to the ER. The pt went to the ER via ambulance. When the pt arrived the ER his temp was 99.5F (Pt was treated with Advil at home. It was noted that the pts neurosigns were normal and the pt reported to have a headache but refused lmetrex. the pt was discharged and no further tests were done. On 11/17/06 the pt recovered. The reporting investigator felt that muscle weakness was related to study therapy. Muscle weakness was considered to be an other important medical event (OMIC).

**Other Meds:** UNK

**Lab Data:** Body temp 11/17/06 101.3F and 99.5F

**History:** Migraines

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268189-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	29-Nov-2006	29-Nov-2006	0	04-Dec-2006	11-Dec-2006	WI		11-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Dizziness

**Symptom Text:** After second dose of a 3 dose series, pt blood pressure increased from normal baseline of 100/60 to 185/135 approx 15-20 minutes after receiving the Gardasil. Pt had near syncopal episode. PT recovered very quickly after ward.

**Other Meds:** Ortho Tri Cyclen

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268271-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	09-Nov-2006	19-Nov-2006	10	05-Dec-2006	06-Dec-2006	PA	WAES0611USA06121	16-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Myalgia, Rash, Skin discolouration

**Symptom Text:** Information has been received from a physician concerning a 19 year old female with no pertinent medical history or drug reactions allergies, who on 11/9/06 was vaccinated at her OB/GYN's office with HPV vaccine. Concomitant therapy included Zyrtec and oral hormonal contraceptives (unspecified). On 11/19/06 the pt developed a rash on the injection site arm, but not at the injections site. On 11/19/06 the pt also experienced extreme myalgia in all four extremities and her hand was discolored (purple). On 11/20/06 lab testing revealed a positive Rapid streptococcal test and the pt was placed on unspecified antibiotics. Other lab findings revealed a neg medical panel, a complete blood count revealed an elevated WBC count with a shift to the left, and a urinalysis was neg but with a trace hemoglobin. At the time of this report, the pt was recovering. The physician felt that one or more of the events were disabling. Additional information has been requested.

**Other Meds:** Zyrtec, Hormonal contraceptives.

**Lab Data:** Medical panel neg, trace hemoglobin 11/20/06, rapid streptococcus positive, WBC count elevated 11/20/06.

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268272-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.8	F	16-Aug-2006	15-Nov-2006	91	05-Dec-2006	06-Dec-2006	IL	WAES0611USA06373	06-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a physician concerning a 21 year old female with an allergy to penicillin. Who on 8/16/06 was vaccinated with the first dose of HPV vaccine. Concomitant therapy included unspecified birth control pills (since 2005). On 11/22/06 the pt was seen by the physician and was scheduled to receive her second dose of HPV vaccine. At that time the pt reported to the physician that the week prior (date not specified) she had suffered a seizure. The physician clarified that the pt had no prior history of seizures and that the pts general health was very good. The physician did not give the pt the second dose of vaccine because she was unsure if the seizure could have been related to the first dose of the vaccine. At the time of this report the pt had recovered from the seizure. Upon internal review the seizure was felt to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:**

**History:** Penicillin allergy.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268286-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	27-Oct-2006	27-Oct-2006	0	05-Dec-2006	06-Dec-2006	TN	WAES0611USA06133	06-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, OMIC, SERIOUS

**MedDRA PT** Hypersensitivity, Injection site rash, Wheezing

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female with an allergy to amoxicillin who on 10/27/06 was vaccinated IM with the first dose of HPV vaccine (lot 653650/0702F). There was no concomitant medications. On 10/27/06 approx 10 minutes after the injection, the pt started to break out in a rash around the injection site. The pt then started to wheeze. The pt was given Benadryl and Depo Medrol injection. however continued to wheeze. The wheeze was then relieved by a unit of Xopenex nebulizer treatment, but after ten minutes the pt started to wheeze again. The pt went to the ER and was admitted to the hospital. The nurse reported that th event was that of a standard allergic reaction. The pt was released from the hospital the next day, however had to continue with albuterol inhaler and prednisone therapy. The pt recovered by 10/29/06 and had not experienced any further complications. The nurse reported that the pt would not be receiving any further vaccinations with HPV vaccine. The events were felt to be other important medical events (OMIC) and immediately life threatening. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:**

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268287-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	25-Sep-2006	Unknown		05-Dec-2006	06-Dec-2006	MA	WAES0611USA06464	06-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0688F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, OMIC, SERIOUS

**MedDRA PT** Epistaxis, Headache, Platelet count decreased

**Symptom Text:** Information has been received from a physician concerning a 21 year old female with no history of drug reactions/allergies, and a history of idiopathic thrombocytopenic purpura who on 9/25/06 was vaccinated IM with HPV vaccine (Lot 653735/0688F). There was no concomitant medications. In Sept 2006, a few days after vaccination the pt experienced a headache, nose bleed and developed thrombocytopenia. The pts platelet count on an unspecified date was 43,000. The pt was hospitalized and received platelet transfusion. A CT of the head and lumbar puncture were performed, however the results were unspecified. The pt subsequently recovered on an unspecified date. The reporting physician felt that one or more of the events was an other important medical event (OMIC) and life threatening. Additional Information has been requested.

**Other Meds:** NONE

**Lab Data:** Head computed axial 9/6 unspecified, spinal tap 9/06 results unspecified. Platelet count 9/06 43000

**History:** Idiopathic thrombocytopenic purpura.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268288-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	21-Nov-2006	21-Nov-2006	0	05-Dec-2006	06-Dec-2006	CO	WAES0611USA07061	06-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 11/21/06 was vaccinated with an initial dose of HPV Vaccine IM in the deltoid. On 11/21/06, after the initial dose, the pt experienced a seizure. The pt was alert shortly after the event and was sent to the emergency department as a precaution. It is unk if the pt was admitted to the hospital. The pt is recovering from seizure. The pt will not continue with subsequent doses of vaccine. Upon internal review, seizure was considered an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** NONE

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268415-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	03-Oct-2006	03-Oct-2006	0	06-Dec-2006	15-Dec-2006	--		15-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Paraesthesia

**Symptom Text:** Injection left deltoid with HPV vaccine, immediate pain, transient finger tingling. Pain persists with movement and pressure only, 10/27/06.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268459-1      **Related reports:** 268459-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	05-Dec-2006	05-Dec-2006	0	06-Dec-2006	07-Dec-2006	NJ		07-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cold sweat, Difficulty in walking, Disorientation, Dizziness, Dyskinesia, Headache, Hyperventilation, Pallor, Paraesthesia, Tinnitus, Tremor

**Symptom Text:** With in five minutes of administration complaint of headache, then felt faint. I had my daughter sit down in the waiting room with her head down before we walked out. Not thinking this had anything to do with the vaccine. We walked out the door and she began have difficlty walking, weaving, I asked her if she was okay and she could only respond yes. I took her arm and tried to turn her back to the Doctor's office and she collapsed on the ground. Though, she remained conscious her eyes were glazed and was disoriented. It happened that another lady was leaving the office and I asked for her assitance to walk her back inside. The nurse immediately had us put her on an exam table. I do not think she was able to hear a blood pressure. At this point, my daughter was extremely pale, clammy, shallow rapid breathing, weak pulse, able to anwser questions. She stated her ears were ringing and that she had tingling in her feet. The doctor naturally examined her as well. They treated her with oral fluids, rest and some sugar cookies(the only thing they had). I am not sure the exact time the vaccine was administered. I believe it was around 5pm. When we left the doctors office, it was 5:45, my daughter felt weak and was shaky (visible). On the drive home she experienced visible muscle contractions in her arms and legs. Legs and arms were involuntarily jerking. This lasted approximately 10 minutes. By 6:00pm she felt "normal".

**Other Meds:** none

**Lab Data:** none

**History:** Shellfish

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 337

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268459-2      **Related reports:** 268459-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	05-Dec-2006	05-Dec-2006	0	09-Jan-2007	18-Jan-2007	NJ	WAES0612USA01029	18-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dyskinesia, Headache, Hyperhidrosis, Injection site pain, Loss of consciousness, Malaise, Pallor, Tremor

**Symptom Text:** Information has been received from a nurse at a physician's office concerning a 14 year old female with no medical history reported. On 05-Dec-2006, the patient was vaccinated with the first single dose vial of HPV vaccine (yeast) (Lot#653978/0955F). It was reported that the patient was "alright at the time of the vaccination". However, the patient on her way out of the physician's office stated that she wasn't feeling well (conflicting information reported as "almost immediately after being vaccinated"), the patient developed a bad headache within seconds and began to turn white, The nurse reported that the patient left the office and by the time she got back out to the parking lot, the patient passed out. The physician's office brought the patient back to the office to be examined. The nurse reported that the patient had developed hypotension, tremors, a bad headache, involuntary movement of her upper and lower extremities which lasted about ten minutes along with some additional symptoms which were not specifically specified. The patient became pale, diaphoretic and felt weak. The patient had no vomiting and had no fever. The physician stated that the patient's experience was not an active seizure. Her blood pressure was initially 60/40 mmHg, then later 80/60 mmHg. The patient was not tachycardic. The patient developed pain at the office site of injection. The physician noted that the patient had not eaten for awhile and the patient felt better after eating. The patient was not seen in the emergency room and was fine the next day. Unspecified medical attention was sought. The physician stated that she did not see the "involuntary movement of her upper and lower extremities", which was reported by the nurse. The physician was not in the from at that time to see that, however, she stated again this was not a seizure. The nurse reported that the patient stayed home from school on 06-Dec-2006 because she still was not feeling herself but was "doing better". The nurse reported that the patient was not planning to r

**Other Meds:** UNK

**Lab Data:** blood pressure 12/05/2006 80/60 mmHg, blood pressure 12/05/2006 60/40 mmHg

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268483-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	05-Sep-2006	05-Sep-2006	0	07-Dec-2006	08-Dec-2006	MD	WAES0610USA00280	08-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	1	Unknown	Unknown	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Abortion, Laboratory test abnormal, Unintended pregnancy

**Symptom Text:** Information has been received from a healthcare worker for the pregnancy registry for HPV vaccine concerning a 22 year old female pt whit a history of abnormal pap who on 6/29/06 was vaccainted with her first dose of HPV vaccine , lot 653650/0697F. On 9/5/06 the pt was vaccinated with her second dose of HPV vaccine, lot 653650/0702F. The reporter indicated that the pt received the 2nd vaccination but did not realize she was about 6 weeks pregnant at the time. Medical attention was sought. An ultrasound and colposcopy was performed. The reporter indicated that there was no fetal pole at the time of the ultrasound and that it would be repeated. There was no adverse experience reported. Follow up information has been received from a physician concerning the female pt, whose last menstrual period was approximately 9/9/06. The estimated date of conception was 8/30/06. An ultrasound performed 9/20/06 showed 16P 5 wk 3 days. This is the pts first pregnancy. The estimated delivery date is 5/21/07. Follow up information has been received. On 11/8/06 the pt underwent an elective termination of her pregnancy at 12 week from LMP. Upon internal review, elective termination of pregnancy was considered to be an other important medical event (OMIC). Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** Colposcopy 9/06, ultrasound 9/06/06 no fetal pole, ultrasound 9/20/06 16P 5 wk 3 days.

**History:** Papanicolaou smear abnormal.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268513-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	04-Dec-2006	05-Dec-2006	1	07-Dec-2006	03-Jan-2007	MN		03-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2094AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site reaction, Pruritus

**Symptom Text:** Local pruritic reaction at injection site without erythema, edema left deltoid.

**Other Meds:**

**Lab Data:** NONE

**History:** Allergic to Septra

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268544-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	05-Dec-2006	06-Dec-2006	1	08-Dec-2006	18-Dec-2006	CA		18-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2457AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Insomnia, Syncope

**Symptom Text:** Several hours after vaccines given pt complained of HA and dizziness, insomnia. Next am s/s worse fainted. taken by paramedics to Hospital ER on 12/6/06.

**Other Meds:**

**Lab Data:** CT Scan

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268587-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	27-Sep-2006	13-Oct-2006	16	09-Dec-2006	11-Dec-2006	CA		12-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Contusion, Pruritus, Rash

**Symptom Text:** Approx. two weeks after I received the HPV vaccine I started breaking out in red bumps mostly all over my lower body and now I have this weird purple spots on my right thigh. It has itched me so bad that I have bruises all over my legs.

**Other Meds:**

**Lab Data:**

**History:** Allergic to penicillin, which I told the doctor.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268628-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Oct-2006	01-Oct-2006	0	11-Dec-2006	12-Dec-2006	NY	WAES0611USA07474	12-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Condition aggravated, Convulsion

**Symptom Text:** Information has been received from a physician concerning a female pt with seizures who in approx Oct 2006, about two months ago, was vaccinated IM with a first 0.5ml dose of HPV vaccine. Right after receiving the vaccination, the pt started to have seizures every day for about two weeks after receiving the vaccine. It was noted that the pt already has seizures but had them once or twice a week not everyday. Subsequently, the pt recovered. Upon internal review, seizures was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** Convulsions

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 268992-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	22-Nov-2006	30-Nov-2006	8	15-Dec-2006	18-Dec-2006	MI		22-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash erythematous

**Symptom Text:** One week after injection, pt. has had a patchy, dry, erythematous rash 1 cm. in circumference show up intermittently on trunk and extremities. Rash remits and recurs. No history of rash.

**Other Meds:** Zithromax, Orthotrycyclen

**Lab Data:** None

**History:** Allergy to Cephalosporins, Penicillin and Sulfa

**Prex Illness:** Dysmonorrhea, Sinusitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269013-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
28.0	F	07-Nov-2006	08-Nov-2006	1	18-Dec-2006	19-Dec-2006	FL	WAES0612USA00854	19-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Diplopia, Vision blurred

**Symptom Text:** Information has been received from a health professional concerning a 28 year old female speech language assistant with no illness at the time of the vaccination and a history of cardiac murmur and migraine who on 07 Nov 2006 was vaccinated with first dose of HPV vaccine (lot 653735/0688F) in the right deltoid at approximately 1100 hours. On 08 Nov 2006, the patient called the medical facility and complained of experiencing blurred vision. On 09 Nov 2006, the patient experienced seeing double. The patient was told to go to the emergency room immediately. On 12 Nov 2006, the patient recovered. It was reported that the events required medical/surgical intervention (other important medical Events) (OMIC). No further information is available.

**Other Meds:** UNK

**Lab Data:**

**History:** Cardiac murmur, migraine.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269038-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	31-Oct-2006	02-Nov-2006	2	18-Dec-2006	19-Dec-2006	NY	WAES0611USA01965	19-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Asthma, Chest pain, Condition aggravated, Dyspnoea

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 14 year old female with asthma, no allergies and a history of vomiting, fever and abdominal cramps after a flu vaccination each time she was vaccinated. The nurse reported that the patients asthma was under good control for more than six months. She also noted that due to the side effects of the flu vaccination, the patient refused to received any more flu shots. On 31 Oct 2006 the patient was vaccinated intramuscularly with a first dose of HPV vaccine (lot 653938/0954F). concomitant therapy included Advair and albuterol inhaler prn. On 02 Nov 2006 the patient had an asthma attack. She developed chest tightening, wheezing and chest pain. The symptoms began after playing basketball. She used her albuterol inhaler with no relief. She went to the ER and was given albuterol and Advair. An EKG and chest X ray were preformed. The patient was not hospitalized. The nurse felt that this asthma attack was an isolated event. She noted that the patients physician felt that it was probably a coincidence that it was after the HPV vaccination. On 04 Nov 2006 the patient recovered. No product quality complaint was involved. The reporter did not considered this asthma attack to be permanently disabling, but that it was disabling because the patient missed school and the shortness of breath during the attack would be considered disabling. Asthma attack was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Albuterol, Advair

**Lab Data:**

**History:** MEDICAL HISTORY: Immunization, Vomiting, Fever, Adverse drug reaction, Abdominal cramp. CONCURRENT CONDITIONS: Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269162-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	10-Oct-2006	10-Oct-2006	0	18-Dec-2006	09-Jan-2007	WY	WAES0610USA12076	01-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Influenza like illness, Vomiting

**Symptom Text:** Initial and follow up information has been received from a Registered Nurse concerning a white female patient who on the afternoon of 10 Oct 206 was vaccinated IM with her first dose of Gardasil (yeast), lot #653650/0720F, and experienced flu-like symptoms and vomiting. No medical attention was sought. Within a day or two, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269163-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	NY	WAES0610USA15083	01-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Hyperhidrosis, Nausea, Pallor

**Symptom Text:** Initial and follow up information has been received from a Nurse Practitioner concerning an approximately 22 year old female patient who in October 2006, was vaccinated IM with a dose of Gardasil (yeast). Subsequently, she experienced nausea, lightheadedness/lightheaded feeling/dizziness, weakness, pallor, and sweating but did not lose consciousness. No medical attention was sought. The nurse practitioner indicated the patient was "doing fine", and had recovered after 20 minutes. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 348

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269164-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
48.0	F	31-Oct-2006	31-Oct-2006	0	18-Dec-2006	09-Jan-2007	--	WAES0611USA00994	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0955F	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Haemorrhage, Injection site induration

**Symptom Text:** Information has been received from a health professional concerning an approximately 48 year old female patient with condyloma with mild to moderate dysplasia who on 31 Oct 2006 was vaccinated IM into the deltoid with a second 0.5mL dose of Gardasil (yeast) (lot # 653978/0955F). Concomitant therapy included aspirin. It was reported that after the nurse gave the injection blood immediately ran out of the site and it was hard and lumpy. It was reported that the nurse used proper placement technique and a standard 1 inch needle (not the prefilled device). The patient had no problems with the first dose. The patient did not report any discomfort from the hard and lumpy area. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** aspirin

**Lab Data:** UNK

**History:** Condyloma, dysplasia

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269165-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	CA	WAES0611USA01091	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a female patient who was vaccinated with a 0.5 mL dose of Gardasil (yeast). Subsequently, the patient fainted. Unspecified medical attention was sought. A short time after vaccination, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269166-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	19-Oct-2006	19-Oct-2006	0	18-Dec-2006	09-Jan-2007	TX	WAES0611USA01331	09-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site mass, Pruritus

**Symptom Text:** Information has been received from a medical assistant concerning a 24 year old female with no other relevant history reported. On 19 Oct 2006, the patient was vaccinated with the first dose of Gardasil (yeast). There were no other concomitant medications reported. On 19 Oct 2006, the patient developed some initial itching at the injection site that resolved (date unknown). On 02 Nov 2006, the patient reported that she awoke with a large red bump at the injection that was itchy "this developed about 13 days post dose". The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269167-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	30-Sep-2006	01-Oct-2006	1	18-Dec-2006	09-Jan-2007	IL	WAES0611USA01335	09-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	By Mouth	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus genital

**Symptom Text:** Information has been received from a nurse concerning a 12 year old female who on 30 Sep 2006 was vaccinated with the first 0.5 mL dose of Gardasil reported as "oral". On 01 Oct 2006, the patient developed intense vaginal itching. The patient sought unspecified medical attention. On 03 Oct 2006, the patient recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269168-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	CT	WAES0611USA01381	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a female physician assistant (age not reported) who on an unspecified date was vaccinated with 1 dose of 0.5 ML of Gardasil (yeast) (Lot#653978/0955F). The physician assistant reported that after she was injected with Gardasil (yeast) she felt numbness from the injection site progress all the way to her fingers. Unspecified medical attention was sought. At the time of this report, the physician assistant had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269169-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	21-Sep-2006	21-Sep-2006	0	18-Dec-2006	09-Jan-2007	IL	WAES0611USA01393	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Urticaria

**Symptom Text:** Information has been received from a health professional concerning a her 19 to 21 year old daughter who on approximately 21 Sep 2006 "about 6 weeks ago" was vaccinated IM with a first dose of Gardasil (yeast). Within 5 to 6 hours of vaccination, the patient developed hives and swelling of her hands and feet. The patient was given (Benadryl) and the symptoms began to heal. Subsequently, the patient recovering. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269170-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	--	WAES0611USA01398	09-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning the experience of another physician's patient. On an unspecified date, a 12 year old female was vaccinated with a dose of Gardasil (yeast). Subsequently the patient developed a rash on her arm. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269171-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	02-Nov-2006	03-Nov-2006	1	18-Dec-2006	09-Jan-2007	IN	WAES0611USA01551	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Rash

**Symptom Text:** Information has been received from a physician concerning a female who on an unspecified date received the first dose of Gardasil (yeast) (Lot # not provided). On 02 Nov 2006 the patient was vaccinated with the second dose of Gardasil (yeast) (Lot # not provided). On 03 Nov 2006 the patient experienced joint pain and developed a rash. Unspecified medical attention was sought. At the time of this report the patient was recovering from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269172-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	01-Nov-2006	01-Nov-2006	0	18-Dec-2006	09-Jan-2007	ND	WAES0611USA01557	09-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0640F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Pain, Urticaria

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who on 01-Nov-2006 was vaccinated with 0.5 ml of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#653650/0640F). At the same time, the patient received medroxyprogesterone acetate (DEPO-PROVERA) " in glut". On 01-Nov-2006 (conflicting information also reported as 02-Nov-2006), the patient developed body aches. On 03-Nov-2006 the patient developed hives all over body and also experienced ankle swelling. The patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** DEPO-PROVERA

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269173-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	SC	WAES0611USA01833	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a health professional concerning a female patient who was vaccinated with a first 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The next morning, the patient felt sick to her stomach. It was noted that once she went to school she felt better. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269174-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	02-Nov-2006	02-Nov-2006	0	18-Dec-2006	09-Jan-2007	IL	WAES0611USA02205	09-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0696F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature decreased, Headache, Nausea, Pain

**Symptom Text:** Information has been received from a nurse concerning a 19 year old female patient who is the daughter of one of the office employees, who on 02-Nov-2006 was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#653650/0696F). Concomitant therapy included hormonal contraceptives (unspecified). On 02-Nov-2006 the patient developed nausea, low grade fever, achiness and a headache post vaccination. It was reported that these events continued into the evening on 02-Nov-2006. On 03-Nov-2006, the next morning the patient had recovered from all of the events. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269175-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	27-Oct-2006	27-Oct-2006	0	18-Dec-2006	09-Jan-2007	--	WAES0611USA02227	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a Nurse Practitioner concerning a female patient who on 27-Oct-2006 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient fainted in the office, hit her head on the floor and required stitches. Medical attention was sought. At the time of the report the patient was recovering. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269176-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	--	WAES0611USA02302	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain

**Symptom Text:** Information has been received from a nurse concerning a female who was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced numbness and pain in her arm. The patient sought unspecified medical attention. Subsequently, the patient recovered from pain in injection arm and is recovering from the numbness. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269177-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	TN	WAES0611USA02316	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female (NOS) who was vaccinated on an unknown date intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently the patient fainted. Subsequently, the patient recovered from the syncope. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269178-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	26-Oct-2006	26-Oct-2006	0	18-Dec-2006	09-Jan-2007	--	WAES0611USA02584	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling abnormal

**Symptom Text:** Information has been received from a health professional concerning a 20 year old female who on 26-Oct-2006 was vaccinated "in the right hip" with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot#654540/0800F). Within 15 minutes, the patient experienced a "funny feeling" in upper right thigh. The patient said "the feeling was gone later that day". No medical attention was sought. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269179-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	NY	WAES0611USA02839	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite tingling" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269180-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	02-Nov-2006	03-Nov-2006	1	18-Dec-2006	09-Jan-2007	--	WAES0611USA02908	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menorrhagia, Migraine, Rash

**Symptom Text:** Information has been received from an office manager concerning a 14 year old female who on 02-Nov-2006 was vaccinated intramuscularly in the arm with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On 03-Nov-2006 the patient started her menses and experienced a migraine. On 06-Nov-2006 the patient experienced a rash on her vaccinated arm which also spread to her face. Unspecified medical attention was sought. The patient was treated with diphenhydramine (BENADRYL) and the rash had subsided. AT the time of report, the patient was recovering from the migraine. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269181-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	IN	WAES0611USA02920	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Face oedema, Oedema peripheral

**Symptom Text:** Information has been received from a physician concerning a 13 year old female who was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced swelling in her face, stomach was extended with fluids and her lower extremities were swollen. Unspecified medical attention was sought. The patient was put on "hydrosteroids". She is scheduled for a follow-up visit the week of November 13th. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269182-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	NY	WAES0611USA03319	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Smear cervix abnormal

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient's pap smear came out positive. Medical attention was sought. Her outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Pap test - positive

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269183-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	PA	WAES0611USA03411	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician concerning a 20 year old female who on an unspecified date was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (0.5 ml). Subsequently, two weeks following vaccination, the patient experienced pain at the injection area. The patient also complained of pain in the same area when lifting her arm. Unspecified medical attention was sought. At the time of this report, the outcome of the events was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269184-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	02-Nov-2006	09-Nov-2006	7	18-Dec-2006	09-Jan-2007	PA	WAES0611USA03416	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Injection site pain, Swelling

**Symptom Text:** Information has been received from a physician concerning an approximately 18 year old female who on approximately 02-Nov-2006 was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On week after vaccination, on approximately 09-Nov-2006, the patient experienced pain at the injection site, and had redness, soreness and swelling. Unspecified medical attention was sought. At the time of this report, the outcome of the events was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269185-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	IL	WAES0611USA03436	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female patient (demographics not provided) who on an unspecified date was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently the patient developed a rash on her face and stomach. The patient sought unspecified medical advice. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269186-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	30-Oct-2006	30-Oct-2006	0	18-Dec-2006	09-Jan-2007	OR	WAES0611USA03446	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a nurse practitioner concerning an 18 year old female with low level depression and anxiety and penicillin allergy and sulfonamide allergy who on 30-Oct-2006 was vaccinated intramuscularly in the right deltoid with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot#653978/0955F). Concomitant therapy included escitalopram oxalate (LEXAPRO), loratadine (CLARITIN) acetaminophen (TYLENOL). On 30-Oct-2006, following vaccination, the patient fainted. Unspecified medical attention was sought. Subsequently, the patient recovered and no other symptoms were noted. Additional information has been requested.

**Other Meds:** TYLENOL, LEXAPRO, CLARITIN

**Lab Data:** NONE

**History:** CONCURRENT CONDITIONS: Depression, Anxiety, Penicillin allergy, Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269187-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	12-Sep-2006	12-Sep-2006	0	18-Dec-2006	09-Jan-2007	AZ	WAES0611USA03478	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning an 15 year old female with a history of polycystic ovary syndrome, who on 12-Sep-2006 was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#654540/0800F). Subsequently, shortly after receiving the vaccination the patient fainted. Subsequently, the patient recovered from the syncope. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** DESOGEN

**Lab Data:**

**History:** CONCURRENT CONDITIONS: Polycystic ovarian syndrome

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269188-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	CO	WAES0611USA03479	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy

**Symptom Text:** Information has been received from a physician's assistant concerning a 11 year old female who on unspecified date was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently the patient developed swollen lymph nodes in groin her area. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269189-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	08-Nov-2006	08-Nov-2006	0	18-Dec-2006	09-Jan-2007	NJ	WAES0611USA03485	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Hyperhidrosis, Injection site erythema, Injection site swelling, Lymphadenopathy, Nausea, Pain, Paraesthesia, Pruritus, Pyrexia

**Symptom Text:** Information has been received from a physician concerning his daughter, a 19 year old female who at 15:00 on 08-Nov-2006 "was feeling great anxiety" before receiving an intramuscular injection with the vaccination HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#654540/0800F). On 08-Nov-2006 after receiving the vaccination the patient experienced throbbing pain, a tingling sensation down length of her arm, elbow, wrist, jaw line and down her neck, fever, swelling and redness at the injection site, was "terribly itchy", had veins protruding, swollen glands, nausea and "felt hot and sweaty" (the patient was reported to be afebrile). Unspecified medical attention was sought. At the time of the report it was unknown if the patient had recovered. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:**

**History:** CONCURRENT CONDITIONS: Anxiety

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269190-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	07-Nov-2006	07-Nov-2006	0	18-Dec-2006	09-Jan-2007	CA	WAES0611USA03521	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Migraine

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with asthma and penicillin allergy who on 26-Sep-2006 was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#not provided). Concomitant therapy included hormonal contraceptives (unspecified). On 07-Nov-2006 the patient was vaccinated with the second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot#6537361/0868F). That same day the patient experienced a migraine with a "blinded spot in one eye", dizziness and was "seeing stars". She was treated with aspirin. At the time of this report it was unknown if the patient had recovered from the event. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:**

**History:** CONCURRENT CONDITIONS: Asthma, Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269191-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	05-Sep-2006	05-Sep-2006	0	18-Dec-2006	09-Jan-2007	UT	WAES0611USA03555	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstrual disorder

**Symptom Text:** Information has been received from a physician concerning an 11 year old female who on 05-Sep-2006 was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On approximately 05-Sep-2006, the patient noted her menstrual cycle increased from every month to every two weeks. The patient sought unspecified medical attention. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269192-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	MA	WAES0611USA04002	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fall, Fracture, Syncope

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who on an unspecified date was vaccinated with Gardasil (yeast). It was reported that the patient was sitting on a bench and when the personnel left the room, the patient apparently fainted and ended up falling off bench. It was reported that it was unsure if the patient had broken her nose but there was blood. At the time of this report, the outcome of the events were unknown. The physician feels that the patient "might be anorexic and had not had anything to eat all day hence the fainting". No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Anorexia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269193-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	31-Oct-2006	31-Oct-2006	0	18-Dec-2006	09-Jan-2007	NY	WAES0611USA04222	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Sensation of heaviness

**Symptom Text:** Information has been received from a mother of an 11 year old female who on 31 Oct 2006 was vaccinated with Gardasil (yeast) (0.5 ml). On 31 Oct 2006, 30 minutes following vaccination, the patient's arm "felt heavy". Subsequently, the patient recovered from the event 30 minutes later. Medical attention was not sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269194-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		18-Dec-2006	09-Jan-2007	WI	WAES0611USA04226	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Pelvic pain

**Symptom Text:** Information had been received from a physician concerning a patient who on an unspecified date was vaccinated with the second dose of Gardasil (yeast). Subsequently the patient experienced abdominal pain and suprapubic pain that radiated to the vaginal region. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269196-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Dec-2006	05-Jan-2007	MI	WAES0611USA04345	05-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Dizziness, Joint stiffness

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with rheumatoid arthritis who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient developed dizziness, stiffness in joints and abdominal cramping. The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the events (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** CONCURRENT CONDITIONS: Rheumatoid arthritis

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269197-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	12-Nov-2006	12-Nov-2006	0	18-Dec-2006	09-Jan-2007	FL	WAES0611USA04349	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0868F	1	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Information has been received from a physician and a nurse concerning a 21 year old female with glaucoma who on 09 Sep 2006 was vaccinated with a first dose of Gardasil (yeast). Concomitant therapy included Xalatan. On 12 Nov 2006, the patient was vaccinated IM, in the right deltoid, with a 0.5 ml second dose of Gardasil (yeast) (lot #653736/0868F). On 12 Nov 2006, 13 hours after the vaccination, the patient developed a rash on both arms. The patient used alcoholol on these areas and the rash went away. On approximately 12 Sep 2006, at an unspecified time, the patient developed hives. The hives were itchy and "looked like slap marks all over her body" including her legs, abdomen, back and face. The welts were raised and swollen. The patient was treated with Benadryl. At the time of the report, the patient was recovering from the hives. There were laboratory or diagnostic tests performed. It was reported that the patient had no reactions after the first dose of Gardasil (yeast). Additional information has been requested.

**Other Meds:** Xalatan

**Lab Data:** NONE

**History:** Glaucoma

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269198-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	01-Nov-2006	09-Nov-2006	8	18-Dec-2006	09-Jan-2007	NY	WAES0611USA04358	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0954F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cellulitis

**Symptom Text:** Information has been received from a physician concerning a 11 year old female who on 01-Nov-2006 was vaccinated with a 0.5 ml first dose of Gardasil (yeast) (lot #653938/0954F). On 09 Nov 2006 the patient developed cellulitis in the arm where vaccine was administered. Unspecified medical attention was sought. At the time of the report, the patient was recovering from the cellulitis. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269199-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	13-Nov-2006	13-Nov-2006	0	18-Dec-2006	09-Jan-2007	VA	WAES0611USA04373	10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Hyperhidrosis, Incorrect route of drug administration, Nausea

**Symptom Text:** Information has been received from a registered nurse concerning her 16 year old daughter who on 13 Nov 2006 was vaccinated with her first dose of Gardasil (yeast). The patient's mother reported that she was vaccinated subcutaneously. Conflicting information was received from the administering licensed practical nurse who reported that she was positive the patient was vaccinated intramuscularly into the deltoid area and not subcutaneously. On 13 Nov 2006, a few minutes after the vaccine was administered, the patient experienced nausea, dizziness and sweating. Unspecified medical attention was sought. Subsequently, the patient recovered from nausea, dizziness and sweating in a few minutes. Additional information has been received from a registered nurse. The nurse reported that her fellow nurse gave the dose of Gardasil (yeast) IM instead of subcutaneous. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269200-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	--	WAES0611USA04378	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema

**Symptom Text:** Information has been received from a nurse practitioner concerning a 19 year old female who on an unspecified date was vaccinated with a 0.5 mL dose of Gardasil (yeast). The patient was experiencing vomiting and diarrhea and had no fever prior to receiving the vaccination. Subsequently, the patient developed swelling of hands and feet and her face got puffy after receiving Gardasil (yeast). The patient sought medical attention and was treated with an unspecified antihistamine. Subsequently, the swelling went away, and the patient was considered recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:** diarrhea, vomiting

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269201-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0611USA04542	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated IM with a first dose of Gardasil (yeast). Subsequently the patient developed a shooting pain down her arm where she received the injection. Reportedly the physician does not think this is an adverse experience. Subsequently, the patient recovered from shooting pain down her arm in less than a minute. The patient does not want to come back for a second injection. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269202-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	09-Jan-2007	PA	WAES0611USA04578	09-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Smear cervix abnormal

**Symptom Text:** Information has been received from a physician concerning a female who in October 2006, was vaccinated with the first dose of Gardasil (yeast) (0.5mL). In approximately October 2006, "shortly after the injection", the patient was examined and learned that she developed an abnormal PAP. Unspecified medical attention was sought. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Pap test 10/?/06-abnormal

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269203-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	13-Nov-2006	13-Nov-2006	0	18-Dec-2006	09-Jan-2007	AZ	WAES0611USA04596	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Decreased appetite, Vomiting

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female who on 13 Nov 2006 was vaccinated intramuscularly with the first dose of Gardasil (yeast) (Lot # not provided). On 13 Nov 2006 the patient experienced nausea, vomiting and decreased appetite. Unspecified medical attention was sought. At the time of this report it was unknown if the patient had recovered from these events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269204-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Nov-2006	09-Nov-2006	1	18-Dec-2006	09-Jan-2007	NJ	WAES0611USA04681	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 16 year old female who on 08 Nove 2006 was vaccinated intramuscularly with the first dose of Gardasil (yeast) (Lot # not provided). On 09 Nov 2006 it was reported that the patient developed hives. Unspecified medical attention was sought. At the time of this report it was unknown if the patient had recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269205-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	26-Sep-2006	26-Sep-2006	0	18-Dec-2006	10-Jan-2007	IL	WAES0611USA04701	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0689F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Pruritus, Urticaria

**Symptom Text:** Information has been received from a registered nurse concerning a 22 year old white female student with no other medical history, no known allergies or adverse drug reactions reported. On 26 Sep 2006, at 12:300 PM, the patient was vaccinated intramuscularly in the left deltoid with the first dose of Gardasil (yeast) (Lot# 653736/0689F), within 2 hours of the injections the patient developed full body hives, itching and swelling of hands and feet. The patient took Benadryl every 4 hours and the symptoms were gone within 24 hours. At the time of this report, the patient had recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269206-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	WA	WAES0611USA04818	10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Dizziness, Hyperhidrosis, Nausea, Syncope

**Symptom Text:** Information has been received from a consumer who is a company representative concerning her 20 year old daughter who on an unspecified date was vaccinated with the second dose of Gardasil (yeast). The patient's mother reported that the vaccination caused the patient to feel faint, and she experienced nausea with chills and sweating. The patient was kept in the office until she felt better. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269207-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NC	WAES0611USA04882	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a practice manager concerning a female patient who on an unspecified date was vaccinated with Gardisal (yeast). Subsequently, following vaccination, the patient experienced syncope. Unspecified medical attention was sought. No further details were provided. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269208-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0611USA04906	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female who was "shot phobic" who on an unspecified date was vaccinated with Gardasil (yeast) (0.5ml). Subsequently, following vaccination, the patient fainted. Unspecified medical attention was sought. The patient subsequently recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** phobia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269209-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	13-Nov-2006	13-Nov-2006	0	18-Dec-2006	10-Jan-2007	WA	WAES0611USA05100	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0954F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Headache, Pain, Tinnitus

**Symptom Text:** Information has been received from a registered nurse at an OB/GYN's office concerning a 14 year old female with penicillin allergy who on 13 Nov 2006 was vaccinated intramuscularly in the left deltoid with Gardasil (yeast) (lot #653938/0954F). There was no concomitant medication. On 13 Nov 2006 the patient experienced pain in the vaccinated arm, headache, dizziness, fatigue, weakness and ringing in the ears. The patient sought treatment from her pediatrician. At the time of this report the patient's pain in the arm, headache, dizziness, fatigue, weakness and ringing in the ears persisted. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Pencillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269210-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	13-Nov-2006	13-Nov-2006	0	18-Dec-2006	10-Jan-2007	WA	WAES0611USA05103	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Influenza like illness

**Symptom Text:** Information has been received from a nurse concerning a female who on 13 Nov 2006 was vaccinated with the first dose of Gardasil (yeast). Subsequently on 13 Nov 2006, following vaccination, the patient experienced a headache and flu-like symptoms. The patient did not have a fever. Unspecified medical attention was sought. At the time of this report, the outcome of the events was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269211-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	14-Nov-2006	15-Nov-2006	1	18-Dec-2006	10-Jan-2007	TN	WAES0611USA05160	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abnormal behaviour, Euphoric mood, Malaise, Nausea

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female with a penicillin allergy and drug hypersensitivity to Zithromax. On 14 Nov 2006, the patient was vaccinated with Gardasil (yeast) ( Lot # 653978/0955F). There were no concomitant medications reported. On 15 Nov 2006, the patient was noted to be very emotional, nauseated, felt dazed and "high". The patient sought unspecified medical attention. No treatment was required. On 16 Nov 2006, the patient had recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Penicillin allergy, drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269212-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0611USA05398	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia, Sensation of heaviness

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a first 0.5 ml Gardasil (yeast). Subsequently the patient experienced a tingle and heaviness. Unspecified medical attention was sought. After twenty minutes the tingle and heaviness went away. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269213-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0611USA05651	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Viral infection

**Symptom Text:** Information has been received from a physician concerning a 25 year old female who on an unspecified date was vaccinated with HPV Vaccine. One week later, the patient was noted to have a positive human papilloma virus infection (date unknown). It was reported that the physician dose not know when the vaccine was given or the dose because she did not administer the vaccine in her office. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Positive HPV test

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269214-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	--	WAES0611USA05682	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation irregular

**Symptom Text:** Information has been received from a health professional concerning a 20 year old female who on an unspecified date was vaccinated with a dose of HPV Vaccine. Subsequently, the patient experienced three menstrual periods during the next month. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:** UNK

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269215-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Nov-2006	09-Nov-2006	1	18-Dec-2006	10-Jan-2007	NJ	WAES0611USA05796	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0697F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 16 year old female with no known drug allergies who on 08 Nov 2006, at 4:00 PM, was vaccinated IM with the first dose of HPV vaccine. On 09 Nov 2006, the patient developed a drug rash. The patient sought unspecified medical attention. On 14 Nov 2006, the patient was recovered from the drug rash. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269216-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Nov-2006	01-Nov-2006	0	18-Dec-2006	10-Jan-2007	PA	WAES0611USA05836	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Information has been received from a nurse practitioner concerning a female (age not reported) who on approximately 01 Nov 2006 was vaccinated with the first dose of HPV vaccine. On approximately 01 Nov 2006, the patient developed total body itching. The patient sought unspecified medical attention. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269217-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	27-Sep-2006	28-Sep-2006	1	18-Dec-2006	10-Jan-2007	OR	WAES0611USA06105	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0637F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Nausea, Pyrexia

**Symptom Text:** Information has been received from a physician's nurse concerning a 15 year old female who on 27 Sep 2006 was vaccinated intramuscularly with HPV vaccine (lot # 653937/0637F). On 28 Sept 2006 the patient experienced nausea, fever and soreness at the injection site. Unspecified medical attention was sought. At the time of this report, the outcome of the events was unknown.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269218-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NC	WAES0611USA06106	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site reaction, Urticaria

**Symptom Text:** Information has been received from a nurse concerning a female who on an unspecified date was vaccinated with HPV vaccine. Subsequently, one week later, the patient developed welts on the arm where the shot was administered. Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269219-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	14-Nov-2006	15-Nov-2006	1	18-Dec-2006	10-Jan-2007	MA	WAES0611USA06158	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness, Injection site erythema

**Symptom Text:** Information has been received from a registered nurse concerning a 20 year old female with no pertinent medical history or drug reactions/allergies who on 14 Nov 2006 was vaccinated intramuscularly with HPV Vaccine. There was no concomitant medications. On 15 Nov 2006, about 24 hours later, the patient developed erythema at the injection site and experienced flu like symptoms. Unspecified medical attention was sought. Subsequently, the patient recovered from the erythema at injection site and flu like symptoms within 72 hours. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269220-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Oct-2006	01-Oct-2006	0	18-Dec-2006	10-Jan-2007	NC	WAES0611USA06372	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a nurse concerning a female patient (age not reported) with a nerve compression (NOS) who on an unknown date in October 2006, was vaccinated intramuscularly in the left deltoid with the second dose of HPV Vaccine (date of first dose and Lot # were not provided). On an unknown date in Oct 2006, the patient experienced numbness in her left arm. The patient was referred to a neurologist, because of her history of pinched nerve. At the time of this report it was unknown if the patient had recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** Nerve compression.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269221-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Nov-2006	08-Nov-2006	0	18-Dec-2006	10-Jan-2007	AZ	WAES0611USA06802	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Dizziness, Syncope

**Symptom Text:** Information has been received from a health professional concerning a female patient with an allergy to amoxicillin and clavulanate potassium who on 08 Nov 2006 at 11:00 AM was vaccinated in the right deltoid with the first dose of HPV vaccine. (Lot #654540/0800F) There was no illnesses at the time of vaccination. On 08 Nov 2006, at 1PM, following vaccination, the patient became lightheaded. Then while walking out of the office, the patient had a syncopal episode. It was reported that there was no detectable seizure activity and the patient was not post ictal. The patient's blood pressure was low, however not documented. The patient subsequently recovered with elevation of her feet and after five minutes, the patient was sent home. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Blood pressure 11/08/06 low.

**History:** Allergic reaction to antibiotics.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269222-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	PA	WAES0611USA07057	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site oedema

**Symptom Text:** Information has been received from a nurse concerning a female who was vaccinated with a first dose of HPV vaccine. It was reported that immediately upon administration of the vaccine, the patient developed excessive swelling near the injection site. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269223-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	--	WAES0611USA07064	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Breast pain

**Symptom Text:** Information has been received from a female health professional who was vaccinated with HPV vaccine 0.5ml. Subsequently the patient experienced extremely sore nipples that lasted 4 days. The patient recovered from extremely sore nipples. The health professional plans on receiving the next two vaccine injections. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269224-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	27-Nov-2006	28-Nov-2006	1	18-Dec-2006	10-Jan-2007	--	WAES0611USA07269	10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Erythema, Hypoaesthesia, Injection site erythema, Injection site oedema, Oedema, Pain

**Symptom Text:** Information has been received from a nurse practitioner concerning an 18 year old female with a history of drug reaction/allergy to VICODIN who on 27 Nov 2006 was vaccinated with first dose of HPV vaccine injection into left arm. Concomitant therapy included influenza virus vaccine (unspecified) injection also administered the same day on 27 Nov 2006 into her left arm, YASMIN, Minocycline. On 28 Nov 2006, the patient experienced tingling, swelling, and redness in her left arm and hand. She also experienced swelling and redness in her right hand thumb, and some soreness in her chest and upper body area. The patient sought medical attention. No diagnostic tests were performed. Additional information was obtained from the nurse practitioner via phone call. The patient was vaccinated with HPV vaccine and a flu vaccine on 27 Nov 2006 in her left arm by her primary care physician. The patient was seen in her clinic less than 24 hours later experiencing swelling and numbness of fingers, and chest wall discomfort. The patient was seen for follow upon 29 Nov 2006 and all symptoms had resolved. Additional information has been requested.

**Other Meds:** YASMIN, Minocycline

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269225-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Nov-2006	22-Nov-2006	0	18-Dec-2006	10-Jan-2007	OH	WAES0611USA07277	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female with on approximately 22 Nov 2006 was vaccinated with a 0.5ml dose of HPV vaccine. On 22 Nov 2006 the patient fainted. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269226-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Nov-2006	15-Nov-2006	7	18-Dec-2006	10-Jan-2007	--	WAES0611USA07365	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Acne

**Symptom Text:** Information has been received from a nurse practitioner concerning an 18 year old female who on 08 Nov 2006 was vaccinated with a 0.5ml dose of HPV vaccine. Within one week the patient developed facial acne. Unspecified medical attention was sought. At the time of this report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269227-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	--	WAES0611USA07417	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Malaise

**Symptom Text:** Information has been received from the mother of a 21 year old female with penicillin allergy who in 2006 was vaccinated with HPV vaccine. There was no concomitant medication. The patient's mother stated that following vaccination, her daughter was sick. Unspecified medical attention was sought. At the time of this report, the patient was recovering. No further information is expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269228-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Nov-2006	28-Nov-2006	27	18-Dec-2006	10-Jan-2007	NY	WAES0611USA07426	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Skin papilloma, Viral infection

**Symptom Text:** Information has been received from a nurse practitioner concerning a 16 year old female with vaginal papilloma who in approximately November 2006, was vaccinated with HPV vaccine. Concomitant therapy included trichloroacetic acid. The nurse practitioner reported that the patient was treated with trichloroacetic acid (strength unspecified) for existing vaginal warts one week after vaccination with HPV vaccine (the warts were existing prior to the vaccination with HPV Vaccine). Three weeks after the trichloroacetic acid treatment, on 28 Nov 2006, the warts appeared raised and very red, which was much different than normal treatment with trichloroacetic acid. Unspecified medical attention was sought. At the time of this report, the patient had not yet recovered. Additional information has been requested.

**Other Meds:** Trichloroacetic acid

**Lab Data:** NONE

**History:** Vaginal papilloma.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269229-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		18-Dec-2006	10-Jan-2007	--	WAES0611USA07504	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a nurse practitioner concerning a patient who was vaccinated with a dose of HPV vaccine. Concomitant therapy included birth control pills. Subsequently, the patient experienced a full body rash. At the time of this report, the patient's outcome was unknown. The reporter felt that full body rash was not related to therapy with HPV vaccine. Additional information has been requested.

**Other Meds:** Hormonal contraceptives.

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269230-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	16-Nov-2006	26-Nov-2006	10	18-Dec-2006	10-Jan-2007	--	WARES0611USA07518	10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 16 year old female with a penicillin allergy who on 16 Nov 2006 was vaccinated with a first 0.5ml dose of HPV vaccine. Concomitant therapy included LOESTRIM. On 26 Nov 2006 the patient broke out into hives. The patient was treated with a steroid and was doing fine. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Loestrin

**Lab Data:** UNK

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269231-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Sep-2006	21-Nov-2006	81	18-Dec-2006	10-Jan-2007	MO	WAES0611USA07529	10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Face oedema

**Symptom Text:** Information has been received from a nurse in a physician's office concerning a 17 year old female who in approximately September 2006, was vaccinated with the second 0.56ml dose of HPV vaccine. On 21 Nov 2006, the patient developed swelling of lips and swelling of face. The patient sought unspecified medical attention. On 22 Nov 2006 within 24 hours, the patient had recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269232-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	01-Nov-2006	01-Nov-2006	0	18-Dec-2006	10-Jan-2007	--	WAES0611USA07572	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female patient in her 20's who in November 2006, was vaccinated with a dose of HPV vaccine. Immediately after administration, the patient passed out. Medical attention was sought. Subsequently, the patient recovered. The physician explained that another physician from a different office administered the vaccination to the patient. Additional information has been requested. There was no product quality complaint involved.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269233-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	OH	WAES0611USA07579	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** information has been received from a health professional concerning a female patient who was vaccinated with a first dose of HPV Vaccine. Subsequently as the patient was leaving the examination room, the patient fainted. Unspecified medical attention was sought. The patient recovered shortly after fainting. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269234-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	11-Sep-2006	Unknown		18-Dec-2006	10-Jan-2007	--	WAES0611USA07581	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>		<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.		0702F		Unknown		Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rhinorrhoea

**Symptom Text:** Information has been received from a physician's assistant concerning a 38 year old female with seasonal allergy and no pertinent medical history who on 11 Sep 2006 was vaccinated intramuscularly with a 0.5ml dose of HPV vaccine (lot #653650/0702F). Concomitant therapy included COMBIVENT and CLARITIN D. The patient reported that within days after 11 Sep 2006, she had to use her inhaler on and off since then. The patient called the physician's office and reported a runny nose and stuffiness since the vaccination with symptoms that continued. The patient took allergy medicine and inhaler without relief. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered.

**Other Meds:** COMBIVENT, CLARITIN D

**Lab Data:** NONE

**History:** Seasonal allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269235-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	28-Nov-2006	28-Nov-2006	0	18-Dec-2006	10-Jan-2007	CA	WAES0612USA00007	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, High-pitched crying, Malaise, Nausea

**Symptom Text:** Information has been received from a nurse concerning a female co worker (age not reported) who on 28 Nov 2006 was vaccinated intramuscularly in the deltoid with the first single dose vial of HPV vaccine. The nurse reported that the patient had an experience during and immediately after being vaccinated. The nurse reported that when the patient was given the shot, she started screaming almost immediately and reported that she did not feel well. The nurse also reported that the patient felt like she was going to pass out and was feeling nauseated. The patient was sent home from work and was now out a second day from work. The patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown as the patient had not returned to work. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269236-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0612USA00214	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a female patient who was vaccinated with a 0.5ml dose of HPV vaccine. Subsequently, the patient fainted. Unspecified medical attention was sought. A short time after vaccination, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269237-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0612USA00215	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a female patient who was vaccinated with a 0.5ml dose of HPV vaccine. Subsequently, the patient fainted. Unspecified medical attention was sought. A short time after vaccination, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269238-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0612USA00216	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a female patient who was vaccinated with a 0.5 ml dose of HPV vaccine. Subsequently the patient fainted. Unspecified medical attention was sought. a short time after vaccination, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269239-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0612USA00217	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a female patient who was vaccinated with a 0.5 ml dos of HPV vaccine. Subsequently, the patient fainted. Unspecified medical attention was sought. A short time after vaccination, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269240-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	16-Nov-2006	18-Nov-2006	2	18-Dec-2006	10-Jan-2007	MI	WAES0612USA00232	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash

**Symptom Text:** Information has been received from a physician concerning a female patient who on approximately 16 Nov 2006 was vaccinated with a 0.5ml IM dose of HPV vaccine. Two days later dosage, on approximately 18 Nov 2006 the patient developed a rash at injection site. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269241-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00272	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with a 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269242-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00273	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269243-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00274	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with a 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 427

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269244-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00275	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with a 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269245-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00276	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269246-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00277	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified ) was vaccinated IM with a 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging" at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269247-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	NY	WAES0612USA00278	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a female who "between the beginning of the September and now" (date not specified) was vaccinated IM with 0.5 ml dose of Gardasil vaccine (yeast). Subsequently on an unspecified date, the patient experienced a "definite stinging " at the injection site. Unspecified medical attention was sought. At the time of this report, the patients outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269248-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	22-Nov-2006	24-Nov-2006	2	18-Dec-2006	10-Jan-2007	--	WAES0612USA00308	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Decreased appetite, Medication error, Nausea

**Symptom Text:** Information has been received from a 19 year old female with a history of papilloma viral infection and no known allergies or adverse drug reactions reported. On 22 Nov 2006, the patient was vaccinated with Gardasil vaccine (yeast). There were no concomitant medications reported. On 24 Nov 2006, the patient reported "feeling sick to her stomach, developed nausea and had trouble eating starting two days after receiving Gardasil vaccine (yeast) and the experience had lasted until now". The patient reported that there was a "possibility she could be pregnant", but would not know until 05 Dec 2006. At the time of this report, the patient had not recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Papilloma viral infection

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269249-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	03-Nov-2006	29-Nov-2006	26	18-Dec-2006	10-Jan-2007	MI	WAES0612USA00311	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Discomfort, Lymphadenopathy, Malaise, Pyrexia

**Symptom Text:** Information has been received from a registered nurse concerning a 24 year old female with a penicillin allergy and had no other pertinent medical history reported. On 03 Nov 2006, the patient was vaccinated intramuscularly in the right deltoid with a 0.5 mL of Gardasil vaccine (yeast) (Lot # 653736/0868F). There were no concomitant medications reported. On 29 Nov 2006, the patient was examined by the physician and was complaining of swelling of the right cervical lymph node and low grade fever. The physician ordered a complete blood count (CBC), which was normal. On 30 Nov 2006, the patient was re-examined and the right cervical lymph node had increased in size and the patient had developed swelling of the right axillary lymph nodes, peri-sternal discomfort and extreme malaise. The physician ordered a throat culture and results were pending. The patient was being referred to her internist for follow up. Unspecified medical attention was sought. At the time of this report, the patient had not recovered from the events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** complete blood cell "normal"; throat culture "results pending"

**History:** penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269250-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	29-Nov-2006	29-Nov-2006	0	18-Dec-2006	10-Jan-2007	FL	WAES0612USA00328	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Injection site anaesthesia

**Symptom Text:** Information has been received from a nurse practitioner concerning a 23 year old female who on 29 Nov 2006 was vaccinated intramuscularly in the right deltoid with the first dose of Gardasil vaccine (yeast) (lot#654389/0961F). Concomitant therapy included fluconazole which was started on 29 Nov 2006 for a pre-existing infection. On 29 Nov 2006 the patient experienced chest pains described as subclavian and numbing at the injection site. Unspecified medical attention was sought. Subsequently, the patient recovered from the subclavian chest pains and numbing at the injection site on 30 Nov 2006. Additional information has been requested.

**Other Meds:** fluconazole

**Lab Data:** NONE

**History:** UNK

**Prex Illness:** infection

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269251-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	CA	WAES0612USA00342	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Vision blurred

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with Gardasil vaccine (yeast). Subsequently the patient experienced dizziness and blurry vision "a short time after her vaccination". Unspecified medical attention was sought. At the time of this report, the outcome of the events was unknown. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269252-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Nov-2006	23-Nov-2006	1	18-Dec-2006	10-Jan-2007	FL	WAES0612USA00352	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a physician concerning an approximately 19 year old female who on 22 Nov 2006 was vaccinated with a 0.5 ml dose of Gardasil vaccine (yeast). On 23 Nov 2006, the patient experienced a sore arm for 2 days. It was noted that it started to get better however on 27 Nov 2006 the pain at the injection site returned with radiating pain to the shoulder and shoulder blade. There was no redness or swelling at the site. The patient stated that "it felt like a heavy weight is on my arm." Unspecified medical attention was sought. The patient's pain at the injection site with radiating pain to the shoulder and shoulder blade persisted. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269253-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	24-Nov-2006	Unknown		18-Dec-2006	10-Jan-2007	--	WAES0612USA00385	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Contusion, Pyrexia

**Symptom Text:** Information has been received from a female consumer who on 24 Nov 2006 "one week ago" was vaccinated with a dose of Gardasil vaccine (yeast). Subsequently the patient experienced bruising at injection site and a low grade fever. No medical attention was sought. No diagnostic laboratory studies were performed. The patient's bruising at injection site and low grade fever persisted. No product quality complaint was involved. Additional information is expected.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269254-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	PA	WAES0612USA00389	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Information has been received from a nurse practitioner concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil vaccine (yeast). Subsequently, the patient developed "total body itching" (date unknown). At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269255-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	MO	WAES0612USA00393	10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia

**Symptom Text:** Information has been received from a nurse in a physician's office concerning a 15 year old female who in approximately September 2006, was vaccinated with the second 0.5 mL dose of Gardasil vaccine (yeast). On an unspecified date, the patient developed joint pain. Within 24 hours, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269256-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	TN	WAES0612USA00967	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female (NOS) who was vaccinated on an unknown date intramuscularly with Gardasil vaccine (yeast) (Lot# not provided). Subsequently the patient fainted. Subsequently, the patient recovered from the syncope. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269257-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	TN	WAES0612USA00968	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female (NOS) who was vaccinated on an unknown date intramuscularly with Gardasil vaccine (yeast) (Lot# not provided). Subsequently the patient fainted. Subsequently, the patient recovered from the syncope. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269258-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	OH	WAES0612USA00978	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a health professional concerning a female patient who was vaccinated with a first dose of Gardasil vaccine (yeast). Subsequently as the patient was leaving the examination room, the patient fainted. Unspecified medical attention was sought. The patient recovered shortly after fainting. No product quality was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269259-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	OH	WAES0612USA00979	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a health professional concerning a female patient who was vaccinated with a first dose of Gardasil vaccine (yeast). Subsequently as the patient was leaving the examination room, the patient fainted. Unspecified medical attention was sought. The patient recovered shortly after fainting. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269260-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	OH	WAES0612USA00980	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a health professional concerning a female patient who was vaccinated with a first dose of Gardasil vaccine (yeast). Subsequently as the patient was leaving the examination room, the patient fainted. Unspecified medical attention was sought. The patient recovered shortly after fainting. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269261-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	AZ	WAES0612USA00986	16-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Syncope

**Symptom Text:** Information has been received from a physician concerning an adolescent female (NOS0 who on an unspecified date was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently, shortly after receiving the vaccination the patient fainted. Subsequently, the patient recovered from the syncope. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269262-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		18-Dec-2006	10-Jan-2007	AZ	WAES0612USA00987	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning an adolescent female (NOS0 who on an unspecified date was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently, shortly after receiving the vaccination the patient fainted. Subsequently, the patient recovered from the syncope. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269263-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Nov-2006	08-Nov-2006	0	18-Dec-2006	10-Jan-2007	NY	WAES0612USA01084	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hyperhidrosis, Nausea

**Symptom Text:** Information has been received from a Nurse Practitioner concerning a female patient who on 08-Nov-2006 was vaccinated IM with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, she experienced nausea, light-headed feeling, dizziness, sweating, but did not lose consciousness. No medical attention was sought. The nurse practitioner indicated the patient recovered after 20 minutes. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269264-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	10-Aug-2006	10-Aug-2006	0	18-Dec-2006	10-Jan-2007	WY	WAES0612USA01119	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Influenza like illness

**Symptom Text:** Initial and follow up information has been received from a Registered Nurse concerning a white female patient who on the morning of 10-Aug-2006 was vaccinated IM with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), lot #653650/0702F, and experienced flu-like symptoms. Concomitant medication included doxycycline. No medical attention was sought. Within a day or two, the patient recovered. Additional information has been requested.

**Other Meds:** doxycycline

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269265-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Sep-2006	08-Sep-2006	0	18-Dec-2006	10-Jan-2007	WY	WAES0612USA01120	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Influenza like illness

**Symptom Text:** Initial and follow up information has been received from a Registered Nurse concerning a female who on the afternoon of 08-Sep-2006 was vaccinated IM with her first dose of HPV vaccine (yeast), lot #653650/0702F, and experienced flu-like symptoms. No medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269331-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Dec-2006	20-Dec-2006	FR	WAES0612CAN00035	20-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Epilepsy

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with HPV vaccine. Subsequently, 5 days after booth dose 1 and dose 2 of HPV vaccine, the patient experienced epileptic seizure. Subsequently, the patient recovered from epileptic seizure. Upon internal review, epileptic seizure was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269332-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Nov-2006	29-Nov-2006	0	19-Dec-2006	20-Dec-2006	FR	WAES0612USA00515	20-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0902F		Unknown	Unknown	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	ABVB221B		Unknown	Unknown	

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Agitation, Crying, Dyspnoea, Tongue oedema

**Symptom Text:** Information has been received from a healthcare professional concerning a 16 year old female patient who on 29 Nov 2006 was vaccinated in the left arm with a dose of HPV vaccine, lot 654884/0902F, batch NE24240. Concomitant suspect therapy included hepatitis B vaccine, Engerix B, batch ABVB221BA, given the same day in the opposite arm. Thirty minutes after administration, while being driven home from the clinic, the patient developed a swollen tongue, difficulty breathing, was panicking and crying. She was treated with Piriton and recovered the same day. The events were considered to be other important medical events as the patient had difficulty breathing (OMIC). Additional information has been requested. Other business partner numbers included E20060652.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269346-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	22-Nov-2006	26-Nov-2006	4	19-Dec-2006	29-Dec-2006	CA		29-Dec-2006

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Itching of entire body 4-5 days after vaccination on 11/22/06. Has continued on and off since then.

**Other Meds:** NONE

**Lab Data:**

**History:** Allergies-Anox, penicillin

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269412-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	19-Dec-2006	19-Dec-2006	0	19-Dec-2006	20-Dec-2006	FL		27-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1065F	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B012AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Syncope

**Symptom Text:** Patient felt dizzy after dTaP, Varicella, and HPV administration. She had a syncopal episode lasting seconds, immediately recovered with stable vital signs. To note patient has a past medical history significant for syncope and did not take her atenolo that morning. She was sent to the ER for fluids and further monitoring.

**Other Meds:** atenolol - but not taken today

**Lab Data:** Bp 117/68 HR 85 after incident

**History:** anxiety syncope

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269481-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	21-Dec-2006	21-Dec-2006	0	21-Dec-2006	04-Jan-2007	CA		05-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives after given HPV.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269633-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	14-Sep-2006	01-Nov-2006	48	27-Dec-2006	28-Dec-2006	--	WAES0612USA01371	28-Dec-2006
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0800F		Unknown	Intramuscular			

**Seriousness:** OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dry eye, Visual disturbance

**Symptom Text:** Information has been received from a medical assistant concerning an 18 year old female with a history of dysfunctional uterine bleeding (DUB) and anaemia who on 14 Sep 2006 was vaccinated with HPV vaccine (lot 0800F, batch 654540), 0.5 ml, IM, once. Concomitant therapy included Yasmin. In approximately November 2006 (last couple weeks), the patient experienced extreme eye dryness after receiving HPV vaccine. The patient's eye was so dry that she had a hard time seeing. On an unspecified date, the patient sought unspecified medical attention. Eventually, the patient had a duct implant put in her eyes by a specialist to help with the dryness. The patient was recovering from the event of extreme eye dryness. Extreme eye dryness was considered to be disabling and an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Yasmin

**Lab Data:**

**History:** Dysfunctional uterine bleeding, Anemia.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269646-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	03-Oct-2006	03-Oct-2006	0	27-Dec-2006	28-Dec-2006	--	WAES0612USA02735	06-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Injection site reaction, Pain, Skin disorder, Urticaria, Vaccine positive rechallenge

**Symptom Text:** Information has been received from a female physician assistant (age not reported) who on 03 Oct 2006 was vaccinated intramuscularly with the first 0.5ml dose of HPV vaccine. Concomitant therapy included an unspecified therapy for asthma. On 03 Oct 2006, immediately after receiving the HPV vaccine, she developed extreme pain on her skin and broke out in hives all over her body. The physician assistant stated that it felt like a cat clawing on her skin. The physician assistant went to the emergency room and was treated with asthma medication but was not admitted. No ER date was provided. On an unspecified date, the patient was recovering from the events. On 05 Dec 2006, the patient was vaccinated with a second dose of HPV vaccine. Subsequently, the patient developed an outbreak of hives in a circle around the site of injection. At the time of this report, the outcome of the event was unknown. The physician assistant considered the events of extreme pain on her skin and broke out in hives all over her body to be other important medical events as the patient was treated with asthma medication in the ER (OMIC). Additional information has been requested.

**Other Meds:** Therapy unspecified

**Lab Data:**

**History:** Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269687-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	11-Dec-2006	11-Dec-2006	0	27-Dec-2006	02-Jan-2007	MO		02-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Right leg	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea, Tremor

**Symptom Text:** 2:30 gave injection. 2:40 Patient complained of being dizzy and nauseous. Laid patient down with wet cloth on head, gave water. 2:50 took blood pressure 100/52. Patient complains of shakiness. 3:05 No better took to urgent care.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269692-1      **Related reports:** 269692-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	22-Nov-2006	22-Nov-2006	0	27-Dec-2006	02-Jan-2007	FL		02-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abasia, Chills, Pain, Rash, Rash macular, Swelling

**Symptom Text:** The patient presented to the ER complained of rash, pain, swelling to lower extremities bilaterally. She had developed a maculopapular rash after the vaccination. She was discharged home on Percoat/Prednisone. Chills and unable to walk.

**Other Meds:** NONE

**Lab Data:** complete blood count, PT/PTT

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269692-2 (S) **Related reports:** 269692-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	22-Nov-2006	22-Nov-2006	0	22-Jan-2007	26-Jan-2007	FL	WAES0701USA00006	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Abasia, Chills, Lymphocyte count abnormal, Pain in extremity, Platelet count normal, Rash maculo-papular, Swelling, White blood cell count increased

**Symptom Text:** Information has been received from a nurse concerning an 18 year old female non-smoker who abstains from alcohol and has no known drug allergies. On 22-Nov-2006, the patient was vaccinated with the first dose of Gardasil vaccine (yeast) (lot number 653937/0637F). On 22-Nov-2006 (also reported as 26-Nov-2006) the patient experienced maculopapular rash to bilateral lower extremities which started on her thighs and moved down to her feet, swelling to bilateral lower extremities with the right leg larger than the left, deep pain of bilateral lower extremity leg muscles particularly below the knee, and chills. The patient was seen in the Emergency Department on 27-Nov-2006. White blood cell count was 14.1 thou/cc/mm (range 4.0-10.0), platelet count was 361 thou/cc/mm (range 150-450), and lymphocyte count was 12.3% (range 20.0-45.0). The deep pain of bilateral lower extremity leg muscles particularly below the knee was so severe the patient could not walk, and it was considered an "emergency medical condition due to the impairment of bodily function". The patient was discharged to home on Percocet and Prednisone. Subsequently the patient recovered from maculopapular rash to bilateral lower extremities, swelling to bilateral lower extremities, deep pain of bilateral lower extremity leg muscles and chills. Deep pain of bilateral leg muscles particularly below the knee of bilateral lower extremities was considered to be disabling. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** platelet count 11/27/06 361 thou 150-450 lymphoblast count 11/27/06 12.3% 20.0-45.0 WBC count 11/27/06 14.1 thou 4.0-10.0

**History:** Non-smoker, abstains from alcohol

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269696-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Dec-2006	21-Dec-2006	0	27-Dec-2006	02-Jan-2007	NY		02-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema

**Symptom Text:** Immediate after Gardasil given pt developed 4cm bright red area at injection site.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269716-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	14-Dec-2006	14-Dec-2006	0	27-Dec-2006	02-Jan-2007	WA		02-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Dyspnoea, Flushing, Nausea

**Symptom Text:** 1 hour after receiving HPV vaccine became dizzy, skin sensation of burning and flushing all over. Nausea with SOB with talking. Generalized weakness.

**Other Meds:**

**Lab Data:** NONE- given Benadryl

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269778-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	11-Dec-2006	20-Dec-2006	9	28-Dec-2006	03-Jan-2007	CA		03-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pregnancy test false positive

**Symptom Text:** Patient pregnancy unbeknownst to provider when vaccine administered. Patient didn't divulge pregnancy test at home. Was positive one month prior.

**Other Meds:** NONE

**Lab Data:** urine pregnancy test in office (12-20-06) positive

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269784-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.2	F	12-Dec-2006	13-Dec-2006	1	28-Dec-2006	03-Jan-2007	FL		03-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Patient developed hives starting at injection site and spreading over entire body. + itching. No respiratory symptoms. Patient used Benadryl without relief and was referred to her PCP for follow up.

**Other Meds:** Yasmin

**Lab Data:**

**History:** Loestrin, Suprax, Pediazol.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269820-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	27-Dec-2006	28-Dec-2006	1	28-Dec-2006	28-Dec-2006	SC		29-Dec-2006

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Syncope

**Symptom Text:** Patient fainted after receiving her second dose of Gardasil Vaccine. Patient c/o headache and pain in back of her head. Returned to office 12/28/06 for exam. Still c/o head pain. To call office prn with followup.

**Other Meds:** none

**Lab Data:**

**History:** Allergy Amoxicillin

**Prex Illness:** none known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269851-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	15-Oct-2006	10-Nov-2006	26	29-Dec-2006	02-Jan-2007	FR	WAES0612USA03500	02-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Headache, Venous thrombosis, Visual disturbance

**Symptom Text:** Information has been received from a physician concerning his daughter a 22 year old female who on approximately 15 Oct 2006 (mid October 2006) was vaccinated with first dose of HPV vaccine (lot # not reported) intramuscularly into the upper arm. ON approximately 22 Oct 2006 (one week later, end of October 2006) she received a dose of influenza vaccine (manufacturer and lot no unknown). On 10 Nov 2006, the patient developed headache and vision disorder (unspecified). On 20 Nov 2006, a magnetic resonance Imaging (MRI) was performed and thrombosis of the venous sinuses was diagnoses. She was treated with Heparin. To be noted, she was not hospitalized. She recovered within an unspecified time. The reporter considered the event to be serious (other important medical event) (OMIC). Other business partner numbers included E200606931. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** Magnetic resonance imaging 20Nov06 thrombosis of the venous sinuses.

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269916-1      **Related reports:** 269916-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
31.0	F	18-Dec-2006	18-Dec-2006	0	02-Jan-2007	05-Jan-2007	NY		05-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1161F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Pt called 12/20/06 and reported that on the evening of 12/18/06 she developed generalized itching and hives, no other symptoms. She was instructed to take 25mg Benadryl Q 6H when needed. No further vaccinations will be administered per Dr.

**Other Meds:**

**Lab Data:**

**History:** Allergic to depacote, Lortab, nuerontin, valicum,

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269916-2      **Related reports:** 269916-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
31.0	F	18-Dec-2006	18-Dec-2006	0	22-Jan-2007	26-Jan-2007	NY	WAES0701USA00131	29-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1161F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Information has been received from a registered nurse concerning a 31 year old female with drug allergies to Depakote, Lortab, Neurotin, Valium and Fioricet. On 18-Dec-2006 (also reported as 18-Dec-1976) the patient was vaccinated with her first dose of Gardasil vaccine (yeast) (lot number 654540/1161F), intramuscularly in the left deltoid. On 18-Dec-2006 in the evening, the patient experienced generalized itching, and hives. The patient was instructed to take Benadryl 25 mg every 6-8 hours until the itching subsided. The patient was informed that she will not be receiving the additional 2 vaccinations. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269922-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	13-Nov-2006	13-Nov-2006	0	02-Jan-2007	03-Jan-2007	VA	WAES0612USA02987	03-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Dizziness, Fracture, Injury, Nausea, Syncope

**Symptom Text:** Information has been received from a 21 year old female with no pertinent medical history or drug reactions/allergies, who on 13 Nov 2006 was vaccinated intramuscularly with HPV Vaccine. Concomitant therapy included Zyrtec and Yasmin. On 13 Nov 2006, following vaccination, the patient felt nauseous and dizzy. As she went out of the room to check out, the patient fainted and broke her nose and got a cut under eye. The patient reported that she was on the floor for seven to eight minutes before she woke up. The patient reported that she had to get her nose fixed and received some stitches afterward. At the time of this report, the patient was recovering. Upon internal review, the facial bones fracture which required surgery was felt to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Zyrtec, Yasmin

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 468

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 269923-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Oct-2006	01-Oct-2006	0	02-Jan-2007	03-Jan-2007	--	WAES0612USA03674	03-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Arthritis, Joint swelling, Myalgia, Urinary tract infection, Viral infection

**Symptom Text:** Information has been received from a physician concerning her 18 year old daughter with a history of HPV and acne who at the beginning of October 2006, was vaccinated with a dose of HPV vaccine. Concomitant therapy included Yasmin and Minocin. One week later, the patient developed a urinary tract infection. Two weeks after vaccination, she had an acute onset of arthritis. She had significant swelling of her finger joints and generalized myalgia. She had blood work to include viral antibody titers which were positive for parvo virus, Epstein Barr and Cytomegalovirus. The patient was treated with steroids and anti inflammatory drugs. At the time of the report she had not recovered. The reporter considered the events to be disabling and other important medical events (OMIC). Additional information has been requested.

**Other Meds:** Yasmin, Minocin.

**Lab Data:** 10/06 viral antibody titer positive for Parvo virus, Epstein Barr virus 10/06 Positive, Cytomegalovirus 10/06 positive.

**History:** Papilloma viral infection, Acne.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270005-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	03-Jan-2007	03-Jan-2007	0	03-Jan-2007	08-Jan-2007	VA		08-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TYP	AVENTIS PASTEUR	Z0664	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB259CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Intramuscular	
	TDAP	AVENTIS PASTEUR	C2491AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Patient became very light headed and dizzy w/in moment of vaccine. Patient was observed and released.

**Other Meds:** Ortha Evra

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270033-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.4	F	28-Dec-2006	28-Dec-2006	0	04-Jan-2007	05-Jan-2007	VA		05-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0637F	0	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Urticaria

**Symptom Text:** 15 minutes after IM injection of Gardasil in right arm. Patient developed hives on her neck right side continued to move up on face. 20 minutes post injection rash and then itching over neck, face and back. Benadryl used IM. Vital signs remained stable.

**Other Meds:** Depo Provera times 2 years

**Lab Data:** NONE

**History:** Latex

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270034-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	28-Dec-2006	28-Dec-2006	0	04-Jan-2007	05-Jan-2007	FL		05-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hot flush, Nausea

**Symptom Text:** Patient complain of nausea, light-headed, hot flashes, right after injection. Told patient to lay down on back on the table, took some water about 25 minutes recheck BP and pulse. Ok to leave.

**Other Meds:** Nuva ring

**Lab Data:**

**History:** Ibuprofen

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270061-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	21-Dec-2006	21-Dec-2006	0	04-Jan-2007	05-Jan-2007	FL	WAES0612USA03857	05-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Blindness transient, Dizziness, Headache, Pallor

**Symptom Text:** information has been received from the mother of a 19 year old female with a drug hypersensitivity to unspecified antibiotics. On 21 Dec 2006, the patient was vaccinated with the first dose of HPV vaccine. There were no concomitant medications reported. On 21 Dec 2006, the patient felt like her head was going to burst, she looked pale and was possibly going to faint. The patient developed temporary blindness that lasted about two minutes. The patient sought unspecified medical attention. On 21 Dec 2006, the patient had recovered from the events, "after a few minutes". Upon internal review, the temporary blindness was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** NONE

**Lab Data:**

**History:** CONCURRENT CONDITIONS: Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270062-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	25-Oct-2006	Unknown		04-Jan-2007	05-Jan-2007	--	WAES0612USA04054	05-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Abortion, Ectopic pregnancy, Laboratory test abnormal

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 25 year old female with no drug reactions/allergies, and unknown date of last menstrual period due to irregular periods and a history of 2 live children (number of pregnancies was not reported) who on 25 Oct 2006 was vaccinated with first dose of HPV vaccine. There was no concomitant medication. The patient sought medical attention. Around 25 Nov 2006, (Thanksgiving time), the patient presented to the office. She had an ectopic pregnancy, went to the emergency room and was administered methotrexate to abort the child. She was monitored for several hours and released. The patient was not hospitalized. It was unk if the patient was pregnant when she was vaccinated with HPV Vaccine due to irregular periods, unknown LMP. At the time of reporting, the patient was recovering, her quantitative HCG was at 85, it should be at 2, but was going downward. The reporter felt that the event required intervention to prevent serious criteria (other important medical event) (OMIC). This report is part of the pregnancy registry. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** Serum alpha human 12/06 85

**History:** Pregnancy; live birth, Pregnancy NOS (LMP unknown), irregular periods.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270063-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	01-Dec-2006	01-Dec-2006	0	04-Jan-2007	08-Jan-2007	NJ		08-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Rash, Upper respiratory tract infection, Urticaria

**Symptom Text:** 12/01/2006 Nausea, headache, urticaria 12/04/2006. URI symptoms developed after rash. Treated with Benadryl, Prednisone, and Zyrtec. Phone call 1 week later, rash completely gone, urticaria due to vaccine VS intercurrent URI.

**Other Meds:** Oral immunotherapy SLIT

**Lab Data:**

**History:** Premature twin, environmental allergies.

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270065-1      **Related reports:** 270065-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	28-Dec-2006	02-Jan-2006	-360	04-Jan-2007	04-Jan-2007	PA		02-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1974AB		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0961F		Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Hypoaesthesia, Muscle rigidity, Neck pain

**Symptom Text:** 17 year old female received Menactra on 12/28/06. On 1/2/06, patient reported pain in neck and head with non-specific bilateral numbness sensation and pain present in lower extremities (thighs, calves, feet (soles)). Bilateral knee and ankle tendon reflexes normal. Also bilateral calf tightness reported.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** UNK

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270065-2 (S) **Related reports:** 270065-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	28-Dec-2006	04-Jan-2007	7	11-Jan-2007	16-Jan-2007	PA	200700033	01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1974AB		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0961F		Right arm	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, OMIC, SERIOUS

**MedDRA PT** Guillain-Barre syndrome, Headache, Hypoaesthesia, Hyporeflexia, Muscular weakness, Neck pain, Pain in extremity

**Symptom Text:** Initial report received on 03 January 2007 from a health care professional. A 17 year old female patient, with unknown past medical history, had received a left deltoid injection of Menactra vaccine, lot number U1974AB, and a right deltoid injection of Gardasil vaccine, lot number 0961F, on 28 December 2006. Five days post-immunization, the patient reported pain in her neck and head, non specific bilateral numbness sensation and pain in her lower extremities (thighs, calves, and feet (soles)), and bilateral knee and ankle tendon reflexes. Additional information was obtained from the treated physician by the manufacturer on 04 January 2007. The treating physician reported the patient's condition had worsened and now had areflexia. Treatments received and diagnostic tests performed were not provided. At the time of this report, the patient had not recovered. This report was referred by the CBC to the Clinical Immunization Safety Assessment network for follow up. The reporter of this case is the same as for non-serious case 2007-00057, involving a tingling sensation in the feet and thighs following the receipt of Menactra and Gardasil. The patient in case 2007-00057 is the sister of the patient reported in case 2007-00033. (OMIC) 02/01/07-records received and reviewed for DOS 01/04-01/06/07 DC DX:Guillain Barre Syndrome Chief complaint, pain and weakness of lower extremities bilaterally, 8 out of 10 in intensity shooting from below buttock to knew and from heel to toes as well as bilateral calf pain. Paresthesias in her feet bilaterally. Onset was day prior to admission. PE:Neuro:strength 5/5 in all 4 extremities, sensation intact coordination intact, bilateral toes downgoing, gait steady, Romberg negative. RX with neurotin and IVIG.

**Other Meds:**

**Lab Data:** Labs: WBC 7.3, CPK 67, myoglobin 9, CRP <0.5. ESR 9 LP:glucose 55, protein 22 RBC 0, WBC 0 Lyme antibodies negative, EBV antibodies negative, CMV negative, C.jejuni negative, mycoplasma pneumonia IgM reactive.

**History:** PMH:GERD. Allergies:Penicillin

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270086-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	03-Jan-2007	03-Jan-2007	0	04-Jan-2007	08-Jan-2007	CA		07-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2638AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site oedema, Injection site warmth

**Symptom Text:** Warm to touch with slight elevation at injection site to LT deltoid.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270093-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		05-Jan-2007	08-Jan-2007	NY		08-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1208F	0	Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling hot, Syncope

**Symptom Text:** 10 minutes after receiving Gardasil #1-patient became dizzy,hot, blacked out. Patient recovered completely after 20 minutes.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270112-1      **Related reports:** 270112-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Dec-2006	27-Dec-2006	1	05-Jan-2007	08-Jan-2007	CA		08-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Eye oedema, Oedema peripheral, Pain, Pruritus, Rash

**Symptom Text:** Pt given vaccine on 12/26. Began to experience generalized pruritis and mild rash on 12/17. By 12/28 had severe urticarial rash requiring oral steroids. Rash did not improved with steroids and antihistamines, and pt developed edema of hands, feet and eyes and some respiratory symptoms on 12/31. Given IV decadron with relief by an outside provider. Symptoms improving but persistent mild rash at time of my recent re-evaluation on 1/2/07. Her hands remain sore.

**Other Meds:** Adderall, Zoloft, Yasmin, Procardia

**Lab Data:** Elevated WBC likely due to steroids.

**History:** Attention deficit disorder, depression, allergy to pediazole

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270112-2      **Related reports:** 270112-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Dec-2006	27-Dec-2006	1	09-Apr-2007	01-May-2007	CA	WAES0703USA00135	01-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653735/0688F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye oedema, Oedema peripheral, Rash, Respiratory disorder, Urticaria

**Symptom Text:** Information has been received from a physician concerning an 18 year old white female with an allergy to erythromycin ethylsuccinate (+) sulfisoxazole acetyl (Pediazole) who on 26, Dec 2006 was vaccinated intramuscularly with HPV rL1 6 11 16 18 VLP vaccine (yeast) lot # 653735/0688F). The patient had no illnesses at the time of vaccination. On 27, Dec 2006 rash. By 28, Dec 2006, the patient developed severe urticarial rash requiring oral steroids and antihistamines. By 31-Dec 2006 the patient developed edema of hands, feet, and eyes and respiratory symptoms. The patient was seen in the emergency room. Treatment included intravenous dexamethasone (Decadron) with relief. Subsequently, the patient recovered. Additional information has been requested

**Other Meds:** unknown

**Lab Data:** neutrophil count, 01/02/07, 0.7 K/cum 1.5 - 8.5 platelet counts 01/02/07, 437.0 K/cum 130,000- WBC count , 01/02/07, 13.9 K/cum. 4.5 - 12.5

**History:** Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270141-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	03-Jan-2007	03-Jan-2007	0	08-Jan-2007	10-Jan-2007	PA		10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Patient passed out/fainted within 5 minutes of HPV Gardasil injection. She came to with smelling salts then fainted again. Ambulance called, transported patient to local hospital.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** History of Turners Syndrome.

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270145-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	20-Nov-2006	22-Nov-2006	2	08-Jan-2007	15-Jan-2007	NY	2006034630	15-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2159A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	FLU	AVENTIS PASTEUR	U2240A	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Flushing, Pruritus

**Symptom Text:** Initial report received from a health care professional in the USA on 12 December 2006. A 18 year old, female patient (with a medical history of no known allergies) developed a flushed, red and itchy face, 2 days after she received Fluzone (lot number U2240AA) intramuscularly in the left deltoid, Menactra (lot number U2159AA) intramuscularly in the right deltoid and Gardasil (lot number unknown) on 20 November 2006. On 24 November 2006, the patient called to reports red spots on hands. The patient did not have any illness at the time of the vaccination. She was treated with Benadryl. She was not seen at the doctor's office and has moved. It was reported that she recovered.

**Other Meds:** Nevacor, Birth control pills, Celexa, Clontin

**Lab Data:**

**History:** No known allergies

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270235-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	03-Jan-2007	03-Jan-2007	0	09-Jan-2007	11-Jan-2007	WI		11-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2108AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0961F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Dizziness, Hyperhidrosis, Nausea, Pallor

**Symptom Text:** Patient received vaccines, then felt nauseous, dizzy, was pale and diaphoretic, BP decreased to 80/50, pt placed supine with feet elevated, given Benadryl 20 mg PO, sips water, felt better after about 1 hour.

**Other Meds:** Prozac, Trisprintac

**Lab Data:** Labs drawn just prior to vaccines (routine).

**History:** Depression

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270237-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	28-Dec-2006	30-Dec-2006	2	09-Jan-2007	10-Jan-2007	MD		24-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B012AA	6	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Feeling hot

**Symptom Text:** Quarter sized area red and hot to touch at injection site of Tdap. Advised to apply cold compress by on call doctor.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270241-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Jan-2007	18-Jan-2007	--	WAES0609USA04678	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0697F		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from a health professional concerning a patient who may have been vaccinated with a dose of with HPV vaccine (yeast) (lot#653650/0697F) in which while preparing the syringe for administration, the safety syringe activated prematurely. It was reported that she may have touched the side of the syringe near the fingers and the activated the safety device. It was also reported that the second syringe scared the patient when it pooped down. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270242-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	09-Jan-2007	18-Jan-2007	IN	WAES0612USA00294	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a female patient (age and demographics not reported) who on 01-Dec-2006 was vaccinated with the first dose of HPV vaccine (yeast) (Lot# not reported). On 01-Dec-2006 immediately after being vaccinated the patient developed widespread hives. No respiratory difficulty was noted. The patient was transported to the emergency room for evaluation and was not admitted to the hospital. At the time of this report the patient had not recovered from the hives. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270243-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	09-Jan-2007	18-Jan-2007	IN	WAES0612USA00383	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pallor, Urticaria

**Symptom Text:** Information has been received from a health professional concerning a female patient who on 01-Dec-2006 was vaccinated IM with a 0.5 ml dose of HPV vaccine (yeast). It was noted that medroxyprogesterone acetate (DEPO-PROVERA) may have been given concomitantly. On 01-Dec-2006 the patient developed hives and turned pale white. She was admitted to the emergency room and there was no further information if she will be admitted. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** DEPO-PROVERA

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270244-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		09-Jan-2007	18-Jan-2007	TX	WAES0612USA00435	18-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who was vaccinated with a 0.5ml dose of HPV vaccine. Subsequently the patient developed a rash 10 minutes after vaccination. The patient was treated with antihistamine. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270245-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
2.0	U	01-Oct-2006	Unknown		09-Jan-2007	18-Jan-2007	--	WAES0612USA00436	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Malaise, Pyrexia, Vomiting

**Symptom Text:** Information has been received from a health professional who was told by her sister in law that in October 2006, a 24 month old patient was vaccinated by mistake with HPV vaccine. It was reported that the patient became very ill and began vomiting and developed a high fever. It was reported that the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270246-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	27-Nov-2006	27-Nov-2006	0	09-Jan-2007	18-Jan-2007	OH	WAES0612USA00441	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Discomfort, Injection site discomfort, Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning her 19 year old daughter with no medical history or drug allergies who on 27 Nov 2006 was vaccinated intramuscularly in the mid top gluteal region with a first dose of HPV Vaccine. There was no concomitant medication. On 27 Nov 2006 the patient mentioned that the site of injection hurt and caused discomfort. The patient was uncomfortable for 24 hours. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270247-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	28-Nov-2006	29-Nov-2006	1	09-Jan-2007	18-Jan-2007	LA	WAES0612USA00464	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0954F	0	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Muscular weakness, Rash

**Symptom Text:** Information has been received from a physician concerning a 19 year old female with a urinary tract infection who on 28 Nov 2006 at 10:15 was vaccainted IM in the left deltoid with the first dose Gardasil (lot#653938/0954F). Concomitant therapy included CIPRO. On 29 Nov 2006 the patient developed a rash on her face and weakness in her legs and arms. Laboratory results completed the same day included complete blood cell count, blood eosinophilic leukocyte count and white blood cell count which were all normal. Subsequently, the patient "slowly" recovered from the rash and weakness in her arms and legs. Additional information has been requested.

**Other Meds:** CIPRO

**Lab Data:** Eosinophil count 11/29/06 complete blood cell 1/29/06, WBC count 11/29/06 all normal.

**History:** Urinary tract infection.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270248-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	01-Dec-2006	01-Dec-2006	0	09-Jan-2007	18-Jan-2007	AZ	WAES0612USA00467	18-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vision blurred

**Symptom Text:** Information has been received from an nurse concerning a 21 year old female with allergic reaction to antibiotics (Septra) who on 01 Dec 2006 was vaccinated intramuscularly in the left deltoid with HPV vaccine. Concomitant therapy included hormonal contraceptives (unspecified). On 01 Dec 2006 about three hours post vaccination the patient developed blurry vision in her left eye. No other symptoms were reported. Unspecified medical attention was sought. At the time of this report the patient had not recovered from the blurry vision. Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:**

**History:** Allergic reaction to antibiotics

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270249-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	29-Nov-2006	30-Nov-2006	1	09-Jan-2007	18-Jan-2007	--	WAES0612USA00474	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0954F	1	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dysgeusia, Headache

**Symptom Text:** Information has been received from a nurse concerning a 17 year old female who on 29 Nov 2006 was vaccinated with the second dose (first dose date not reported) Gardasil (Lot 653938/0954F). Concomitant therapy included Adderall tablets and Zoloft. On 30 Nov 2006 the patient experienced dizziness, a bad taste in her mouth and a headache. It was reported that the patient was able to attend school that day. The patient's dizziness and bad taste and headache persisted. It was noted that the patient did not have adverse events after her first dose of Gardasil. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Adderall Tablets. Zoloft

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270250-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	U	27-Nov-2006	28-Nov-2006	1	09-Jan-2007	18-Jan-2007	FL	WAES0612USA00494	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypersensitivity, Pruritus

**Symptom Text:** Information has been received from a physician concerning a 24 year old patient who on 27 Nov 2006 was vaccinated in the arm with the first dose of HPV Vaccine. There was no concomitant medications. On 28 Nov 2006, it was reported that the patient developed generalized itching throughout her body. The patient called the physician on the following day and reported she was itchy. The physician stated that she believed the patient experienced an allergic reaction and dose not want to give the second and third shot. It was reported that the patient sought unspecified medical attention. It was reported that a couple of days later, the patient had recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270251-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	01-Nov-2006	01-Nov-2006	0	09-Jan-2007	18-Jan-2007	PA	WAES0612USA00495	18-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information has been received from a physician concerning a female in her early 20's who sometime in mid November was vaccinated with her first dose of HPV Vaccine. It was reported that within 24 hours the patient experienced numbness in one of her legs and in her arm. The physician stated the patient still had numbness and that it had been over a week now and it had not subsided. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270252-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Jan-2007	18-Jan-2007	TN	WAES0612USA00605	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pharyngeal oedema

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with a 0.5 ml dose of HPV Vaccine. Subsequently, the patient experienced throat swelling. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 497

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270253-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	25-Sep-2006	26-Sep-2006	1	09-Jan-2007	18-Jan-2007	OH	WAES0612USA00669	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blister, Fluid retention, Injection site erythema, Injection site oedema, Urinary bladder rupture

**Symptom Text:** Information has been received from a nurse concerning a 17 year old female with no medical history or allergies, who on 25 Sept 2006 was vaccinated IM into the left deltoid with a first 0.5ml dose of HPV vaccine (lot 653735/0688F). There was no concomitant medication. Twenty four hours after vaccination, the patient experienced redness and swelling at the injection site and one vesicle was fluid filled and ruptured. Unspecified medical attention was sought. No diagnostic studies were performed. Subsequently, the patient recovered. The nurse stated that the physician will discontinue the therapy and will not be administering any further doses of this vaccine to this patient. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270254-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	04-Dec-2006		09-Jan-2007	22-Jan-2007	--	WAES0612USA00784	22-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Swelling

**Symptom Text:** Information has been received from a medical assistant concerning a female (age not reported) who (approximately one month ago) in approximately November 2006, was vaccinated with Gardasil (yeast). On 04 Dec 2006, the patient just now experienced redness and swelling at what the patient believes is the injection site. The patient had not yet been seen at the office at the time of the reporting. The outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270255-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	03-Nov-2006	03-Nov-2006	0	09-Jan-2007	22-Jan-2007	CA	WAES0612USA00785	22-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Chest pain, Dyspnoea, Hypoaesthesia

**Symptom Text:** Information has been received from a physician concerning an 18 year old female with no pertinent medical history or drug reactions/allergies, who on 03 Nov 2006 was vaccinated with Gardasil (yeast) (0.5 ml). There was no concomitant medication. On 03 Nove 2006 the patient experienced shortness of breath, chest pain, chest tightness and numbness in the arm that lasted approximately 30 minutes. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270256-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	20-Nov-2006	22-Nov-2006	2	09-Jan-2007	22-Jan-2007	NY	WAES0612USA00864	22-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Flushing, Hypersensitivity, Pruritus, Skin burning sensation

**Symptom Text:** Information has been received from a physician concerning a 19 year old female with depression, anxiety and hypercholesterolaemia and no history of drug reactions/allergies, who on 20 Nov 2006 was vaccinated intramuscularly with the first dose of Gardasil (yeast) (0.5 mL) (lot #653938/0954F). Concomitant therapy included Seasonale, Mevacor, Celexa, and Xlonopin. Concomitant vaccinations on 20 Nov 2006 included Menactra and influenza virus vaccine (unspecified). On 22 Nov 2006, the patient developed facial flushing and chin itching and burning. On 23 Nov 2006, the patient developed red spots on both hands and abdomen. On 23 Nov 2006, the patient sought medical attention at an emergency room while out of town. The patient was diagnosed with having an allergic reaction and administered Benadryl. The patient fully recovered on an unspecified date. Additional information has been requested.

**Other Meds:** Celexa, Klonopin, Seasonale, Mevacor

**Lab Data:** NONE

**History:** depression, anxiety, hypercholesterolaemia

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270257-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	16-Aug-2006	16-Aug-2006	0	09-Jan-2007	22-Jan-2007	--	WAES0612USA00928	22-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Initial and follow up information has been received from an RN concerning an 18 year old white female student who on 16 Aug 2006 was vaccinated with her first dose of Gardasil (yeast). It was reported that she experienced pain at injection site several days post injection. On 13 Oct 2006 the patient received her second dose of Gardasil (yeast), IM, lot #653736/0689F. After the injection the patient complained of pain at injection site with radiating pain even at shoulder blade area several days post injection. Medical attention was sought. On 16 Oct 2006 the patient recovered from injection site pain and radiating pain. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270258-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	05-Dec-2006	05-Dec-2006	0	09-Jan-2007	22-Jan-2007	TX	WAES0612USA00948	22-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0637F	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Dizziness, Syncope

**Symptom Text:** Information has been received from an RN concerning an 18 year old female patient with allergies to penicillin and morphine who on an unspecified date was vaccinated with her first dose of Gardasil (yeast). Concomitant therapy included Midrin. The patient was " a little lightheaded" during the first injection. On 05 Dec 2006 the patient was vaccinated with her second dose of Gardasil vaccine (yeast), lot # 653937/0637F. She developed syncope less than 10 minutes after the second injection was given. Her blood pressure dropped and she did not awake for 15 minutes. The patient was sent to the emergency room, and the nurse reported she was not sure if she recovered. Additional information has been requested.

**Other Meds:** Midrin

**Lab Data:** UNK

**History:** penicillin allergy, drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270259-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	21-Nov-2006	05-Dec-2006	14	09-Jan-2007	22-Jan-2007	FL	WAES0612USA00964	22-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0868F	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Information has been received from a Certified Medical Assistant concerning a 22 year old female patient with genital warts and history of abnormal Pap smears who on 21 Nov 2006 was vaccinated IM in the left deltoid with her first dose of Gardasil (yeast), lot #653736/0868F. Concomitant therapy included Ortho Tri-Cyclen Lo. The patient called to report that prior to the vaccination she had 2 undiagnosed "bumps" in the vulva area. Two weeks after the vaccination, on 05 Dec 2006, the patient had an increase in amount of genital warts (3 more "bumps" appeared in the surrounding area). Medical attention was sought. The patient had undergone a Pap smear and cervical biopsy on 21 Nov 2006 (results were not reported). At the time of the report the patient had not recovered. Additional information has been requested.

**Other Meds:** Ortho Tri-Cyclen Lo

**Lab Data:** UNK

**History:** papanicolaou smear abnormal, genital wart

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270260-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Jan-2007	22-Jan-2007	NC	WAES0612USA00981	22-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated IM with a first dose of Gardasil (yeast). Subsequently, the patient developed a few hives in the upper abdominal area. It was noted that the patient plans to continue with the vaccine series by getting the second and third dose as recommended. Unspecified medical attention was sought. On 04 Dec 2006, the patient recovered. No product quality complaint was involved. Additional informatio has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270261-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		09-Jan-2007	22-Jan-2007	--	WAES0612USA00993	22-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash

**Symptom Text:** Information has been received from a nurse practitioner concerning an approximately 22 year old female patient who in 2006 was vaccinated with a first dose of Gardasil (yeast). In 2006, the patient experienced a raised, red, itchy lump at the injection site. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270262-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	01-Nov-2006	23-Nov-2006	22	09-Jan-2007	19-Jan-2007	MS	WAES0612USA01065	22-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy

**Symptom Text:** Information has been received from a physician concerning a 23 year old female who on 01 Nov 2006 was vaccinated with a dose of Gardasil (yeast). On approximately 23 Nov 2006, the patient developed swelling in her lymph node area. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 507

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270263-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	10-Oct-2006	Unknown		09-Jan-2007	19-Jan-2007	GA	WAES0612USA01067	22-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0688F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Alopecia, Attention deficit/hyperactivity disorder, Eating disorder

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 17 year old female with an eating disorder and attention deficit/hyperactivity disorder who on 10 Oct 2006, was vaccinated with a dose of Gardasil. The patient was concomitantly vaccinated with a dose of Menactra. Concomitant therapy included unspecified therapy for ADHD. Subsequently, the patient experienced thinning of hair/alopecia. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** (therapy unspecified)

**Lab Data:** UNK

**History:** eating disorder, attention deficit/hyperactivity disorder

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270264-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	06-Nov-2006	06-Nov-2006	0	09-Jan-2007	18-Jan-2007	TN	WAES0612USA01069	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Pruritus

**Symptom Text:** Information has been received from a physician and a nurse concerning a 25 year old female who on 06 Nov 2006 was vaccinated intramuscularly with the first single dose vial of Gardasil. On 06 Nov 2006, that evening, the patient developed itching all over her body, but no rash was associated with it. The physician and nurse reported that the patient also developed nausea. Unspecified medical attention was sought. The nurse told the patient to try some over the counter Benadryl to treat the itching as was recommended by the physician. There was no lot number provided. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270265-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
9.0	F	03-Nov-2006	Unknown		09-Jan-2007	18-Jan-2007	GA	WAES0612USA01074	08-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Alopecia, Hypotrichosis

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 9 year old female with no pertinent medical history or drug reactions/allergies, who on 05 Sept 2006 and 03 Nov 2006 was vaccinated with the first and second doses of Gardasil (lot 653735/0688F). There was no concomitant medication. Subsequently the patient experienced thinning of hair or alopecia. Unspecified medical attention was sought. At the time of this report the patient had not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270266-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Jan-2007	18-Jan-2007	FL	WAES0612USA01254	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of HPV Vaccine (Lot not provided) Subsequently, the day after she was vaccinated the patient developed a sort of rash all over her body. The physician recommended that the patient treat the rash with Benadryl, which the patient did. subsequently, the rash resolved and no additional treatment was needed. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270267-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	05-Dec-2006	08-Dec-2006	3	09-Jan-2007	18-Jan-2007	--	WAES0612USA01380	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Menstruation irregular

**Symptom Text:** Information has been received from a 25 year old female consumer who on 05 Dec 2006 was vaccinated with HPV vaccine. Concomitant therapy included hormonal contraceptives (unspecified). The consumer stated that her period is normally 7 days long, and it started on 04 Dec 2006. On 08 Dec 2006, her period ended. two days earlier than normal. The consumer did not seek medical attention and stated the adverse experience did not improve. Additional information has been requested.

**Other Meds:** Hormonal contraceptives.

**Lab Data:** NONE

**History:** UNK

**Prex Illness:** UNK

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270268-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Dec-2006	08-Dec-2006	0	09-Jan-2007	18-Jan-2007	PA	WAES0612USA01386	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fear, Pallor, Presyncope

**Symptom Text:** information has been received from a physician concerning a 16 year old female who on 08 Dec 2006 was vaccinated in the arm with a pre filled syringe of HPV Vaccine. There was no concomitant medication. On 08 Dec 2006, immediately following the vaccination, the patient turned white and nearly passed out. The patient was not hospitalized and was not pregnant. Subsequently, the patient fully recovered. The physician felt that the events were not a result of the vaccine, however a result of the patient being afraid of injections. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** Fear

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270269-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Nov-2006	01-Nov-2006	0	09-Jan-2007	18-Jan-2007	AZ	WAES0612USA01528	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Information has been received from a physician concerning an 18 or 19 year old female patient who in approximately Nov 2006, was vaccinated with a dose of HPV vaccine. Concomitant suspect therapy included YAZ, an oral contraceptive, which was started at the same time (dose and duration not reported). Subsequently, the patient developed papillary rash and pruritis on lower extremities after Gardasil injection. Medical attention was sought. It was reported that the rash went away after therapy with YAZ was discontinued. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270270-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	05-Dec-2006	05-Dec-2006	0	09-Jan-2007	18-Jan-2007	TX	WAES0612USA03803	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Syncope

**Symptom Text:** Information has been received from an RN concerning a female patient who on 05 Dec 2006 was vaccinated with her first dose of HPV vaccine. While she was receiving the injection she developed syncope and a drop in blood pressure. The nurse reported that the patient recovered and was sent home after 30 minutes. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270271-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Jan-2007	18-Jan-2007	AZ	WAES012USA03878	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with a dose of HPV Vaccine and developed rash and pruritus. The patient's outcome was unknown. Additional information had been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270291-1      **Related reports:** 270291-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	28-Dec-2006	07-Jan-2007	10	09-Jan-2007	10-Jan-2007	--		10-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1974AB		Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0961F		Right leg	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia

**Symptom Text:** Reporter states 19 year old female received Menactra on 12/28/06. On Jan. 7, 2007, patient reported tingling sensation from feet to thighs. Returned to school. Will be seen by physician.

**Other Meds:** not provided

**Lab Data:**

**History:** not provided

**Prex Illness:** unknown

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270291-2      **Related reports:** 270291-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	28-Dec-2006	07-Jan-2007	10	18-Jan-2007	19-Jan-2007	PA	200700057	19-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1974AB		Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0961F		Right leg	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Guillain-Barre syndrome, Hyporeflexia, Pain, Paraesthesia, Paraesthesia

**Symptom Text:** Seriousness criteria other medically significant. Initial information received on 08 January 2007 from a health care professional. A 19 year old female received a dose of Menactra, lot number U1974AB, administered intramuscularly in the left thigh, and ad dose of Gardasil, lot number 0961F, administered intramuscularly in the right thigh on 28 December 2006, Ten days later, on 07 January 2007, the patient developed a tingling sensation from her feet to her thighs. She was seen by a physician and later returned to college in another state. She will follow up with another physician. Her recovery status was not reported. The reporter of this case is the same as for serious case 2007-00033, which involves events of non specified bilateral numbness sensation in lower extremities, areflexia, pain on loser extremities, head pain, neck pain and calf discomfort. The patient in case 2007-00033 is the sister of the patient described in case 2007-00057. Follow up information received on 11 January 2007 from a health care professional. AS based upon the new information obtained in this follow up, the case has been upgraded to serious. The patient's mother had a history of multiple sclerosis. The patient returned from college on Tuesday 09 January 2007 and was taken to hospital, where she was seen by a neurologist. She had decreased reflexes in her lower extremities, as well as sensitivity pain and tingling. She was not admitted to the hospital. She had a spinal tap and CBC in the emergency room and both were negative. She was discharged from the ER and is scheduled to follow up with a physician on 11 January 2007. She may have an EMG during the follow up appointment. The patient has not received treatment for her symptoms. The reporting physician stated that the patient has a working diagnosis of Guillain Barre syndrome, but this has not been finalized. The patient has not recovered from the events.

**Other Meds:**

**Lab Data:** A spinal tap and CBC were negative.

**History:** Information regarding the patients past medical history or concomitant medication use was not provided. It is unknown whether the patient had any illnesses at the time of vaccination. From follow up information received on 11 January 2007, it as reported that the patient's mother had a history of multiple sclerosis.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270301-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	15-Dec-2006	Unknown		09-Jan-2007	10-Jan-2007	--	WAES0701USA00254	10-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Injection site erythema, Pruritus, Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 19 year old female who on 15 Dec 2006 was vaccinated with her first dose of HPV Vaccine. Subsequently the patient experienced welts on her legs, itching and redness of her injection site arm. The patient was treated with BENADRYL, and she recovered. The patient sought unspecified medical attention. The reporter considered the patient's welts on her legs, itching and redness of her injection site arm to be other important medical events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270302-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	20-Nov-2006	20-Nov-2006	0	09-Jan-2007	10-Jan-2007	NY	WAES0612USA01040	10-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Abortion, Unintended pregnancy

**Symptom Text:** Initial and follow up information has been received from a licensed practical nurse through the manufacturer pregnancy registry concerning a 24 year old female with a history of two miscarriages in the past and not planning on being pregnant, a spontaneous abortion (March 2006) and no known allergies reported. On 20 Nov 2006, the patient was vaccinated intramuscularly in the left deltoid with the first 0.5ml dose of HPV vaccine (lot #653978/0955F). On 20 Nov 2006, the patient had a pelvic ultrasound performed due to pelvic pain. The pelvic ultrasound revealed fluid in pelvis and no intrauterine pregnancy was seen (previously reported as was negative for pregnancy). On an unspecified date, post vaccination, the patient presented to the office stating that she took a urine home pregnancy test and it was positive. On 04 Dec 2006, the patient had blood work drawn which revealed positive for pregnancy. The patient was approximately 6 weeks gestation with last menstrual period noted as approximately 21 Oct 2006. The patient was scheduled for a follow up blood test on 07 Dec 2006 and an ultrasound and blood lab was scheduled on 11 Dec 2006. On 17 Dec 2006 the patient experienced spontaneous abortion. The patient sought unspecified medical attention. At the time of this report, the outcome of the event was unknown. Upon internal review, the spontaneous abortion was considered to be an other important medical event (OMIC).

**Other Meds:** UNK

**Lab Data:** 12/04/06 blood work positive for pregnancy, 11/20/06 negative for pregnancy, 11/20/06 fluid in pelvis no IUP seen, Urine beta human positive.

**History:** Miscarriage, Abortion spontaneous.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270322-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	21-Dec-2006	05-Jan-2007	15	10-Jan-2007	11-Jan-2007	PA		11-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Joint range of motion decreased

**Symptom Text:** 01/05/07 pt called c/p left arm still sore after 2 weeks after receiving vaccine unable to raise arm over head denies redness or swelling.

**Other Meds:** Ortho tricyclen LO

**Lab Data:** Pt seen by doctor on 1/6/07 no swelling or redness good ROM REC NSAIDS and warm compresses. RTO 1-2 weeks

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270352-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	10-Jan-2007	10-Jan-2007	0	10-Jan-2007	11-Jan-2007	KY		11-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Pt has dizziness and then pass out at the office. She was kept for observation her; VS were stable and then discharge home. She still feeling dizziness after later phone call.

**Other Meds:** N/A

**Lab Data:** HPV , Pt with good health.

**History:** NONE

**Prex Illness:** PT HAS FLU LIKE ONE OR 2 WEEKS PREVIOUS IN GOOD HEALTH AT TIME OF VACCINE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270357-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	10-Jan-2007	10-Jan-2007	0	11-Jan-2007	11-Jan-2007	CA		11-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling hot, Hyperhidrosis

**Symptom Text:** Pt c/o being hot and sweaty. Pt laid down on exam bed and given water. Pt stayed in clinic for 30 mins and stated she was feeling fine.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270358-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	09-Jan-2007	09-Jan-2007	0	11-Jan-2007	11-Jan-2007	CT		11-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1213F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT:** Urticaria

**Symptom Text:** Hives

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270362-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	11-Oct-2006	01-Nov-2006	21	11-Jan-2007	12-Jan-2007	--	WAES0701USA00486	12-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, OMIC, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Decreased appetite, Dehydration, Diarrhoea, Gastrointestinal disorder, Lymphadenopathy, Vomiting, Weight decreased

**Symptom Text:** Information has been received from a nurse practitioner concerning an 18 year old female with no pertinent medical history and no drug reactions or allergies who on 11 Oct 2006 was vaccinated with the first, 0.5 ml dose of HPV vaccine. Concomitant therapy included YAZ. On 11 Dec 2006, the patient received the second, 0.5ml dose of HPV vaccine (lot 653650/0696F). About three weeks after the first dose, approximately 01 Nov 2006, the patient experienced Gastrointestinal problems including, diarrhea, vomiting and decreased appetite. The patient had a swollen right intraglandular lymph node. The patient had lost 12 pounds since the start of her symptoms. The patient was hospitalized overnight and treated for dehydration with intravenous fluids on 12 Nov 2006, 18 Nov 2006 and 31 Dec 2006. laboratory evaluation revealed normal complete blood count and normal ultrasound of the pelvic area. The patient was referred to a gastrointestinal physician but had not been examined yet. At the time of the report, the patient had not recovered. The patient sought medical attention. The reporter considered the patients gastrointestinal problems, diarrhea, vomiting, decreased appetite, swollen right intraglandular lymph node, lost 12 pounds, and dehydration to be disabling. The reporter considered the patients gastrointestinal problems, diarrhea, vomiting, decreased appetite, swollen right intraglandular lymph node, lost 12 pounds, and dehydration to be other important medical events (OMIC). Additional information has been requested.

**Other Meds:** YAZ

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270365-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	27-Nov-2006	28-Nov-2006	1	11-Jan-2007	12-Jan-2007	NY		12-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1052F	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	09546	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB141AA	0	Unknown	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1932AB	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Feeling hot, Tenderness

**Symptom Text:** Right deltoid erythematous, warm and tender.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270395-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Nov-2006	29-Nov-2006	0	11-Jan-2007	12-Jan-2007	FR	B0453076A	01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NE24240		Unknown	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB221BA		Unknown	Intramuscular	

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Dyspnoea, Paraesthesia

**Symptom Text:** This case was reported by a regulatory authority and described the occurrence of breathlessness in a 16 year old female subject who was vaccinated with Hepatitis B vaccine, HPV vaccine for prophylaxis. On 29 November 2006 the subject received unspecified dose of Hepatitis B vaccine (intramuscular) and unspecified dose of Human Papilloma Type 6+11+18 vaccine (intramuscular). On the same day, 30 minutes after vaccination with Hepatitis B vaccine, at an unspecified time after vaccination with HPV vaccine, the subject experienced breathlessness, oral tingling and tongue tingling. The regulatory authority reported that the events were clinically significant (or requiring intervention). The subject was treated with antihistamine. On 25 November 2006, the events were resolved.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270405-1      **Related reports:** 270405-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	20-Nov-2006	05-Dec-2006	15	11-Jan-2007	12-Jan-2007	ID		16-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Alopecia, Pruritus, Thermal burn

**Symptom Text:** States feeling like her head was burning and itching. States hair has been steadily been falling out starting 2 weeks post vaccine and continuing over the past two months.

**Other Meds:**

**Lab Data:**

**History:** Postpartum x 8 weeks when vaccinated

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270405-2      **Related reports:** 270405-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES 0701USA02454	16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Alopecia

**Symptom Text:** Information has been received from a registered nurse (also reported as a physician) concerning a 21 year old female who was vaccinated with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) 0.5 ml. Subsequently the patient experienced excessive hair loss. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270411-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
52.0	F	11-Jan-2007	11-Jan-2007	0	11-Jan-2007	12-Jan-2007	MO		15-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	142AA	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Pallor, Syncope

**Symptom Text:** Patient felt faint, nauseated, pale. Patient laid down symptoms resolved after 10 minutes.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270413-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	11-Jan-2007	11-Jan-2007	0	11-Jan-2007	15-Jan-2007	KY		15-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Five minutes after injection patient became nauseous and vomited. Pulse 100. BP 118/76. Patient waited 20 minutes after vomiting. Felt fine. Left office.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270433-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	03-Jan-2007	03-Jan-2007	0	12-Jan-2007	16-Jan-2007	NY		16-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2116AA		Left arm	Unknown	
	FLU	AVENTIS PASTEUR	U2271AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0961F		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site warmth, Skin ulcer, Tenderness

**Symptom Text:** Left Deltoid 5cm x 3 1/2 cm circular erythematous tender and warm to touch lesion arm very tender.

**Other Meds:**

**Lab Data:**

**History:** Latex allergy.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270528-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
37.0	F	09-Oct-2006	22-Oct-2006	13	16-Jan-2007	16-Jan-2007	FL	WAES0611USA06403	16-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0868F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Abortion, Medication error, Unintended pregnancy

**Symptom Text:** Information has been received through the manufacturer pregnancy registry and from a medical assistant concerning a 37 year old female who on 09-OCT-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (lot # 653736/0868F). It was reported that on 22-OCT-2006 "the patient discovered she was 7 weeks pregnant) method of confirmation of pregnancy was reported to be a pap smear. The patient sought unspecified medical attention. At the time of this report, the outcome of the event was unknown. Additional information was received from a medical assistant who reported that on 15-DEC-2006 the patient experienced vaginal spotting. That same day the patient was seen by her obstetrician who performed an abdominal ultrasound. The ultrasound confirmed that there was no fetal heartbeat. On an unspecified date a total serum human chorionic gonadotropin test was performed, results not provided. On 18-DEC-2006, the patient underwent an uncomplicated uterine dilation and curettage as an outpatient. On 02-JAN-2007 the patient was seen by her obstetrician for a post-operative exam which revealed that the patient had a full recovery without complications. The patient was advised to return to full regular activity. Upon internal review, the spontaneous abortion was considered to be an other medical event (OMIC). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270529-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	16-Nov-2006	16-Nov-2006	0	16-Jan-2007	16-Jan-2007	KY	WAES0612USA00985	16-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0800F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, OMIC, SERIOUS

**MedDRA PT** Abortion, Medication error, Unintended pregnancy

**Symptom Text:** Information has been received from a registered nurse for the pregnancy registry for Gardasil concerning an 18 year old white female with seasonal allergies and no medical history, who on 16-NOV-2006 was vaccinated IM with a 0.5 ml dose of Gardasil (lot# 654540/0800F). Concomitant therapy included Depo-Provera and Nasonex. On 16-NOV-2006, the patient's pregnancy test was negative. On 05-DEC-2006, the patient's pregnancy test was positive. It was noted that the patient may have an abortion but that was not related to the vaccine. Unspecified medical attention was sought. No product quality complaint was involved. Follow-up information indicated that the patient's LMP was on 28-OCT-2006 (estimated delivery date is 04-AUG-2007). On 03-JAN-2007 (reported as 03-JAN-2006), the patient had an elective termination. Upon internal review, elective termination was considered to be an other important medical event (OMIC). No further information was available.

**Other Meds:** Depo-Provera; Nasonex

**Lab Data:** beta-human chorionic 11/16/06 - negative; beta-human chorionic 12/05/06 - positive

**History:** Pregnancy (LMP = 10/28/2006); Seasonal allergy; Contraception

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270530-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
36.0	F	16-Dec-2006	16-Dec-2006	0	16-Jan-2007	16-Jan-2007	FR	WAES0701PHL00001	16-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Erythema, Feeling hot, Hypokinesia, Oedema peripheral, Pain, Skin burning sensation, Skin exfoliation

**Symptom Text:** Information has been received from a physician concerning a 36 year old female with diabetes who on 16-DEC-2006 was vaccinated with GARDASIL. Concomitant therapy included metformin HCL (HUMAMET) and sibutramine hydrochloride (REDUCTIL). Patient was vaccinated in the morning of 16-DEC-2006. Later in the afternoon, the patient experienced swelling, redness and hot feel of both hands and feet. Reportedly, patient could not close fist as it caused pain. On 17-DEC-2006, patient was brought to the emergency room and admitted. Patient was prescribed with descloratadine tablet for 2 weeks and an unspecified ointment. On 19-DEC-2006, patient was discharged. Subsequently, patient experienced peeling of palms and soles. Subsequently, the patient recovered from swelling of both hands and feet. The patient's peeling of palms and soles persisted. The reporting physician and patient felt that swelling of both hands and feet and peeling of palms and soles were related to therapy with GARDASIL vaccine. Additional information has been requested.

**Other Meds:** HUMAMET, Jul06-cont; REDUCTIL, Jul06-cont

**Lab Data:**

**History:** Diabetes

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270531-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	19-Dec-2006	19-Dec-2006	0	16-Jan-2007	16-Jan-2007	--	WAES0701USA00376	16-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** OMIC, SERIOUS

**MedDRA PT** Convulsion, Crying, Loss of consciousness

**Symptom Text:** Information has been received from the mother of a 17 year old female patient with acne and pertinent medical history and drug reactions/allergies reported as none who on 19-DEC-2006 was vaccinated with an initial dose of Gardasil, injection in the left upper arm. Concomitant therapy included sulfamethoxazole/trimethoprim. On 19-DEC-2006, the patient experienced two seizures after receiving the Gardasil vaccine. The patient's mother reported that the patient "blacked out" about one to two minutes after receiving the injection and was unconscious for about a minute before she experienced the first seizure. The patient had felt nauseous when she had regained consciousness. The patient's mother then reported that the patient "blacked out again" and had the second seizure which was more "severe". When the patient came out of it she started crying. The patient's mother reported that the physician kept them at the office for about three hours to watch her and she was given water. The patient was instructed to see a neurologist. Subsequently at the time of this report, the patient recovered from seizures. Seizures was considered to be an other important medical event (OMIC). Additional information has been requested.

**Other Meds:** Sulfamethoxazole(+)trimethoprim

**Lab Data:** Blood pressure, 12/19/06: 90/60; Blood glucose, 12/19/06: normal; Total heartbeat count, 12/19/06: 62

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 536

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270532-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	03-Jan-2007	03-Jan-2007	0	16-Jan-2007	16-Jan-2007	FL	WAES0701USA00620	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Blindness transient, Dehydration, Headache, Loss of consciousness, Nausea, Oral intake reduced, Pyrexia, Staring, Syncope, Syncope vasovagal, Vomiting

**Symptom Text:** Information has been received from a physician concerning a 12 year old female with a penicillin allergy and latex allergy who on 03-JAN-2007 was vaccinated intramuscularly with a 0.5 mL first dose of Gardasil. Concomitant therapy included Concerta. Later that evening, on 03-JAN-2007, the patient developed nausea and vomited once. At approximately 07:00 am on 04-JAN-2007, the patient developed a headache and temporal blindness that lasted approximately 40 seconds. The patient was taken to the emergency room. At 10:03 am, the patient had a second incidence of headache and temporal blindness that also lasted approximately 40 seconds. At the time of this reported, the patient was stable but was to be admitted to the hospital for observation. At the time of this report, the outcome was unknown. Additional information has been requested. 01/22/07-records received and reviewed from West Boca Medical Center for DOS 01/0407-transferred with DX of new onset seizures to Joe DiMaggio's Children's Hospital. Records requested. CT brain without contrast: negative exam, recommend MRI. 01/30/07-records received for DOS 01/04-01/05/07 DC DX: 1. Vasovagal response secondary to dehydration 2. Syncope secondary to #1. Hospital Course: Transferred from West Boca Med Ctr. Admitted with vomiting decreased oral intake since yesterday, complained of blindness and severe headaches this morning with fever of 101.4. Experienced 35-45 second of complaining of blindness, loss of consciousness and staring episode at West Boca Med Ctr. PMH: Status post Kawasaki disease two weeks after developing chicken pox, attention deficit/hyperactivity disorder.

**Other Meds:** Concerta

**Lab Data:** CT of brain: normal Urine toxicology normal WBC 6.6, polys 85, lymphocytes 6, monocytes 6, eosinophils 2. Total protein over albumin is 6.9/4.2, calcium 9.2, magnesium 1.9. EEG: normal.

**History:** Penicillin allergy; latex allergy Status post Kawasaki disease two weeks after developing chicken pox, attention deficit/hyperactivity disorder.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270548-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	22-Nov-2006	26-Nov-2006	4	16-Jan-2007	17-Jan-2007	KY		18-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F	0	Right arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2241AA	2	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash generalised

**Symptom Text:** Four days following the Gardasil vaccine, the patient developed a rash all over her body that was itchy and skin colored. It seemed to be worse on the arm of injections site. The patient received an antihistamine and cortisone creme.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270598-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Jan-2007	18-Jan-2007	--	WAES0701USA01070	18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Anaphylactic reaction, Pharyngeal oedema, Pruritus, Pruritus

**Symptom Text:** Information has been received from a physician concerning a female who was intramuscularly, vaccinated with the second dose of HPV vaccine. Subsequently the patient developed an anaphylactic reaction (swelling of the throat, itching of hands and feet). At the time of the report, it was not reported if the patient recovered. The physician determined that the patient's anaphylactic reaction (Swelling of the throat, itching of hands and feet) was considered to be immediately life threatening, disabling and an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270606-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	02-Jan-2007	03-Jan-2007	1	17-Jan-2007	18-Jan-2007	CA		18-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1405F	1	Right arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	1095F	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site cellulitis

**Symptom Text:** Cellulitis at injection site right upper arm.

**Other Meds:** NONE

**Lab Data:** CBC normal

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270610-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		17-Jan-2007	18-Jan-2007	NY		18-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1427F	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** 5 mins after receiving Gardasil pt had vasovagal symptoms, lasted approx 5-10 min.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270611-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		17-Jan-2007	18-Jan-2007	MO		18-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Flushing, Malaise, Skin warm, Somnolence, Vomiting

**Symptom Text:** 01/04/07 pt started getting sick around 2pm, her face was warm and flush, no recorded fever, threw up one time. Fell asleep until 5pm woke up ate a little dinner went back to sleep until next morning.

**Other Meds:** Birth control

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270631-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	09-Nov-2006	09-Nov-2006	0	17-Jan-2007	18-Jan-2007	CA		18-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2609AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site warmth, Pain

**Symptom Text:** pt stated post last vaccine admin. arm was hot to touch and sore

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** HA, sinus pressure no temp

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270766-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	08-Jan-2007	08-Jan-2007	0	18-Jan-2007	19-Jan-2007	NJ	WAES0701USA01029	08-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Grand mal convulsion

**Symptom Text:** Information has been received from a 27 year old female consumer with sulfa drug allergy and pertinent medical history reported as none who on 08 Jan 2007 was vaccinated with Gardasil (lot # not reported) 0.5ml injection. Concomitant therapy included Montelukast sodium, ALLEGRA and birth control (unspecified). The consumer reported that on 08 Jan 2007, she had a grand mal seizure after receiving Gardasil. Medical attention was sought. Unspecified blood test were performed. At the time of reporting, the outcome was unspecified. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Allegra, Hormonal contraceptives, Singulair.

**Lab Data:** Diagnostic laboratory 01/08/07 unspecified.

**History:** Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270784-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.5	F	22-Dec-2006	22-Dec-2006	0	18-Jan-2007	19-Jan-2007	OR		19-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Erythema, Pallor, Palpitations, Pyrexia, Rash, Rash macular

**Symptom Text:** 5 hours after receiving HPV pt had low grade fever (99), felt dizzy, pale, had a blotchy red rash on both arms (upper) onto back. No rash elevation, no hives. Pt went to bed, rash was gone by am without further side effects. During episode heart was also pounding.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** History of Dysplasia (hips)

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270836-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	28-Dec-2006	28-Dec-2006	0	19-Jan-2007	22-Jan-2007	--	WAES0701USA01415	22-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Nausea

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female with a history of two past episodes of seizures (one occurred in 8th grade and another occurred when the patient had her ears pierced) who on 28-Dec-2006 was vaccinated with a first dose of HPV vaccine (yeast) (lot 654389/0961F). The nurse reported that after the dose was administered, the patient felt nausea and while she was lying down, she experienced a "20 second seizure". The patient received unspecified medical attention. The nurse stated that the series would not be completed. At the time of this report, the outcome was unknown. Upon internal review, the patient's seizure was considered an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Convulsion

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270907-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	04-Jan-2007	05-Jan-2007	1	22-Jan-2007	23-Jan-2007	OH		23-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0741R	0	Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity, Pyrexia, Rash macular

**Symptom Text:** Pain in left arm started four hours after injection could not life or move arm without pain. 24 hours after injection had elevated temp of 100.5 and red blotches below the injection site (but not at the injection site). 72 hours after injection temperature returned to normal and pain was slowly diminishing. 96 hours after injection pain is gone, red blotches are fading. 10 days after injection, red blotches are gone.

**Other Meds:**

**Lab Data:** NONE

**History:** J-Pouch (Ileo-anal anastmosis), Crohn's Disease

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270913-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Jan-2007	Unknown		22-Jan-2007	23-Jan-2007	NE		23-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0697F	0	Right arm	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea

**Symptom Text:** 36 hrs after vaccine pt had severe chest pain and SOB. Went to ER, Neg EKG and neg CXR. Symptoms resolved on their own.

**Other Meds:** Depo (also given same day).

**Lab Data:** Neg EKG and Neg CXR

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270914-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	10-Jan-2007	11-Jan-2007	1	22-Jan-2007	23-Jan-2007	NC		23-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site oedema, Oedema

**Symptom Text:** Pt's mother called MD office stating that about 36 hrs after 2nd injection, the patient experienced swelling in her right arm that radiated down her arm into finger tips with middle of her back on right side. Her father is MD gave her 10 mg Prednisone with 800 mg Motrin. This was repeated by Dr next day. Manufacturer rep notified.

**Other Meds:** Risperdal

**Lab Data:**

**History:** NKDA pt has asthma

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270917-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	14-Dec-2006	15-Dec-2006	1	22-Jan-2007	23-Jan-2007	--		23-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Chills, Dizziness, Pyrexia, Tremor

**Symptom Text:** High fever, shaky, shills, rigors, dizzy.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270920-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	11-Jan-2007	14-Jan-2007	3	22-Jan-2007	23-Jan-2007	MI		01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Pruritic rash covering majority of body neck down.

**Other Meds:** Nuvaring, Allegra 180 mg

**Lab Data:** NONE

**History:** Seasonal allergies

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270921-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
7.0	M	15-Jan-2007	16-Jan-2007	1	22-Jan-2007	23-Jan-2007	NC		23-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	IPV	AVENTIS PASTEUR	Z0018	3	Right leg	Intramuscular	
	HEPA	MERCK & CO. INC.	1209F	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1400F	0	Left leg	Subcutaneously	
	DTAP	AVENTIS PASTEUR	U1985CA	4	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site oedema, Injection site warmth

**Symptom Text:** Redness, swelling and warmth at site.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270964-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	20-Dec-2006	20-Dec-2006	0	23-Jan-2007	24-Jan-2007	--	WAES0701USA01090	06-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	1	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Syncope, Vaccine positive rechallenge

**Symptom Text:** Initial and follow-up information has been received from a physician concerning a year old female with no known allergies and a history of "occasional" migraines who on an unspecified date was vaccinated with the first dose of Gardasil (yeast) (lot number 654540/0800F). Concomitant therapy included hepatitis A virus vaccine (unspecified). Subsequent to the first dose, the patient experienced fainting and "signs of seizure". Clinical outcome was not reported. On 20-DEC-2006 (also reported as 20-DEC-2007), the patient was vaccinated with a second dose of Gardasil (yeast) (lot number 654389/0961F). On 20-DEC-2006 (also reported as 20-DEC-2007), the patient experienced fainting. Clinical outcome was not reported. Signs of seizure was considered an other important medical event. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** Migraine

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270965-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	04-Jan-2007	04-Jan-2007	0	23-Jan-2007	24-Jan-2007	NY	WAES0701USA02133	24-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0962F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Body temperature increased, Dyspnoea, Influenza, Pain

**Symptom Text:** Information has been received from a registered nurse concerning a 19 year old female who on 04-JAN-2007 was vaccinated with a first dose of Gardasil (yeast) (0.5 ml) (lot # 654510/0962F). Subsequently, on 04-JAN-2007, the patient was rushed to the emergency room with symptoms of body aches, breathing problems and a temperature of 103. The patient was released from the emergency room within 12 hours. The nurse reported that the emergency room physician believed that the above reaction was due to influenza. The patient recovered. The reporter considered the patient's experience to be disabling. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 270972-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	10-Jan-2007	10-Jan-2007	0	23-Jan-2007	24-Jan-2007	--	WAES0701USA01386	24-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspnoea, Erythema, Pruritus, Throat irritation, Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 24 year old female with allergic rhinitis, asthma, gastric ulcer, anemia and migraine and a "history of high-risk HPV" who on 10-JAN-2007 was vaccinated with the second dose of Gardasil vaccine (yeast) (lot#655165/1425F), 0.5 ml, one time, IM. Concomitant therapy included NUVARING, ZYRTEC-D and NASAREL. Initial vaccination of Gardasil vaccine (yeast) was received on 16-NOV-2006. On 10-JAN-2007, the patient developed throat tickle, chest redness, itchiness, chest and neck hives and intermittent shortness of breath 15 minutes after administration of Gardasil vaccine (yeast). The patient was administered BENADRYL and the symptoms resolved after 10 minutes. The patient left the office in good condition without residual problems. Throat tickle, chest redness, itchiness, chest and neck hives and intermittent shortness of breath were considered to be other important medical events. Additional information has been requested.

**Other Meds:** ZYRTEC-D, NUVARING, NASAREL

**Lab Data:**

**History:** General symptoms

**Prex Illness:** Rhinitis allergic, asthma, gastric ulcer, anemia, migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271007-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	16-Jan-2007	16-Jan-2007	0	24-Jan-2007	24-Jan-2007	CA		24-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site nerve damage, Muscle spasms, Tension

**Symptom Text:** Pt called on call phone 1/17/07 at 8PM C/O tenseness and spasms to left neck increase spasms when turning head to left. Went to ER that night and was told a nerve may have been hit. Given inj of Valium and anti inflammatory was RX'd Naproxen.

**Other Meds:** NONE

**Lab Data:**

**History:** Cipro Hives

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271011-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.5	F	11-Jan-2007	11-Jan-2007	0	24-Jan-2007	24-Jan-2007	WI		24-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Headache, Injection site pain, Pyrexia

**Symptom Text:** Onset fever 103.0-103.6 F (orally) 6 hours post injection chills, mild headache, mild pain at injection site. Resolved by 12 hours, except for mild pain at injection site.

**Other Meds:** Oral contraceptives, Zyrtec, Zomig

**Lab Data:** NONE

**History:** Seasonal, environmental allergies, migraine HA, Eczema, Allergies to pineapple, tomatoes, bananas.

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271014-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	16-Jan-2007	17-Jan-2007	1	24-Jan-2007	25-Jan-2007	CA		25-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1154F	1	Left arm	Subcutaneously	
	MNQ	AVENTIS PASTEUR	U2082AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0954F		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Injection site erythema, Injection site oedema, Injection site pain

**Symptom Text:** Pain, redness, swelling on (L) upper arm, feels weak no fever.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271016-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	17-Jan-2007	17-Jan-2007	0	24-Jan-2007	25-Jan-2007	PA		25-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Flank pain, Nausea

**Symptom Text:** Pt C/O severe L flank pain with nausea, dizziness 10 min after receiving vaccine.

**Other Meds:** Multivitamin

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271056-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	11-Jan-2007	11-Jan-2007	0	24-Jan-2007	25-Jan-2007	NY	WAES0701USA01725	25-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness, Nausea, Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female with osteopenia who on 11-JAN-2007 was vaccinated with Gardasil vaccine (yeast) (lot#655165/1425F), intramuscularly in the left arm. Concomitant therapy included FOSAMAX and calcium (unspecified). Subsequently, on 11-JAN-2007, the patient "passed out", "fainted", was dizzy and nauseated. The patient recovered. There were relevant diagnostic or laboratory tests. It was noted that the patient had eaten before vaccination. Unspecified medical attention was sought. The reporter considered the patient's experience to be disabling because the patient was incapacitated for a short time. Additional information has been requested.

**Other Meds:** FOSAMAX, calcium (unspecified)

**Lab Data:** NONE

**History:**

**Prex Illness:** Osteopenia

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 560

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271092-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	15-Jan-2007	15-Jan-2007	0	24-Jan-2007	25-Jan-2007	MA		01-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Complicated migraine, Dyskinesia, Headache, Loss of consciousness, Myoclonic epilepsy, Oedema peripheral, Road traffic accident

**Symptom Text:** About 1-2 hrs after vaccination, while driving, lost consciousness, crashing into a car and mailboxes before regaining consciousness. 01/31/07-records received and reviewed. Neuro consult 1/17/07. Assessment:episodes of loss of consciousness. Differential diagnoses could include Juvenile Myoclonic Epilepsy, complicated migraine or cardiac arrhythmia. Holter monitor to evaluate for dysrhythmia. Psychotherapy with respect to her depression and medical management. PMH:This past summer had an episode where she suddenly got dizzy with the onset of sharp headache and then lost consciousness. She go back up and then blacked out again. No tongue biting or urinary incontinence. Disorientation lasted few minutes. Felt tired and achy but no further dizziness. In October 2006, episode of dizziness without loss of consciousness. Lips turned blue and whole body numb and tingling, greater on right side than left side. Head injury in October with concussion, confusion and dazed afterwards. EEG in October 2002 normal, MRI in March 2003 normal. On 1/15/07 while driving she was unaware that she had hit two mailboxes and a car. Half hour before accident she received HPV and noted swelling and throbbing at injection site. Experienced headache with this. Reports some occasional body jerks, especially noted at night when she is tired. PMH: depression, migraines which started in middle school, eczema, asthma and chicken pox.

**Other Meds:**

**Lab Data:** NONE CT cervical spine:minor scoliosis convex left. 24 hour ambulatory EEG:No epileptiform activity or persistent focal asymmetries occurred.

**History:** Depression, 1x syncope 06/06 migraines

**Prex Illness:** H/X nasal congestion

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271096-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	10-Jan-2007	10-Jan-2007	0	25-Jan-2007	26-Jan-2007	TX		26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Disorientation, Fall, Loss of consciousness

**Symptom Text:** Shortly after administration of vaccine, patient loss consciousness, fell from exam table to floor. Was out for 2-3 minutes, was very disoriented and seemed to have difficult time waking. Blood pressure was checked about 5 minutes later when move back to table. Had dropped from initial measurement of 100/70 to 80/40-patient rested for approximately 30 minutes and pressure went back up to 90/70. Patient allowed to leave. Patient has no history of any reactions to injections.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 562

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271101-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	16-Oct-2006	16-Oct-2006	0	22-Jan-2007	26-Jan-2007	MI	WAES0612USA01297	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pregnancy test positive, Ultrasound uterus, Vaginitis bacterial

**Symptom Text:** Information has been received from a physician through the pregnancy registry concerning a 17 year old female with episodic reflux and dyspepsia and no know drug allergies and no previous pregnancies who on 16-Oct-2006 was vaccinated intramuscularly with the first dose of Gardasil vaccine (yeast) (0.5 ml) (lot3653735/0688F). Concomitant therapy included Prilosec OTC. From 20-Oct-2006 to 26-Oct-2006 the patient was placed on therapy with Flagyl 500 mg twice daily for bacterial vaginitis. On 31-Oct-2006 the patient was found to have a positive pregnancy test. LMP was 11-Sep-2006. Unspecified medical attention was sought and the patient was placed on prenatal vitamins. On 19-Dec-2006, an ultrasound revealed gestational age 24.7 weeks which was not consistent with the estimated date of LMP. No other symptoms were noted. At the time of this report, the outcome of the events was unknown. Additional information has been requested.

**Other Meds:** PRILOSEC OTC mg

**Lab Data:** ultrasound 12/19/06 - gest age 24.7 weeks, beta-human chorionic 10/31/06 - positive

**History:** Pregnancy NOS (LMP = 9/11/2006), Gastroesophageal reflux, Dyspepsia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271102-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	CO	WAES0612USA01594	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Sneezing

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated intramuscularly with 0.5 ml of Gardasil vaccine (yeast). Subsequently, the patient sneezed consistently for 12 hours. The patient sought unspecified medical attention. It was reported that the patient recovered "12 hours after it started" (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271103-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	--	WAES0612USA01650	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a "nurse" via a company representative concerning an 18 year old female who, on an unspecified date, was vaccinated with a dose of Gardasil vaccine (yeast). The nurse reported that the patient experienced nausea and dizziness the same day as the vaccination, It was reported that the patient had "blood work" done (results not reported). It was not known whether the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** diagnostic laboratory - "blood work" results not reported

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271104-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	NJ	WAES0612USA01717	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema

**Symptom Text:** Information has been received from a physician concerning a 22 year old female who was vaccinated with a dose of Gardasil vaccine (yeast). Subsequently, after receiving the vaccination, the patient developed red lesions around the injection site on her arm. On an unspecified date, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271105-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	13-Dec-2006	13-Dec-2006	0	22-Jan-2007	26-Jan-2007	MD	WAES0612USA02247	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0961F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Heart rate normal, Pallor, Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on 13-Dec-2006 was vaccinated intramuscularly in the left deltoid with the first dose of Gardasil vaccine (yeast) (0.5 ml) (lot#654389/0961F). There was no concomitant medication. On 13-Dec-2006, shortly after vaccination the patient fainted and her skin color was pale. The patient was aroused by shaking her right arm and with smelling salts. The patient's vital signs were found to be normal upon discharge from the office. No further details were provided. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** vital sign 12/13/06 - normal

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271106-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	11-Dec-2006	12-Dec-2006	1	22-Jan-2007	26-Jan-2007	FL	WAES0612USA02255	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral

**Symptom Text:** Information has been received from a nurse at a physician's office concerning a female patient with a history of hepatitis C who on 11-Dec-2006 was vaccinated with Gardasil vaccine (yeast). On 12-Dec-2006 the patient reported that she had developed swelling of her hands. Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Hepatitis C

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271107-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	21-Oct-2006	28-Oct-2006	7	22-Jan-2007	26-Jan-2007	IL	WAES0612USA02256	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Infectious mononucleosis

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female patient with asthma, penicillin allergy, sulfonamide allergy and a history of infectious mononucleosis in December 2005, who on 21-Oct-2006 was vaccinated with the second dose of Gardasil vaccine (yeast) (lot# 654540/0800F). There was no concomitant medication. It was reported by the patient's mother that one week following vaccination, on approximately 28-Oct-2006 the patient developed mononucleosis which had been confirmed by a blood test taken at the university the patient attended. Unspecified medical attention was sought, however the patient received no treatment. At the time of this report the patient had not yet recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** serum Epstein-Barr 10/28?/06 - positive

**History:** Infectious mononucleosis, asthma, penicillin allergy, Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271108-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	08-Dec-2006	09-Dec-2006	1	22-Jan-2007	26-Jan-2007	KY	WAES0612USA02283	29-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F		Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Breast swelling

**Symptom Text:** Information has been received from a physician concerning a 24 year old female with no pertinent medical history or drug reactions/allergies, who on 08-Dec-2006 was vaccinated intramuscularly with Gardasil vaccine (yeast) (0.5 ml) (lot#653736/0868F). Concomitant vaccination given on an unspecified date included influenza virus vaccine (unspecified). Other concomitant medication included hormonal contraceptives (unspecified). On 09-Dec-2006, one day after receiving the Gardasil vaccine (yeast), the patient experienced breast swelling. It was reported that there was no significant pain, however the patient could not lie on her breast. Unspecified medical attention was sought. At the time of this report, the patient was recovering. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271109-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	12-Dec-2006	12-Dec-2006	0	22-Jan-2007	26-Jan-2007	MO	WAES0612USA02339	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Hypotension, Nausea

**Symptom Text:** Information has been received from a health professional concerning a female who on 12-Dec-2006 was vaccinated with what was thought to be the first dose of Gardasil vaccine (yeast). On 12-Dec-2006, following vaccination, the patient felt dizzy, weak, and nauseous and was noted to have a low blood pressure with a systolic of 100. The patient did not faint. The patient did not recover in the office and was therefore sent to the emergency room. She was not admitted. At the time of this report, the outcome of the events was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** blood pressure - low

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271110-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	27-Nov-2006	01-Dec-2006	4	22-Jan-2007	26-Jan-2007	TX	WAES0612USA02345	26-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0641F	0	Unknown	Unknown	
	FLU	CHIRON CORPORATION	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Headache

**Symptom Text:** Information has been received from a physician concerning a 16 year old female who on approximately 27-Nov-2006 was vaccinated with the first dose of Gardasil vaccine (yeast) (0.5 ml) (lot#653650/0641F). Concomitant vaccination the same day included Fluvirin vaccine. It was reported that " a few days after receiving the vaccination", on approximately 01-Dec-2006, the patient experienced dizziness when standing and walking and experienced a headache. Unspecified medical attention was sought. Subsequently, the patient recovered from the dizziness and headache on an unspecified date. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271111-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	26-Oct-2006	26-Oct-2006	0	22-Jan-2007	26-Jan-2007	--	WAES0612USA02408	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site irritation

**Symptom Text:** Information has been received from a consumer concerning her 11 year old daughter who on 26-Oct-2006 was vaccinated IM with "one shot" of Gardasil vaccine (yeast). The patient felt like it was burning. She is recovering on an unspecified therapy. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271112-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	MN	WAES0612USA02416	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site pain, Lymphadenopathy

**Symptom Text:** Information has been received from a pharmacist concerning her 13 year old daughter who in approximately October 2006 was vaccinated intramuscularly in the upper deltoid of left arm with the first dose of Gardasil vaccine (yeast). On an unspecified date, the patient developed lots of pain and tenderness in her arm around the injection site for a few days after receiving Gardasil vaccine (yeast). The pharmacist reported that her daughter developed three swollen and tender lymph nodes on her left side of her neck. The lymph nodes were really swollen for about three weeks and the tenderness lasted for about two weeks. The pharmacist was planning to have her daughter vaccinated again with the second of Gardasil vaccine (yeast) some time around 25-Dec-2006. At the time of this report, the patient had recovered from the events "about three weeks after the first dose". Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271113-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	13-Dec-2006	13-Dec-2006	0	22-Jan-2007	26-Jan-2007	MD	WAES0612USA02568	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Lymphadenopathy, Neck pain, Pyrexia

**Symptom Text:** Information has been received from a certified medical assistant concerning a 19 year old female with a mold allergy who on 13-Dec-2006 was vaccinated IM into the left deltoid with a 0.5 ml dose of Gardasil vaccine (yeast) (lot#654540/0800F). Concomitant therapy included Advair, Allegra, montelukast sodium, Ortho-Tri-Cyclen Lo and Lexapro. On 13-Dec-2006 the patient experienced a fever of 101.4 degrees F, head pain, neck pain and swollen glands. Her fever decreased to 99.1 degrees F. On 14-Dec-2006, she called the office to report these events. Unspecified medical attention was sought. At the time of this report, the patient was recovering. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** LEXAPRO ORTHO TRI CYCLEN LO ALLEGRA ADVAIR SINGULAIR

**Lab Data:** body temperature 12/13/06 101.4 degrees - fever body temperature 12/13/06 99.1 degrees

**History:** Mycotic allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271114-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	30-Nov-2006	30-Nov-2006	0	22-Jan-2007	26-Jan-2007	VT	WAES0612USA02571	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a nurse practitioner concerning a 17 year old female with no medical history or allergies, who on 30-Nov-2006 was vaccinated IM with a 0.5 ml dose of Gardasil vaccine (yeast). Concomitant therapy included an unspecified hormonal contraceptives (unspecified). On 30-Nov-2006, the patient experienced severe injection site pain. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271115-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	VT	WAES0612USA02573	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female with no medical history or allergies, who was vaccinated IM with 0.5 ml dose of Gardasil vaccine (yeast). Concomitant therapy included unspecified hormonal contraceptives (unspecified). Subsequently, the patient experienced severe injection site pain at the time of immunization. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271116-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	NY	WAES0612USA02574	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Acne

**Symptom Text:** Information has been received from a physician concerning a 22 year old female who on an unknown date was vaccinated with a first dose of Gardasil vaccine (yeast). Subsequently, the patient broke out with acne all over her face. Unspecified medical attention was sought. No diagnostic studies were performed. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271117-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	26-Jan-2007	CA	WAES0612USA02604	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Allergy to vaccine

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who was "positive for one strain of papilloma viral infection". On an unspecified date, the patient was vaccinated intramuscularly with the first "single dose vial" of Gardasil vaccine (yeast). Subsequently, the patient developed an "allergic reaction". The patient was sought unspecified medical attention. The patient was treated with a "steroid dose pack". At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Papilloma viral infection

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271118-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	27-Sep-2006	28-Sep-2006	1	22-Jan-2007	29-Jan-2007	MI	WAES0612USA02630	29-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Acne, Dry skin, Hypersensitivity, Rash pruritic

**Symptom Text:** Information has been received from the mother of a 14 year old female who on 27 Sep 2006 was vaccinated with a dose of Gardasil. Vaccination the same day included a dose of influenza virus vaccine (unspecified). Concomitant therapy included Allegra. On 28 Sep 2006, the next day, the patient developed little, itchy bumps on her legs and pimple like bumps on her back. The patient's mother reported that it may or may not have been an allergic reaction, or it "could have been" dry skin. The patient takes therapy with Allegra every day, although, the mother was unsure if the patient had taken it the day of the vaccination. Unspecified medical attention was sought. Subsequently, the patient fully recovered the same day. No other vaccinations have been given. Additional information has been requested.

**Other Meds:** Allegra

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271119-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	12-Dec-2006	12-Dec-2006	0	22-Jan-2007	29-Jan-2007	--	WAES0612USA02666	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site haemorrhage

**Symptom Text:** Information has been received from a physician concerning a female who on 12 Dec 2006 was vaccinated with a "full" dose of Gardasil. At the time of administration, a small amount of bleeding was reported at the injection site. The bleeding was controlled prior to the patient leaving the physician's office on 12 Dec 2006. The patient called the office the day (13 Dec 2006) and reported that she had bled from the injection site and that the "blood had run down her arm". The patient feels that she did not get the full vaccination because of the bleeding problem. It was reported that the patient sought unspecified medical attention. As of 13 Dec 2006, the patient had recovered from bleeding at the injection site. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271120-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Oct-2006	21-Oct-2006	0	22-Jan-2007	29-Jan-2007	TN	WAES0612USA02744	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0702F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site oedema, Smear cervix abnormal, Smear cervix normal, Vaginitis bacterial

**Symptom Text:** Information has been received from a nurse practitioner concerning a 19 year old female with an allergy to penicillin who on 21 Oct 2006 was vaccinated intramuscularly in the left deltoid with the first dose of Gardasil (Lot #653650/0702F). Concomitant therapy included hormonal contraceptives (unspecified). On 21 Oct 2006 the patient experienced minor redness and swelling at the injection site, which later resolved. On 08 Dec 2006 the patient presented with bacterial vaginosis and had a positive pap smear test for high risk HPV types. It was noted that on an unspecified date in November 2006 and on 09 Dec 2005 the patient's pap smear tests were negative. Subsequently, unspecified medical attention was sought and the patient had not recovered from positive pap smear test. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** cervical smear, 12/8/06, + High risk HPV types; cervical smear 11/04, negative; cervical smear 12/09/05, negative.

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271121-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	--	WAES0612USA02748	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Adverse drug reaction

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil. Subsequently, the patient developed an "adverse reaction". No details were given of the adverse experience. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271122-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	NC	WAES0612USA02774	05-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a Nurse Practitioner concerning a 15 year old female patient who was vaccinated with her first dose of Gardasil. Subsequently, the patient experienced prolonged dizziness. Medical attention was required. The patient recovered. The nurse practitioner reported that she was unsure if the 2nd dose of Gardasil should be administered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271123-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	01-Nov-2006	Unknown		22-Jan-2007	29-Jan-2007	NC	WAES0612USA02786	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Laboratory test, Ophthalmological examination, Ophthalmological examination abnormal, Urine analysis

**Symptom Text:** Information has been received from a nurse practitioner concerning an 11 year old female with a history of Lyme disease, and ear infection, "reactive airways" and no known allergies or adverse drug reactions reported. On 01-Nov-2006, the patient was vaccinated intramuscularly with 0.5 ml of Gardasil vaccine (yeast). Subsequently, the patient developed dizziness for about three weeks. It was reported that the patient "had some lab studies done and was referred to a neurologist (she had not seen him yet). The laboratory diagnostics included blood sugar, a urinalysis and vision screening (results not reported). The nurse practitioner reported that there were some family issues that were occurring also be a cause. The patient was referred to an eye physician because she failed her school eye exam. At the time of this report, the patient was recovering from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** diagnostic urinalysis ophthalmological exam blood glucose

**History:** Lyme disease, Ear infection, Reactive airway disease

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271124-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	07-Dec-2006	07-Dec-2006	0	22-Jan-2007	29-Jan-2007	FL	WAES0612USA02801	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a female (NOS) who on approximately 07-Dec-2006 was vaccinated with the first dose of Gardasil vaccine (yeast) (lot# not provided). Immediately after receiving the injection on approximately 07-Dec-2006 the patient developed hives in the same arm where she received the injection. The patient sought unspecified medical attention. At the time of this report it was unknown if the patient had recovered from the hives.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271125-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	14-Dec-2006	14-Dec-2006	0	22-Jan-2007	29-Jan-2007	CO	WAES0612USA02807	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0697F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with sulfonamide allergy who on 14-Dec-2006 was vaccinated with a first dose of Gardasil vaccine (yeast) (lot#653650/0697F) pre-filled syringe IM into the left deltoid. Concomitant vaccination on 14-Dec-2006 included a dose of influenza virus vaccine (unspecified) (manufacturer unknown). On 14-Dec-2006 the patient experienced broke out in rash all over her body. There was no fever associated with the rash. It was unclear if there was any local rash or reaction at the injection site. At the same visit the patient was given amoxicillin for an unknown reason. As of 15-Dec-2006 the rash persisted. Additional information has been requested.

**Other Meds:** amoxicillin influenza virus vaccine

**Lab Data:** NONE

**History:** sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271126-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	16-Nov-2006	17-Nov-2006	1	22-Jan-2007	29-Jan-2007	NY	WAES0612USA02899	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Full blood count normal, Injection site pain, Red blood cell sedimentation rate normal

**Symptom Text:** Information has been received from a physician concerning a 20 year old female with an allergy to antibiotics who on 16-Nov-2006 was vaccinated with a first dose of Gardasil vaccine (yeast). On 17-Nov-2006 the patient developed pain at the injection site. The patient began to have joint pain throughout her body. The location of the joint rotated and was in her right knee at the time of this report. Laboratory evaluations revealed that erythrocyte sedimentation rate and complete blood count were normal. The patient was to be seen by a neurologist. The physician reported that she would most likely hold off on the second dose of Gardasil vaccine (yeast). At the time of this report, the patient's joint pain persisted. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** complete blood cell 11/??/06 - normal erythrocyte 11/??/06 - normal

**History:** Allergic reaction to antibiotics

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271127-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	17-Oct-2006	17-Oct-2006	0	22-Jan-2007	29-Jan-2007	TN	WAES0612USA02924	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Upper respiratory tract infection

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female with gastric reflux who on 17-Oct-2006 was vaccinated IM with a first dose of Gardasil vaccine (yeast) (lot#653735/0688F). Concomitant therapy included Nuvaring and Aciphex. That evening the patient experienced quite a bit of nausea and a headache. It was noted that the patient couldn't study. On 18-Oct-2006, the nausea was gone. The patient thought that her headache was due to new contacts. On 19-Oct-2006, the patient's headache went away after she took her contacts out. One month later the patient experienced an upper respiratory infection but the nurse practitioner did not think it was related to the vaccine. Unspecified medical attention was sought. No diagnostic laboratory studies were involved. At the time of this report the outcome of upper respiratory infection was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NUVARING ACIPHEX

**Lab Data:** NONE

**History:** Gastroesophageal reflux

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271128-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
51.0	F	11-Dec-2006	11-Dec-2006	0	22-Jan-2007	29-Jan-2007	FL	WAES0612USA02952	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug hypersensitivity, Face oedema, Lip swelling, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a 51 year old female with an allergy to benzoyl peroxide who on 11-Dec-2006 was vaccinated intramuscularly with the first dose of Gardasil vaccine (yeast). Concomitant therapy included Yasmin. On 14-Dec-2006 the patient began to experience muscle aches, and on 17-Dec-2006 the patient began experiencing swelling of her face and lips, but no rash. The patient treated herself with Benadryl and was scheduled to see her physician on 18-Dec-2006. At the time of this report, the muscle aches and swelling of her face and lips persisted. Additional information has been requested.

**Other Meds:** YASMIN

**Lab Data:** NONE

**History:** HYPERSENSITIVITY

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271129-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	15-Dec-2006	15-Dec-2006	0	22-Jan-2007	29-Jan-2007	PA	WAES0612USA02967	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Information has been received from a physician concerning a 19 year old female with no persistent medical history or drug reactions/allergies, who on 15-Dec-2006 was vaccinated with Gardasil vaccine (yeast) (0.5 ml0. There was no concomitant medication. On 15-Dec-2006, following, vaccination, the patient developed a red itchy rash "all over". Unspecified medication attention was sought. At the time of this report the patient had not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** diagnostic laboratory 12/??/06 - results not provided

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271130-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	14-Aug-2006	14-Aug-2006	0	22-Jan-2007	29-Jan-2007	SD	WAES0612USA03013	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dry skin, Dysgeusia, Feeling hot and cold, Influenza like illness, Nasopharyngitis, Nausea, Weight decreased, White blood cell count normal

**Symptom Text:** Information has been received from a physician and a registered nurse concerning a 27 year old female with narcolepsy and migraines and a history of cervical dysplasia and papilloma viral infection, and no known allergies, who on 14-Aug-2006 was vaccinated intramuscularly in the left deltoid with the first dose of Gardasil vaccine (yeast) (lot#653937/0637F). Concomitant therapy included "a medication for narcolepsy", Imitrex tablets, Excedrin Migraine, Aviane and dextroamphetamine. On 14-Aug-2006, following the vaccination, the patient experienced flu-like symptoms, nausea, hot and cold sensations, weight loss, decreased energy, cold respiratory symptom, dry skin, and a taste of iron in her mouth. On 04-Oct-2006, the patient was seen by her primary care physician and her white blood count was noted to be within normal range. The patient received the second dose of Gardasil vaccine (yeast) in the right deltoid on 20-Oct-2006. On 14-Dec-2006 the patient called her physician's office and stated that she was experiencing the same type of flu-like symptoms and thought it was related to the vaccine. At the time of this report, the patient had not recovered . Unspecified medical attention was sought. The nurse reported that the patient missed work or school due to the symptoms, however the nurse did not feel the events were serious. It was recommended to the patient not to receive the third dose of Gardasil vaccine (yeast). Additional information has been requested.

**Other Meds:** (therapy unspecified) EXCEDRIN MIGRAINE dextroamphetamine AVIANE IMITREX TABLETS

**Lab Data:** WBC count 10/04\*06 - WNL

**History:** Cervical dysplasia, Papilloma viral infection

**Prex Illness:** Narcolepsy, Migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271131-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	IN	WAES0612USA03102	05-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Amenorrhoea

**Symptom Text:** Information has been received from a physician concerning a female patient (demographics not provided) who on an unspecified date was vaccinated with the first dose of Gardasil vaccine (yeast) (lot# not provided). Subsequently the patient experienced a missed menstrual period. The patient sought unspecified medical attention. At the time of this report the patient had not recovered from the missed menstrual period. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271132-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	11-Dec-2006	13-Dec-2006	2	02-Jan-2007	26-Jan-2007	NM	WAES0612USA03120	26-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0868F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Information has been received from a Nurse Practitioner concerning an 18 year old female who on 11 Dec 2006 was vaccinated with the first dose of Gardasil (yeast) (Lot # 653736/0868F). Concomitant therapy included hormonal contraceptives (unspecified). Within 48 hours post vaccination, on approximately 13 Dec 2006 the patient experienced a severe headache. The patient sought unspecified medical attention. The headache was treated with Tylenol and resolved "in one day". Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271133-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	07-Nov-2006	07-Nov-2006	0	22-Jan-2007	29-Jan-2007	--	WAES0612USA03130	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Tachycardia

**Symptom Text:** Information has been received from a nurse concerning a 24 year old female with a history of panic attacks who on 07-Nov-2006 was vaccinated with a 0.5 ml dose of Gardasil vaccine (yeast) (lot#653938/0954F). Concomitant therapy included Asacol. On 07-Nov-2006 later that night, the patient experienced tachycardia and difficulty breathing. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product complaint was involved. Additional information has been requested.

**Other Meds:** ASACOL

**Lab Data:** UNK

**History:** PANIC ATTACK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271134-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	19-Dec-2006	19-Dec-2006	0	22-Jan-2007	29-Jan-2007	TX	WAES 0612USA03131	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site, Pain, Sciatic nerve injury, Sciatica

**Symptom Text:** SCIATICA; DRUG ADMINISTERED AT INAPPROPRIATE SITE. Information has been received from a nurse practitioner concerning a female patient who on 19-DEC-2006 was vaccinated IM into the dorsogluteal muscle with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medications. On 19-DEC-2006, the patient experienced sciatic nerve pain (noted that when the patient was vaccinated the sciatic nerve was hit). The pain went up her back and then it crossed over to the middle onto the left back. The pain occurred right after the injection. It was noted that there was no bruising or inflammation. Unspecified medical attention was sought. No laboratory diagnostic studies were performed. At the time of this report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271135-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	--	WAES 0612USA03151	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a clinical coordinator at a doctor's office concerning a female who was vaccinated with a first and second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (0.5 ml). Subsequently, the patient fainted after receiving both doses. The patient recovered. There were no relevant diagnostic test or laboratory data. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271136-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
53.0	M	22-Nov-2006	22-Nov-2006	0	22-Jan-2007	29-Jan-2007	--	WAES 0612USA03152	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	By Mouth	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Nausea

**Symptom Text:** Information has been received from a consumer concerning her 53 year old father with liver problems and no drug allergies who on 22-NOV-2006 inadvertently received HPV rL1 6 11 16 18 VLP vaccine (yeast) (0.5 ml), orally. There was no concomitant medication. Subsequently, "in late November" the patient experienced nausea, dizziness and weakness. At the time of the report, the patient had not recovered. There were no relevant diagnostic tests or laboratory data. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Liver disorder

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271137-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	18-Dec-2006	18-Dec-2006	0	22-Jan-2007	29-Jan-2007	--	WAES 0612USA03188	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Pain in extremity

**Symptom Text:** Information has been received from a registered nurse concerning her 20 year old daughter with no medical history or allergies, who on 18-DEC-2006 was vaccinated IM with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. On 18-DEC-2006, the patient experienced throbbing pain in her arm. Unspecified medical attention was sought. No diagnostic studies were performed. At the time of this report, the patient's pain was subsiding. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271138-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	--	WAES 0612USA03315	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from an office manager concerning a 17 year old female patient who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast), 0.5 mL, injection. concomitant medication was not reported. Subsequently on an unspecified date, the patient fainted after she received the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient sought unspecified medical attention. The office manager stated that the patient did not have anything to eat prior to receiving the injection. Subsequently on an unspecified date, the patient recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271139-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	--	WAES 0612USA03323	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast), 0.5 mL, injection. Concomitant medication was not reported. Subsequently on an unspecified date, the patient developed a rash while being administered HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient sought unspecified medical attention. The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271140-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	18-Dec-2006	20-Dec-2006	2	22-Jan-2007	29-Jan-2007	NY	WAES 0612USA03353	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	654540/1161F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pruritus

**Symptom Text:** Information has been received from a nurse concerning a 19 year old female patient with asthma, depression and allergies to valproate sodium, diazepam, gabapentin and acetaminophen (+) butalbital (+) caffeine who on 18-DEC-2006 was vaccinated with her first dose of HPV rL1 6 11 16 18 VLF vaccine (yeast), 1pt #654540/1161F. Concomitant therapy included montelukast sodium (MSD), escitalopram oxalate, lansoprazole, and metoprolol succinate. On 20-DEC-2006 the patient called the office and stated that the injection site was itchy. Medical attention was sought. The physician's office to follow up with patient, her outcome was unknown. Additional information has been requested.

**Other Meds:** Lexapro, Prevacid, Toprol XL tablets, Singulair

**Lab Data:** NONE

**History:** Asthma; Depression; Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271141-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	01-Dec-2006	01-Dec-2006	0	22-Jan-2007	29-Jan-2007	--	WAES0612USA03390	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness, Pain

**Symptom Text:** Initial and follow-up information has been received from a health professional concerning a 14 year old female who in "early" December 2006, was vaccinated with Gardasil. There was no concomitant medication. Subsequently in "early" December 2006, the patient experienced flu-like symptoms and pain for about 4 days after injection. The sought unspecified medical attention. No diagnostics were performed. Subsequently, in "mid-December" the patient recovered from flu-like symptoms and pain for about 4 days after injection. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271142-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	13-Dec-2006	13-Dec-2006	0	22-Jan-2007	29-Jan-2007	--	WAES 0612USA03396	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a clinical manager concerning a female who on "13-DEC-2006 or 14-DEC-2006" was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). On 13-DEC-2006, or 14-DEC-2006, the patient fainted almost immediately after receiving the vaccination. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271143-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	22-Jan-2007	29-Jan-2007	--	WAES 0612USA03521	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Vaccination complication

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who in approximately December 2006, was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). In approximately December 2006, when administering the vaccine with the prefilled syringe, the nurse release the spring before removing the syringe, therefore causing the patient pain at the injection site. No additional information was available at the time of reporting. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271144-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	--	WAES0612USA03533	30-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning a 22 year old female with pertinent medical history and drug reaction/allergies not reported who on an unspecified date was vaccinated with the initial dose of Gardasil injection. Concomitant medication was not reported. In December 2006 ( a few weeks ago), the patient fainted after Gardasil was administered. The patient sought unspecified medical attention. The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271145-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	19-Dec-2006	19-Dec-2006	0	22-Jan-2007	29-Jan-2007	MD	WAES0612USA03566	30-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Flushing, Hypotension, Malaise

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 20 year old female who had hypersensitivity reported as "Motrin for allergies". On 19 Dec 2006, the patient was vaccinated intramuscularly with the first "single dose vial" of Gardasil (Lot # 653938/0954F). Concomitant therapy included Motrin, Desogen, Allegra and Zantac. On 19 Dec 2006, "almost immediately after vaccination", the patient became a little flushed in the face and had to take a minute to sit and gather herself together. The patient was noted to have a blood pressure of 101/65 mmHg (date unknown). The patient sought unspecified medical attention. It was reported that the patient "improved within seconds". On 19 Dec 2006, the patient had recovered from the event. The licensed practical nurse reported that they were planning to vaccinate for the second and third dose as indicated in the "PI". Additional information has been requested.

**Other Meds:** Desogen, Allegra, Motrin, Zantac

**Lab Data:** blood pressure, 12/19/06, 101/6 mmHg

**History:** hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271146-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	27-Nov-2006	01-Dec-2006	4	22-Jan-2007	30-Jan-2007	--	WAES0612USA03644	30-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0641F		Unknown	Intramuscular	
	FLU	CHIRON CORPORATION	72222		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness postural, Headache

**Symptom Text:** Information has been received from a physician concerning an 18 year old white female who on 27 Nov 2006 was vaccinated with Gardasil (lot number 653650/0641F). Concomitant therapy on 27 Nov 2006 included Fluvirin. On 01 Dec 2006 the patient experienced dizziness with walking or standing. On 02 Dec 2006 the patient experienced headache on top of her head. Subsequently, the patient recovered from dizziness with walking or standing and headache on top of her head. A prescription treatment was given for the experiences (not specified). Additional information is not expected.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271147-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	30-Jan-2007	OR	WAES0612USA03827	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Burning sensation, Pain

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with Gardasil. Subsequently, following vaccination, the patient experienced pain and a burning sensation in the arm. Unspecified medical attention was sought. At the time of this report, the patient's pain and burning sensation in the arm persisted. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271148-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	18-Dec-2006	22-Dec-2006	4	22-Jan-2007	30-Jan-2007	NC	WAES0612USA03830	30-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anogenital warts, Pain

**Symptom Text:** Information has been received from a pharmacist and a 25 year old female patient with sulfonamide allergy reporting that on 18 Dec 2006 the patient was vaccinated IM with a first dose of Gardasil. Concomitant therapy included Lexapro. Four days later, on approximately 22 Dec 2006, the patient developed painful genital warts. The patient's painful genital warts persisted and she sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Lexapro

**Lab Data:** NONE

**History:** sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271149-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	25-Aug-2006	Unknown		22-Jan-2007	30-Jan-2007	PA	WAES0612USA03950	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Herpes virus infection

**Symptom Text:** Information has been received from a certified medical assistant concerning a patient who on 25 Aug 2006 was vaccinated with a first dose of Gardasil, intramuscularly. Subsequently the patient developed a herpes virus infection. The patient's pediatrician had concluded that the infection was not due to Gardasil. It was also reported that the patient's second dose was delayed because some time after the first dose, because she developed the herpes virus infection. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271150-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	30-Jan-2007	--	WAES0612USA04030	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea

**Symptom Text:** Information has been received from a female patient (age not reported) who on an unspecified date was vaccinated with the initial dose of Gardasil. Concomitant medication was not reported. In December 2006, the patient experienced really bad diarrhea after receiving the first dose of Gardasil. The outcome of the event was not reported. No further information is available.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271151-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	30-Jan-2007	--	WAES0612USA04034	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Presyncope

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil. Concomitant medication was not reported. Subsequently on an unspecified date, the patient almost fainted immediately after receiving Gardasil. The nurse at the physician's office stated that the girl seemed "afraid of needles." The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271152-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	30-Jan-2007	FL	WAES0612USA04148	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Lymphadenopathy, Nausea, Pharyngolaryngeal pain, Vomiting

**Symptom Text:** Information has been received from a physician via a company representative concerning a female (age not reported) who, on an unspecified date, was vaccinated with a first dose o Gardasil (Lot # not reported). The physician reporeted that after the first dose, the patient experienced nausea, diarrhea and vomiting. The physician also reported that after the second dose of Gardasil, the patient experienced a sore throat and swollen glands. The patient sought unspecified medical attention. There was no product quality complaint involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271153-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	20-Dec-2006	24-Dec-2006	4	22-Jan-2007	30-Jan-2007	IL	WAES0612USA04161	30-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a consumer concerning her 14 year old daughter who on 20 Dec 2006 was vaccinated with a first dose of Gardasil. On 24 Dec 2006, the patient developed a full body rash. The patient did not seek medical attention for her experience. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271154-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	30-Jan-2007	--	WAES0612USA04171	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from a female pharmacist who was vaccinated IM with a second dose of Gardasil. The pharmacist reported that she did not feel the second injection. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271155-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Nov-2006	22-Nov-2006	0	22-Jan-2007	30-Jan-2007	FL	WAES0701USA00013	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician concerning a female patient who on 22 Nov 2006 was vaccinated with a 0.5 ml dose of Gardasil. On approximately 22 Nov 2006, the physician reported that the patient experienced reaction a "tendonitiis like" pain near the injection site. It was noted that there were no signs of cellulitis and the pain has not been responsive to OTC non-steroidal medication. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271156-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	27-Dec-2006	30-Dec-2006	3	22-Jan-2007	30-Jan-2007	--	WAES0701USA00040	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Contusion, Rash

**Symptom Text:** Information has been received from a 26 year old female pharmacist who on 27 Dec 2006 was vaccinated with a 0.5 mL dose of Gardasil. On 30 Dec 2006, the patient developed bumps on skin, located mainly on the back, sporadic on the chest, 5-6 noted, and also on belly: none on legs. The pharmacist reported that they were painful and "felt like bruises," The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271157-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	29-Nov-2006	29-Nov-2006	0	22-Jan-2007	30-Jan-2007	PA	WAES0701USA00048	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Information has been received from the mother of an 11 year old female with an allergy to Rondec and migraines who on 25 Oct 2006 was vaccinated intramuscularly with the first dose of Gardasil. Concomitant therapy included an unspecified migraine therapy. The mother reported that her daughter received the second dose of Gardasil approximately 35 days after receiving the first dose. The mother was informed by her physician that it was "okay" and that the patient did not have to restart the series. The mother also reported that following the second vaccination, on 30 Nov 2006, her daughter experienced pain in the arm in which she was vaccinated. Unspecified medical attention was sought. The patient subsequently recovered from the pain on an unspecified date. Additional information has been requested.

**Other Meds:** therapy unspecified

**Lab Data:** NONE

**History:** hypersensitivity, migraine

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271158-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	27-Dec-2006	27-Dec-2006	0	22-Jan-2007	30-Jan-2007	--	WAES0701USA00101	05-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia oral, Lip swelling

**Symptom Text:** Information has been received from a nurse practitioner concerning a 15 year old female who on 27 Dec 2006 was vaccinated with a first dose of Gardasil concomitantly with a dose of influenza virus vaccine (unspecified) using a different injection site. On 27 Dec 2006, approximately 2 hours after the vaccination, the patient experienced swelling and numbness in her lower lip. On approximately 29 Dec 2006, the patient recovered without treatment. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271159-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	27-Dec-2006	27-Dec-2006	0	22-Jan-2007	30-Jan-2007	NJ	WAES0701USA00109	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral

**Symptom Text:** Information has been received from a nurse concerning a female who on approximately 27 Dec 2006 was vaccinated with a second dose of Gardasil. On approximately 27 Dec 2006 the patient developed swelling in the arm. The patient was treated with Benadryl. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271160-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	04-Dec-2006	05-Dec-2006	1	22-Jan-2007	30-Jan-2007	NJ	WAES0701USA00115	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0868F	1	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Information has been received from an office manager concerning a 16 year old female who on 04 Dec 2006 was vaccinated IM, into the left deltoid, with 0.5 ml second dose of Gardasil (lot #653736/0868F). On 05 Dec 2006 the patient developed an itchy rash on her arm. The patient was treated with Benadryl and the rash was gone the on the night of 05 Dec 2006. On 06 Dec 2006, the patient recovered. The office manger reported that there was no adverse reaction after the patient's first dose of Gardasil. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271161-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	04-Dec-2006	05-Dec-2006	1	22-Jan-2007	30-Jan-2007	--	WAES0701USA00119	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0868F	1	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a teenage female who on 04 Dec 2006 was vaccinated with the second dose of Gardasil (lot#653736/0868F), IM injection. Concomitant medication was not reported. On 05 Dec 2006, the patient developed a rash on her forearms. The physician reported that the patient was seen by another physician in the office, who prescribed Benadryl to treat the rash. The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271162-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	27-Dec-2006	27-Dec-2006	0	22-Jan-2007	30-Jan-2007	NJ	WAES0701USA00120	30-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Injection site pain, Injection site rash, Rash

**Symptom Text:** Information has been received from an RN concerning a 21 year old female patient who on 23 Oct 2006 was vaccinated IM with her first dose of Gardasil, lot #654540/1162F. On approximately 27 Dec 2006 the patient was vaccinated with her 2nd dose of Gardasil. On 27 Dec 2006 the patient developed a painful injection site after vaccination and also developed a red rash going up and then down her arm and around the injection site. She was given Benadryl and advised to keep an ice pack on it for the rest of the day. As of the report date the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271163-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	28-Dec-2006	28-Dec-2006	0	22-Jan-2007	30-Jan-2007	--	WAES0701USA00122	30-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaphylactoid reaction

**Symptom Text:** Information has been received from a registered nurse via a company representative concerning a 19 year old female with a latex allergy, who on 28 Dec 2006 was vaccinated with a 0.5 mL dose of Gardasil. The nurse reported that on 28 Dec 2006, the patient experienced "a near anaphylactic reaction". The patient's status was not reported. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Latex allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271164-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	20-Oct-2006	19-Dec-2006	60	22-Jan-2007	29-Jan-2007	IL	WAES0701USA00156	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from a registered nurse concerning a 15 year old female who on 20-Oct-2006 was vaccinated with the first dose of Gardasil vaccine (yeast) (lot# not provided). Concomitant therapy included Ortho Evra. On 19-Dec-2006 the patient was diagnosed with mononucleosis by her primary care physician. The patient sought unspecified medical attention. At the time of this report the patient's mononucleosis persisted. The reporter felt that the mononucleosis was not related to therapy with Gardasil vaccine (yeast). Additional information has been requested.

**Other Meds:** ORTHO EVRA

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271165-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Dec-2006	Unknown		22-Jan-2007	29-Jan-2007	TX	WAES0701USA00223	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Amenorrhoea

**Symptom Text:** Information has been received from a physician concerning a 12 year old female who on 01-Dec-2006 was vaccinated with the first dose of Gardasil vaccine (yeast) (lot# not provided). On unspecified date in December, 2006, the patient separate two periods (dates not provided). The patient sought unspecified medical attention. At the time of this report it was unknown if the patient had recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271166-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	KY	WAES0701USA00226	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pruritus, Injection site swelling

**Symptom Text:** Information has been received from a health professional concerning a 19 year old female with a hypersensitivity to "sepna" who on an unspecified date was vaccinated (at another unspecified physicians office) with the first dose of Gardasil vaccine (yeast) (lot# not provided). Concomitant therapy included naproxen sodium (Aleve) and ibuprofen. Subsequently, the patient reported that she experienced itching and swelling at the injection site which spread to her body. The patient sought unspecified medical attention. At the time of this report it was unknown if the patient had recovered from the event. Additional information has been requested.

**Other Meds:** ibuprofen ALEVE

**Lab Data:**

**History:** HYPERSENSITIVITY

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 628

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271167-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	MI	WAES0701USA00228	29-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hepatitis acute, Liver function test abnormal

**Symptom Text:** Information has been received from a physician concerning a 12 year old female who on an unspecified date was vaccinated intramuscularly with the first dose of Gardasil vaccine (yeast) (lot# not provided). Concomitant therapy included Strattera and Concerta. Subsequently, the patient presented to the reporting physicians office for her second dose of Gardasil vaccine (yeast) and the patient's mother reported that the patient had been diagnosed with "acute immune hepatitis". The physician reported that the patient was asymptomatic, looked fine and was not sick. The physician did not give the second dose of the vaccine at that time based on the report from the mother. The physician reported that she is watching the patient's liver function tests which have progressively risen to 70. The reporting physician felt that the auto immune hepatitis was not related to therapy with Gardasil vaccine (yeast). Additional information has been requested.

**Other Meds:** STRATTERA CONCERTA

**Lab Data:** hepatic function tests 70

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271168-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		22-Jan-2007	29-Jan-2007	NJ	WAES0701USA00462	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Allergy to vaccine

**Symptom Text:** Information has been received from an RN concerning a patient who has an allergic reaction after being vaccinated with a dose of Gardasil vaccine (yeast). The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271169-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	22-Jan-2007	29-Jan-2007	--	WAES0701USA00932	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Gluteous maxima	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Vaccination complication

**Symptom Text:** Information has been received from a registered nurse concerning a female who in approximately December 2006, was vaccinated with Gardasil vaccine (yeast). In approximately December 2006, when administering the vaccine with the pre-filled syringe, the nurse released the spring before removing the syringe, therefore causing the patient pain at the injection site. No additional information was available at the time of reporting. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271170-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	--	WAES0701USA00967	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil vaccine (yeast), 0.5 ml, injection. Concomitant medication was not reported. Subsequently on an unspecified date, the patient developed a rash while being administered Gardasil vaccine (yeast). The patient sought unspecified medical attention. The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271171-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		22-Jan-2007	29-Jan-2007	IN	WAES0701USA01303	29-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation irregular

**Symptom Text:** Information has been received from a physician concerning a female (demographics not provided) who on an unspecified date was vaccinated with the first dose of Gardasil vaccine (yeast) (lot# not provided). Subsequently the patient experienced a missed menstrual period. The patient sought unspecified medical attention. At the time of this report the patient had not recovered from the missed menstrual period. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271177-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	13-Jan-2007	13-Jan-2007	0	25-Jan-2007	26-Jan-2007	NY	WAES0701USA02032	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, LIFE THREATENING, SERIOUS

**MedDRA PT** Blood test normal, Computerised tomogram normal, Convulsion, Fall, Fatigue, Loss of consciousness

**Symptom Text:** Information has been received from a health professional concerning a 16 year old female who on 11-NOV-2006 was vaccinated intramuscularly with 0.5 ml of the first dose of Gardasil vaccine (yeast) (lot#654510/0962F) and had no difficulties with the vaccine. On 13-JAN-2007 the patient was given her second dose of Gardasil vaccine (yeast) (lot# not provided). Within a few moments of receiving the vaccine the patient experienced a seizure, had a very brief loss of consciousness and fell to the floor. The patient was sent to the emergency room for evaluation. The patient was not admitted to the hospital. While in the emergency room she had a CT scan, chest-x-ray and unspecified blood work. The results of these tests were all negative. The patient was seen for a follow-up appointment by the physician on 16-JAN-2007. The patient reported that she was tired, however had not suffered any additional seizures. The patient was referred for a neurology consult. The physician considered the event to be life-threatening. At the time of this report the patient had not recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** chest x-ray 01/13/07 - normal, computed axial 01/13/07 - normal, electrocardiogram 01/13/07 - normal

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271178-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	11-Jan-2007	11-Jan-2007	0	25-Jan-2007	26-Jan-2007	--	WAES0701USA01948	26-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Arthralgia, Dermographism, Gait disturbance, Oedema peripheral, Oedema peripheral, Urticaria

**Symptom Text:** Information has been received from a physician concerning her 20 year old daughter who on 11-JAN-2007 was vaccinated IM with a 0.5 ml dose of Gardasil vaccine (yeast) (lot#653938/0954F). Concomitant therapy included Yasmin. On 11-JAN-2007, fifteen minutes after the vaccination, welts appeared on the patient's neck and spread all over the body. Dermatographia resulted all over the patient's body, her hands and feet were swollen, and she experienced arthritic pain in her joints. It was reported that the patient was not able to walk because of the pain. The patient was treated with Zyrtec, dexamethasone and hydroxyzine. Unspecified blood tests were performed (results not reported). At the time of this report, the patient was not recovered. Welts, dermatographia, peripheral swelling, arthritic-like joint pain and the patient's inability to walk were considered to be disabling events. Additional information has been requested.

**Other Meds:** Yasmin

**Lab Data:** diagnostic laboratory 01/11?/07 - results not reported

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271180-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	23-Jan-2007	23-Jan-2007	0	25-Jan-2007	26-Jan-2007	UT		26-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0906F	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Injection site rash

**Symptom Text:** pt had a rash at the injection site, and had a severe headache

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:** NONE~~~0~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271273-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	U	Unknown	Unknown		22-Jan-2007	02-Feb-2007	--	WAES0612USA04046	02-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARZOS	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** No adverse effect, Wrong drug administered

**Symptom Text:** Information has been received from a health professional and a pharmacist concerning a 13 year old patient who on an unspecified date was vaccinated with a dose of Zostavax. Unspecified medical attention was sought. The patient was not experiencing any know symptoms. it was reported that the error was not a result of product confusion. The patient's vaccination history reported to include a first dose of varicella virus vaccine live on an unspecified date, but not a second dose of varicella virus vaccine live. There was no product quality complaint involved. No further information was available. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271281-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	U	Unknown	Unknown		22-Jan-2007	01-Feb-2007	--	WAES0701USA00186	01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARZOS	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** No adverse effect, Wrong drug administered

**Symptom Text:** Information has been received from a health professional and a pharmacist concerning a 20 year old patient who on an unspecified date was vaccinated with a dose of Zostavax vaccine instead Gardasil vaccine (yeast). Unspecified medical attention was sought. The patient was not experienced any known symptoms. It was reported that the error was not a result of product confusion. There was no record of the patient ever receiving Varicella virus vaccine live. There was no product quality complaint involved. No further information was available. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271302-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	09-Jan-2007	10-Jan-2007	1	26-Jan-2007	26-Jan-2007	KS		29-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1162F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Gardasil given 1/9/07. On 1/10/07 complained of lightheadedness, nausea. Ran fever 1/13, 1/14, 1/15.

**Other Meds:** Tegretol, Ovcon 35

**Lab Data:**

**History:** Seizure disorder

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271334-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	23-Jan-2007	24-Jan-2007	1	26-Jan-2007	29-Jan-2007	AZ		29-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1144F	1	Left arm	Subcutaneously	
	TDAP	AVENTIS PASTEUR	C2689AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1209F	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1424F	0	Gluteous maxima	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2002AC	0	Gluteous maxima	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site inflammation, Injection site irritation, Injection site vesicles

**Symptom Text:** Gardasil was given in office. Pt. reported only some irritation at site following the administration of vaccine. The following day she developed local erythema and sm. blister. She was seen again in the office on 1/25/07. Superficial blister/inflammation of approx. 0.5 x 1.5cm was noted. No cellulitis noted. Area was lt. pink in color. Advised pt. to keep area clean and dry, apply antibiotic oint. if desired. Only local treatment needed. No further treatment anticipated.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271341-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.3	F	25-Jan-2007	25-Jan-2007	0	26-Jan-2007	30-Jan-2007	TN		01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	1	Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	UNKNOWN	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Wrong drug administered

**Symptom Text:** Patient was administered a vaccination of gardasil by accident instead of the scheduled comvax. It was administer on 1/25/06. It has been only one and no symptoms have been observed. Gardasil is approved for patients of 9 years to 26 years. No studies have been done for a patient of 15 months.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271365-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	01-Nov-2006	01-Nov-2006	0	29-Jan-2007	30-Jan-2007	KS	WAES0701USA02456	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a health professional concerning a 22 year old female patient who on approximately 01-NOV-2006 was vaccinated with a first IM dose of Gardasil vaccine (yeast). On approximately 01-NOV-2006 the patient experienced seizure. The reporter had no further information. It was noted that patient was 2 weeks late for her second dose of Gardasil vaccine (yeast) and had not yet received it. Upon internal review, seizure is considered an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271366-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	10-Nov-2006	11-Nov-2006	1	29-Jan-2007	30-Jan-2007	CT	WAES0701USA03418	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Condition aggravated, Crohn's disease

**Symptom Text:** Information has been received from a physician concerning a patient (age and gender unknown) with Crohn's disease who on 10-NOV-2006 was vaccinated intramuscularly with a 0.5 mL dose of Gardasil vaccine (yeast) (Lot # 653978/0955F). On 11-NOV-2006 the patient had a flair up of Crohn's disease after receiving the Gardasil vaccine (yeast). The flair up was so severe that the patient had to be out of school for a month. The patient sought unspecified medical attention. No product quality complaint was involved. At the time of this report, the patient was recovering. The flair up of Crohn's disease was considered to be disabling. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Crohn's disease

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271367-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		29-Jan-2007	30-Jan-2007	NY	WAES0701USA03718	30-Jan-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a physician concerning a female (age unspecified) with unspecified history of drug reaction/allergies and no pertinent medical history who on an unspecified date was vaccinated with Gardasil vaccine (yeast) (lot# not reported) 0.5 ml by injection. Concomitant therapy was not reported. Subsequently, the patient experienced a seizure after the injection of Gardasil vaccine (yeast). Medical attention was sought. At the time of reporting, the patient had recovered. Upon internal review, seizure was determined to be an Other Important Medical Event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271368-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	11-Jan-2007	13-Jan-2007	2	29-Jan-2007	30-Jan-2007	--	WAES0701USA02394	30-Jan-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female who on 11-Jan-2007 was vaccinated with Gardasil vaccine (yeast), intramuscularly. Concomitant therapy included Allegra and Nuvaring. On 13-Jan-2007 the patient had a "rash from her neck down". The patient was seen in the emergency room and was given Prednisone. At the time of the report, the patient was recovering. The reporter was considering giving the patient Benadryl and Prednisone before the next vaccination with Gardasil vaccine (yeast). The patient's experience was considered to be an other medical event. Additional information has been requested.

**Other Meds:** NUVARING, ALLEGRA

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271369-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	10-Jan-2007	10-Jan-2007	0	29-Jan-2007	30-Jan-2007	NJ	WAES0701USA03376	30-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Convulsion, Loss of consciousness

**Symptom Text:** Information has been received from a Registered Nurse concerning a female patient (demographics not reported) who on 10-JAN-2007 was vaccinated intramuscularly with the first dose of Gardasil vaccine (yeast) (lot # not provided). Concomitant therapy included BOOSTRIX and hepatitis A virus vaccine (manufacturer unknown). On 10-JAN-2007 immediately post vaccination the patient "passed out and went into a seizure." The patient sought unspecified medical attention. At the time of this report it was not reported if the patient had recovered from her experience. Upon internal review the seizure was considered to be an other medical event. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271387-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	26-Jan-2007	26-Jan-2007	0	29-Jan-2007	30-Jan-2007	DE		31-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Patient got dizzy, passed out.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271411-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	10-Jan-2007	12-Jan-2007	2	29-Jan-2007	30-Jan-2007	RI		09-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	HPV4

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Grand mal convulsion, Postictal state, Syncope

**Symptom Text:** 48 hours post injection-appeared to have witnessed tonic clonic seizures with postictal phase lasting less than 1 min. 03/01/07-records received from facility for DOS 01/12/2007-DX fainting. 03/01/07-records received from facility for DOS 01/12/2007-DX fainting.

**Other Meds:** Singulair

**Lab Data:** Ct- Brain Nec Labs received 3/1/07-strep screen negative for group A strep. CBC WNL except for lymphocyte 21.6. CT cranial-no intracranial abnormality. Some evidence her for mild paranasal sinus disease particularly on the left side

**History:** seasonal allergies, asthma

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271456-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	15-Jan-2007	17-Jan-2007	2	29-Jan-2007	01-Feb-2007	MO		01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2638AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0694F	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0954F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site oedema

**Symptom Text:** Mild erythema and edema to Left deltoid. Prescribed over the counter Motrin 400 mg every 6-8 hours as needed.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271470-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	24-Jan-2007	Unknown		30-Jan-2007	31-Jan-2007	CA		31-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2209AA	0	Right arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2310AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0868F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling

**Symptom Text:** Child attended Karate class and instructor was tapping the injection not knowing that the child had received immunizations the day before. Red swollen the size of a baseball at site of injection on right deltoid. Area was tender to touch.

**Other Meds:** None

**Lab Data:** None

**History:** eczema no allergies noted

**Prex Illness:** Seeing provider for eczema

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271473-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	17-Jan-2007	21-Jan-2007	4	30-Jan-2007	31-Jan-2007	MO		31-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Confusional state, Disorientation, Feeling abnormal

**Symptom Text:** Awoke from nap on 01/21/2007 and was disoriented and confused. Taken to the ER where multiple tests were performed. This last several hours. Psychiatry was consulted as well. Patient states she felt funny the next day, but was ok by 01/23/2007.

**Other Meds:** Lexapro

**Lab Data:** CBC, chemistry profile, thyroid tests, drug screen, head CT, EEG - all tests were NORMAL

**History:** Depression

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271476-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	26-Jan-2007	29-Jan-2007	3	31-Jan-2007	31-Jan-2007	CA		31-Jan-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** I began to itch 3 days after my vaccination shot. At first, I thought it was my eczema acting up, but then I began to itch and scratch all over my arms, underarms, legs, and on my hip bones. Hives have appeared on these areas. i applied flucanionide on the itchy areas, but they still remain itchy. I will see the doctor tomorrow, but I do not believe I can see the doctor who recommended the vaccination.

**Other Meds:**

**Lab Data:**

**History:** I have seasonal allergies, as well as allergies to animals, dust, plants, grasses, and trees.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271531-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		31-Jan-2007	01-Feb-2007	--	WAES0701USA04270	01-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a registered nurse (also reported as a physician) concerning a female who was vaccinated with her first dose of Gardasil vaccine (yeast) 0.5 ml. Subsequently the patient had a seizure. Subsequently, the patient recovered from the seizure. Therapy with Gardasil vaccine (yeast) will not be reintroduced. Upon internal review, seizure was considered an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271532-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	16-Jan-2007	16-Jan-2007	0	31-Jan-2007	01-Feb-2007	NC	WAES0701USA03520	01-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Hypersensitivity, Oxygen saturation normal

**Symptom Text:** Information has been received from a LPN concerning a 17 year old female with asthma who on 16-JAN-2007 was vaccinated with a first dose of Gardasil vaccine (yeast). On 16-JAN-2007 the patient experienced burning in her chest and lungs. The patient was seen at an Urgent Care facility and her lungs were found to be clear and her oxygen saturation was within normal limits. The Urgent Care physician's impression was that the patient experienced some type of allergic reaction. The patient was treated with Tylenol and Benadryl and instructed to come back if the symptoms did not improve or if they exacerbated. The LPN felt that there was a possibility of hospitalization at the time, however, at the time of this report, the patient was recovering and improving on treatment. No product quality complaint was involved. The reporter felt that allergic reaction was an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** pulse oximetry-within normal limits

**History:** ASTHMA

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271541-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	25-Jan-2007	25-Jan-2007	0	31-Jan-2007	01-Feb-2007	MA		01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Presyncope

**Symptom Text:** After receiving vaccine and getting off table felt dizzy walked to appointment desk and became very "oozy" almost fainted mom caught her put in trendelenberg position, given orange juice quickly felt better.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271545-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	27-Dec-2006	04-Jan-2007	8	31-Jan-2007	01-Feb-2007	MI		01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus, Rash, Urticaria

**Symptom Text:** One week after the injection,my daughter broke out with big hives,rash and itching. She was put on predizone.That did not sseem to help very much. It is a little over a month and she is better but still breaks out with red bumps and hives.

**Other Meds:** allegra

**Lab Data:**

**History:** allergic to peanuts

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271559-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	17-Jan-2007	25-Jan-2007	8	31-Jan-2007	01-Feb-2007	PA		01-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1046F	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash vesicular

**Symptom Text:** Started with signs of chicken pox 8 days after vaccine over entire back, neck, front, abdomen. No comitant symptoms no fever, no stomach symptoms, no pain, no cough, no runny nose, no sore throat. Positive puritis.

**Other Meds:** Asmarx, Albuterol, Florim cream

**Lab Data:**

**History:** Eczema, Asthma

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271577-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	04-Jan-2007	22-Jan-2007	18	01-Feb-2007	02-Feb-2007	--		05-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0637F		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash pruritic

**Symptom Text:** On 1/4/2007, pt was given first dose of Gardasil vaccine. Also, on that day, changed OCP from Lo-ovral to Ovcon-35 because of spotting. Presented 1/22/07 with pruritic rash consisting of fine erythematous papules on arms/legs/trunk

**Other Meds:** Ovcon-35

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271583-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	08-Jan-2007	08-Jan-2007	0	01-Feb-2007	02-Feb-2007	MD	WAES0701USA01621	02-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion induced, Drug exposure during pregnancy, Drug exposure during pregnancy, Pregnancy, Pregnancy test positive, Ultrasound scan

**Symptom Text:** Initial and follow up information has been received from a health professional concerning a 20 year old female patient with a history of 2 therapeutic abortions (2000 and 2004) abdominal pain, mild rectal bleeding, papilloma viral infection and sexually transmitted disease who on 08-JAN-2007 was vaccinated IM into the left deltoid with a second 0.5 ml of Gardasil vaccine (yeast) (lot#655619/1427F). Concomitant therapy included Risperdal and Celexa. The patient was reportedly pregnant at this time and did not tell the office. An HCG pregnancy test was done. The patient is scheduled for a prenatal visit on 19-JAN-2007. Her LMP was approximately 11-OCT-2006 and EDD 19-JUL-2007. An ultrasound on 18-JAN-2007 for gestational dates revealed of 7 weeks of 7 weeks and 3 days. The patient had an elective termination on 23-JAN-2007. There was no further information available. The patient received a first 0.5 ml dose of Gardasil vaccine (yeast) (lot#654540/0800F) on 23-OCT-2006 IM into the left deltoid. Upon internal review, elective termination was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Celexa, Risperdal

**Lab Data:** ultrasound 01/18/2007 - 7 week 3 day gestational dates urine beta-human 01/08?/07

**History:** Abdominal pain, Rectal bleeding, Papilloma viral infection, Sexually transmitted disease, Termination of pregnancy elective.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271607-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Jan-2007	30-Jan-2007	1	01-Feb-2007	02-Feb-2007	MA		02-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	1	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Rash, Rash, Rash, Swelling, Urticaria

**Symptom Text:** itching, swelling and hivelike rash with bumps on face the 1st day. next day, rash over face, neck, chest, upper arms. worse with exposure to cold air. resolved after warming about 15-20 min 1st day. 2nd day resolved with benadryl 25mg x 1.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271629-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	19-Jan-2007	19-Jan-2007	0	02-Feb-2007	05-Feb-2007	--		05-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

**Seriousness:** PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dizziness, Erythema, Nausea, Oedema peripheral, Pain in extremity

**Symptom Text:** Patient received 1st dose of Gardasil vaccine and the next day her arm got red and swollen and she experienced nausea and dizziness. 4 days later she reports arm continued to swell and be painful, but denies fever or chills. Patient was advised to take dihenhydramine and use ice on the area.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 661

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271631-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	06-Jan-2007	07-Jan-2007	1	02-Feb-2007	02-Feb-2007	NY		05-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	1210F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Headache, Malaise, Pruritus, Rash generalised, Sneezing, Throat irritation

**Symptom Text:** Very severe skin rash covering the entire body. Itchy skin, some sneezing scratchy throat. Headache, stomach ache overall feeling of being unwell. After 4 days rash not gone. Treatment: Benadryl every 5 hours, Aveeno baths.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271650-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	09-Jan-2007	14-Jan-2007	5	02-Feb-2007	05-Feb-2007	MA		05-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** 5 days after being administered the 2nd in a series of Gardasil developed hives requiring Benadryl and a visit to local ER. No facial edema, difficulty breathing or SOB occurred

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271654-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	24-Jan-2007	30-Jan-2007	6	02-Feb-2007	05-Feb-2007	SD		05-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	61784AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Aphthous stomatitis, Malaise, Pain, Pain, Pharyngolaryngeal pain

**Symptom Text:** Canker type sores in mouth still present. Complained of sore throat, achy, abdominal pain, general malaise the past couple of days but feeling better yesterday. Important to note is that she has a boyfriend who may have been infected with HG (herpes gladiatorum)-his wrestling team had "ringworm" and "staph" and now area wrestlers are showing up with HG which is said to be confused often times with staph skin infections. Cold sores are common with HG and are contagious of course, so it might be possible that she contracted the sores by kissing her boyfriend who may have been infected with HG?? Not sure and can't prove that he was infected.

**Other Meds:** Adderal and Seroquel

**Lab Data:** Started not feeling well 1/30/07 pm. Stayed home the next day (1/31/07) due to above listed complaints. That evening she developed bad stomach pain. Taken to ER to rule out appendicitis-felt much better the next day but then began developing

**History:** good physical health

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271695-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	29-Jan-2007	02-Feb-2007	4	05-Feb-2007	06-Feb-2007	RI		06-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011UEXP21MA R09	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash pruritic, Urticaria

**Symptom Text:** Patient complained of itchy rash on legs/arms for 3-4 days. She presented 2 days after the shot with raised hives on legs, feet and hands. She was placed on Medrol dose pack, Atarax, 100 1 qd

**Other Meds:** Fluoxetine, Zometa, Trisprintec

**Lab Data:** Allergic reaction, unspecified

**History:** Depression, No prior allergies

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271697-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	17-Jan-2007	17-Jan-2007	0	05-Feb-2007	06-Feb-2007	MI		06-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1162F	0	Gluteous maxima	Unknown	TD	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** Patient suffered a vasovagal (syncope) reaction after vaccine given. Sent to ER

**Other Meds:** NONE

**Lab Data:** EKG-ne

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271819-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		06-Feb-2007	07-Feb-2007	MA		07-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2158AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1447F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Musculoskeletal pain, Pain in extremity

**Symptom Text:** 2 days after giving Menactra and HPV vaccine #1, pt developed L shoulder and L arm pain, with ok strength but pain with motion.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271892-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	05-Feb-2007	05-Feb-2007	0	07-Feb-2007	09-Feb-2007	OH		09-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2157BA	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	1280F	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	00144	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Feeling abnormal, Loss of consciousness, Vomiting

**Symptom Text:** Pt was receiving Gardasil, Hep A and Then Menactra. Right after administering the Menactra she said I feel funny and passed out. She was out for about 10 seconds. Then vomited 1x. Said she felt really tired.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271896-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	26-Jan-2007	26-Jan-2007	0	07-Feb-2007	08-Feb-2007	NY	WAES0702USA00217	08-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Aphasia, Blood electrolytes normal, C-reactive protein normal, Chills, Computerised tomogram normal, Full blood count normal, Pharyngolaryngeal pain, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 24 year old female with no pertinent medical history and no history of drug reactions/allergies who on 26-JAN-2007 was vaccinated with Gardasil vaccine (yeast) (lot# not reported), IM. There was no concomitant medication. On 26-JAN-2007, the patient developed a sore throat, fever, and chills later that evening. She went to the emergency room on 30-JAN-2007 where she exhibited expressive aphasia. A computed tomography (CT) scan showed nothing. She was admitted to the hospital where she a neurology consult. All tests have come up negative (CT scan, magnetic resonance imaging, complete blood count, electrolytes, and C-reactive protein). The physician stated that the patient has 3 chinchilla pets and one of them has a fungal infection which is currently being treated with myconazole spray. The physician consulted the veterinarian as well as an infectious disease specialist. The physician saw the patient today and she was able to form some sentences. The physician is observing the patient and will order some additional tests. The physician reported the event will be a disability if this adverse event continues. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** computed axial 01/30/07 - negative, magnetic resonance 01/30/07 - negative, complete blood cell 01/30/07 - negative, serum c-reactive 01/30/07 - negative, serum electrolytes test 01/30/07 - negative, temperature measurement 01/30/07 - fever

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 669

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271904-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	04-Jan-2007	16-Jan-2007	12	07-Feb-2007	08-Feb-2007	--	200700247	08-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2091AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	DPHVA017A		Left arm	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Chest X-ray normal, Erythema multiforme, Genital pruritus female, Lip swelling, Pneumonia, Pyrexia, Rales, Rash, Urine analysis normal

**Symptom Text:** Initial report received on 26 January 2007, from another manufacturer, under the reference number B0454855A, concerning a patient. A 12 year old female patient, was enrolled in the other manufacturers study and received on 04 January 2007 a dose of Menactra (lot number U2091AA) intramuscular into the left upper deltoid and the first dose of study vaccine of Gardasil (lot number DHPVA017A). Since 16 January 2007, since 12 days post administration, the patient had been experiencing pneumonia and developed erythema multiforme and was hospitalized. The patient had been to the (study) office two days prior to admission with fever, swollen lips and vaginal itch. Exam failed to reveal significant findings other than rales over left posterior lung fields (urine analysis and chest X ray were normal). A clinical diagnosis of rash fitting description of erythema multiform was made. The patient was discharged with symptomatic treatment. She was seen in emergency room the next day and admitted on 18 January 2007 for intravenous treatment (rochepepin). The event was unresolved at the time of reporting. The other manufacturer's investigator considered that there was a reasonable possibility that the erythema multiforme may have been caused by Gardasil and Menactra and was due to pneumonia.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271932-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	07-Feb-2007	Unknown		07-Feb-2007	09-Feb-2007	AZ		09-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	UE552AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U22522A	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood glucose normal, Blood pressure normal, Convulsion, Electrocardiogram normal, Syncope vasovagal

**Symptom Text:** Patient had a vasovagal syncopal episode with seizure seconds after receiving the vaccine. Checked blood sugar and BP and EKG and everything looked normal. Observed patient in clinic and no problems after.

**Other Meds:**

**Lab Data:** EKG, Blood sugar

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271956-1      **Related reports:** 271956-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	23-Jan-2007	24-Jan-2007	1	08-Feb-2007	09-Feb-2007	MA		09-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV	UNKNOWN MANUFACTURER	1426F	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Nausea

**Symptom Text:** headache and nausea different than usual migraine for 2 wks beginning day after Gardasil vaccine administration

**Other Meds:** Mircette, Claritin prn, Imitrex, Naprosyn, Valtrex

**Lab Data:**

**History:** migraines, eczema, condyloma, herpes simplex, lactose intolerance

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271956-2      **Related reports:** 271956-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	23-Jan-2007	24-Jan-2007	1	16-Mar-2007	21-Mar-2007	MA	WAES0702USA01267	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1426F	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Sinusitis

**Symptom Text:** Information has been received from a certified medical assistant concerning a 23 year old female with migraine headaches who on 23-JAN-2007 was vaccinated IM with a second 0.5ml dose of Gardasil (lot #655205/1426F). The next day, the patient experienced headache and rated it 5 out of 10 on a pain scale. The patient took EXCEDRIN, EXCEDRINE MIGRAINE, TYLENOL, ALEVE, and IMITREX which did not relieve her headache. Her headache was constant. The patient also complained of nausea. On 08-FEB-2007, the patient was seen by her physician and was prescribed a Z pack and MUCINEX D for sinusitis. At the time of this report, the patient had not recovered. It was also reported that on 14-NOV-2006 the patient was vaccinated with a first dose of Gardasil. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 271999-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	15-Jan-2007	20-Jan-2007	5	09-Feb-2007	12-Feb-2007	NJ		12-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	V1974AM		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1425F		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abnormal sleep-related event, Dyskinesia, Tremor, Tremor

**Symptom Text:** Gardasil and Menactra given 1/11/07 beginning 1/22/07 jerking, tremors, shaking episodes occurring only during sleep

**Other Meds:**

**Lab Data:** EEG, CBC, SMAC, chest x-ray and barium swallow

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272010-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Feb-2007	12-Feb-2007	IL	WAES0702USA00543	13-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Computerised tomogram abnormal, Dizziness, Dizziness, Nausea, Vertigo

**Symptom Text:** Information has been received from a nurse concerning a female patient (age unknown) who, on an unspecified date, was vaccinated with a 0.5 ml dose of Gardasil vaccine (yeast). The day after vaccination, the patient felt dizzy and lightheaded and experienced nausea. The patient was admitted to the hospital for 2 days. A CT scan performed at the hospital revealed vertigo. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** computed axial - vertigo

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272037-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	08-Feb-2007	09-Feb-2007	1	09-Feb-2007	12-Feb-2007	CA		13-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral, Petechiae

**Symptom Text:** 14 y/o girl had distal swelling of both hands with erythema and some petechiae within one day of receiving 1st dose of gardasil. No other symptoms. Mother gave benadryl

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272065-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	07-Feb-2007	07-Feb-2007	0	09-Feb-2007	13-Feb-2007	TX		13-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness, Dyspnoea, Headache, Heart rate increased

**Symptom Text:** Headachem dizziness, increased heart rate, light-headness, shortness of breath. Symptoms began approximately 40 minutes after vaccination.

**Other Meds:** NONE

**Lab Data:** blood glucose 86 mg/dl, temperature 97.1, pulse 88 and regular, BP 110/76 SpO2 99%

**History:** ASTHMA

**Prex Illness:** NONE per patient

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272066-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	09-Feb-2007	09-Feb-2007	0	12-Feb-2007	14-Feb-2007	CA		14-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** R arm sore at injection site

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272080-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	02-Jan-2007	06-Jan-2007	4	12-Feb-2007	13-Feb-2007	--	WAES0701USA05054	13-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Haematoma, Injection site cellulitis, Injection site erythema, Injection site haematoma, Injection site induration, Injection site pain, Injection site pain

**Symptom Text:** Information has been received from a physician concerning her daughter, a 19 year old female who on 13-OCT-2006 was vaccinated with the first dose of Gardasil vaccine (yeast) (lot#653938/0954F) without any difficulties. On 02-JAN-2007 the patient received the second dose of Gardasil vaccine (yeast) (lot#654389/0961F). Concomitant therapy included fluoxetine HCl (SARAFEM) and "Femcon" (NOS). On approximately 06-JAN-2007 the patient developed a tender reddened firm area in her upper arm around the injection site that "hurt her to sleep on". On an unspecified date the patient went to the emergency room and was diagnosed with cellulitis and treated with Cephalexin (Keflex). After 10 days of treatment with cephalexin was completed the patient's "reddened firm area went down and was less tender". However, with 48 hours of stopping the therapy with cephalexin the area was "reddened, firm and tender". After 5 days the patient was seen at her university health services office, who "refused to treat her for cellulitis and referred her back to her gynecologist who gave her the vaccine". On approximately 01-FEB-2007 the patient was then seen by the internist who diagnosed her with a hematoma. At the time of this report the cellulitis was considered resolved and the hematoma was resolving. The physician reported that the patient will continue with the third vaccination in her other arm. The reporting physician consider the cellulitis to be a serious other medical event. Additional information has been requested.

**Other Meds:** Sarafem, Hormonal contraceptives.

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272081-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	25-Jan-2007	26-Jan-2007	1	12-Feb-2007	13-Feb-2007	NY	WAES0702USA00186	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Lethargy, Nausea, Rash pruritic

**Symptom Text:** Information has been received from a registered nurse concerning her 11 year old daughter with asthma, penicillin allergy and drug hypersensitivity to cephalexin (KEFLEX) who on 25-JAN-2007 was vaccinated with a dose of Gardasil vaccine (yeast). Concomitant therapy included lansoprazole (PREVACID), triamcinolone acetonide (NASACORT) and diphenhydramine HCl (BENADRYL). On 26-JAN-2007 the patient developed nausea, lethargy and a rash with pruritus on back. Unspecified medical attention was sought. There was no laboratory or diagnostic tests performed. At the time of the report, the patient was recovering. The registered nurse considered nausea, lethargy and pruritic rash to be disabling events. Additional information has been requested.

**Other Meds:** Benadryl, Prevacid, Nasacort

**Lab Data:** NONE

**History:** Asthma, Penicillin allergy, Drug Hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272082-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	25-Jan-2007	28-Jan-2007	3	12-Feb-2007	13-Feb-2007	UT	WAES0702USA00410	13-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fatigue, Injection site pain, Pruritus, Urticaria

**Symptom Text:** Information has been received from a Nurse Practitioner concerning a 19 year old white female who on 25-JAN-2007 was vaccinated intramuscularly with Gardasil (lot number not provided). On 28-JAN-2007 the patient experienced injection site pain and fatigue and developed pruritus and hives on her whole body. The patient was seen on an unspecified date by her primary care physician (contact information not provided) and treated with Vistaril 50 mg, PO every 6 hours and "comfort measures". On an unspecified date the patient was considered to have recovered from the hives, injection site pain and fatigue. The reporter considered the pruritus and hives to be serious other medical events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272106-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	04-Jan-2007	12-Jan-2007	8	12-Feb-2007	13-Feb-2007	PA		14-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Somnolence, Tremor

**Symptom Text:** Mother reported that on 1/12/07 patient was found in dorm room shaking rapidly, unarousable for several minutes, dizzy when she did awaken and complain of headache next day. College infirmary said normal BP and neuro status intact. Patient denies use of any alcohol or drugs.

**Other Meds:** NONE? Fluticasone?

**Lab Data:** NONE - no testing performed by school

**History:** NKA

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272108-1      **Related reports:** 272108-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	25-Jan-2007	26-Jan-2007	1	12-Feb-2007	13-Feb-2007	KS		14-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00110	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Pyrexia, Vomiting

**Symptom Text:** Headache, nausea, vomiting, subjective fever.

**Other Meds:** ZYRTEC, oral contraceptive pill

**Lab Data:**

**History:** Seasonal allergies

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272108-2      **Related reports:** 272108-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	25-Jan-2007	26-Jan-2007	1	16-Mar-2007	21-Mar-2007	KS	WAES0702USA00442	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Pyrexia, Vomiting

**Symptom Text:** Information has been received from a physician concerning a 15 year old female student with seasonal allergies who on 25-JAN-2007 at 3:00 Pm was vaccinated intramuscularly in the right deltoid with the first dose of Gardasil (lot #654702/0011U). There were no illnesses at time of vaccination. Concomitant therapy included hormonal contraceptives (unspecified). It was reported that on 26-JAN-2007, at 4:30AM, the patient experienced subjective fever, nausea, vomiting and headache. It was reported that the patient was unable to attend school for five days. The patient subsequently recovered from the events on 03-FEB-2007. No further information is expected.

**Other Meds:** Hormonal contraceptives

**Lab Data:** NONE

**History:**

**Prex Illness:** Seasonal allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272155-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	06-Feb-2007	07-Feb-2007	1	12-Feb-2007	15-Feb-2007	MD		16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TD	AVENTIS PASTEUR	U1704DA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Injection site induration, Injection site pain, Injection site pain

**Symptom Text:** 5cm tender induration at site (R biceps) with redness extending entire fore arm and pain at site of injection (Gardasil).

**Other Meds:**

**Lab Data:** Required ER TX plus 2 additional MD office visits RX Prednisone.

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272166-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	03-Jan-2007	Unknown		13-Feb-2007	15-Feb-2007	CA		15-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TYP	AVENTIS PASTEUR	205722	0	Unknown	Intramuscular	
	SMALL	WYETH PHARMACEUTICALS, INC	4020076	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pregnancy test negative, Pregnancy test positive

**Symptom Text:** Pt had negative pregnancy test 1/3/07, given smallpox vaccine and HPV. Had positive pregnancy test 1/27/07.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272170-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	04-Dec-2006	Unknown		13-Feb-2007	15-Feb-2007	TN		15-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site induration, Injection site pain, Nerve injury

**Symptom Text:** Knot on arm after x 2 days, nerve damage, pain at site.

**Other Meds:** Metformin

**Lab Data:** CT Scan

**History:** PCOS

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272173-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	22-Nov-2006	01-Dec-2006	9	13-Feb-2007	15-Feb-2007	VA		15-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paralysis

**Symptom Text:** Episodes of transient paralysis.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272191-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Dec-2006	21-Dec-2006	0	13-Feb-2007	14-Feb-2007	--	WAES0702USA00017	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Hypokinesia, Pain in extremity

**Symptom Text:** Information has been received from a physician concerning a 20 year old female with a penicillin allergy and no other reported health history who on 21-DEC-2006 was vaccinated with a first dose of Gardasil (lot # 654389/0961F) (0.5 ml), intramuscularly. Concomitant therapy included birth control pills. Subsequently, she had experienced severe pain in the arm since the vaccination. She was unable to raise her arm more than a 45 degree angle. She had been seen by her family physician who diagnosed her with "Frozen Arm Syndrome". it was reported that she would be seen by an orthopedic surgeon in a few days. It was noted that the patient is "thin build, weighed 119 pounds and was five feet six inches tall. It was noted that there was no previous injury to area or to arm. Unspecified medical attention was sought. At the time of the report, the patient was considered to be not recovered. The patient's experiences were considered to be disabling. Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:** UNK

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272192-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Nov-2006	01-Jan-2007	61	13-Feb-2007	14-Feb-2007	PA	WAES0702USA00726	14-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

**MedDRA PT** Blood glucose increased, Diabetes mellitus, Pollakiuria, Thirst

**Symptom Text:** Information has been received from a physician and the mother of a 12 year old female who in November 2006, was vaccinated intramuscularly with the first dose of Gardasil. It was reported that the patient returned to the physician's office to receive her second dose of Gardasil and the patient's mother mentioned to the physician that her daughter had recently complained of always being thirsty, frequent urination and her blood sugar was noted as 674. In January 2007, the patient was diagnosed with diabetes and was hospitalized. The patient was in the hospital for several days and was released (date unknown). At the time of this report, the outcome of the event was unknown. It was unknown if the patient received her second dose of Gardasil. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Blood glucose 674

**History:** UNK

**Prex Illness:** UNK

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272196-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Feb-2007	07-Feb-2007	0	13-Feb-2007	15-Feb-2007	NY		16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB115BA		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Fall, Head injury, Loss of consciousness, Tremor

**Symptom Text:** Approx 2-5 minutes after receiving vaccines patient passed out while getting dressed. There was no witness to the event. Patient lost consciousness and fell from the seated position hitting head in 3 places. Blood pressure had dropped. Patient had a short episode of tremors during the recovery phase. Patient was allowed to rest and rehydrate until blood pressure returned to normal (100/80) 30 minutes later.

**Other Meds:** NONE

**Lab Data:** Brain/C spin CT negative.

**History:** Allergic to Ceclor

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272208-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	07-Feb-2007	08-Feb-2007	1	13-Feb-2007	15-Feb-2007	FL		16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0186U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Malaise, Pruritus

**Symptom Text:** Pruritis, Malaise

**Other Meds:** Ibuprofen PRN

**Lab Data:**

**History:** Sulfa allergy, headaches, overweight, Metrol/ Menorrhagia.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272216-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	07-Nov-2006	07-Nov-2006	0	14-Feb-2007	15-Feb-2007	MD		15-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	08005	0	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1213R	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Malaise, Nausea, Vomiting

**Symptom Text:** On 11/7/2006, Patient was administered Hepatitis B vaccine (dose #2) and Gardasil (dose #1), and developed severe nausea and vomiting approximately 12 hours later, lasting for approximately 1 hour. Patient felt ill the following day, then recovered. No rash, no fevers. No other reactions. No prior reactions to HepB vaccine.

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272217-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	24-Jan-2007	24-Jan-2007	0	14-Feb-2007	15-Feb-2007	MD		15-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1162F	1	Left arm	Intramuscular	HEP

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Malaise, Nausea, Retching, Vomiting

**Symptom Text:** Patient administered vaccine, then developed severe nausea and vomiting including "dry heaves" approximately 6 hours later, lasting for approximately 1 hour. Patient felt ill the following day, and had vomiting x1 that morning. Then patient fully recovered,

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272237-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
39.0	F	30-Jan-2007	Unknown		14-Feb-2007	20-Feb-2007	TX		21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U	1	Right arm	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Erythema multiforme, Hypersensitivity

**Symptom Text:** See note (attached) 02/15/2007-record received and reviewed. Office visit of 02/08/07-Assessment. Allergic reaction on chest back and left arm. Patient thinks it is related to Gardasil. Received treatment in Mexico. Treated with Betamethasone. Diagnosed with erythema multiforme. Right arm at injection site is not irritated or edematous. Allergic reaction mostly in the contralateral side.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272245-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	09-Feb-2007	10-Feb-2007	1	14-Feb-2007	15-Feb-2007	TN		16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	HPV4

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oedema, Pruritus, Rash

**Symptom Text:** 16 year old female developed edema, rash and pruritus within 24 hours of receiving second Gardasil shot.

**Other Meds:** oral contraceptives

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272267-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	26-Jan-2007	Unknown		15-Feb-2007	16-Feb-2007	MD		16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Nausea, dizziness

**Other Meds:** Zolof

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 697

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272272-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	17-Oct-2006	16-Oct-2006	-1	15-Feb-2007	16-Feb-2007	WA	WAES 0610USA12632	05-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, No adverse effect, Wrong drug administered

**Symptom Text:** Initial and follow up information has been received through the Merck regulatory pregnancy registry from a registered nurse at a health department and an unspecified family member concerning a 23 year old white female smoker who was 34 weeks pregnant with cervical incompetence, allergies to erythromycin and moxifloxacin hydrochloride (AVALOX) and had a history of premature labour from a prior pregnancy, a history of 3 pregnancies and 2 live births, a yeast infection, a threatened abortion, "ruptured membranes/delivery" and cervical dysplasia that had required a LEEP surgery, however, this procedure was not performed as the patient became pregnant. On 14-APR-2006, the patient underwent an ultrasound which revealed "positive intrauterine pregnancy (IUP), gestational sac only, negative fetal heart tone, right corpus". On 21-APR-2006, the patient underwent an ultrasound which revealed "positive intrauterine pregnancy (IUP), positive fetal heart tone, singleton, right corpus". On 02-MAY-2006, the patient underwent an ultrasound which revealed "positive intrauterine pregnancy (IUP), positive fetal heart tone, singleton, right corpus" and "gestational age, threatened abortion". On 26-JUN-2006, the patient underwent a maternal serum alphafetoprotein (MSAFP) which revealed "in range normal". It was reported that on an unspecified date, the patient had been hospitalized due to "lower back contractions". The patient had been diagnosed with a kidney infection and was advised to see her primary care physician for a flu shot. On 17-OCT-2006, (conflicting information also reported as 20-OCT-2006), the patient went to her physician and received one dose of 0.5 mL of HPV rL1 6 11 16 18 VLP vaccine (yeast) administered intramuscularly instead of the flu shot. Concomitant therapy included prenatal vitamins and unspecified therapies (reported as "tributylene", "suflexan" and "cyclomenzaprene"). On 16-OCT-2006 (conflicting information also reported as 20-OCT-2006), the patient was not having any adverse reaction. It was reported tha

**Other Meds:**

**Lab Data:** Test, Date, Value, Unit, Normal Range, Comment diagnostic nonstress test, 06/26/06, "maternal serum alphafetoprotein-in range normal" fetal nonstress test, 11/15/06 fetal nonstress test, 11/15/06 fetal nonstress test, 11/16/06 fetal no

**History:** Hospitalisation: premature labour, yeast infection, artificial rupture of membrane, abortion threatened. Pregnancy NOS (LMP=3/1/2006), kidney infection, smoker, premature labour, cervical dysplasia, cervical incompetence, allergic reaction to antibiotic, hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 698

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272273-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Aug-2006	01-Aug-2006	0	15-Feb-2007	16-Feb-2007	FL	WAES 0611USA05105	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** Information has been received from a physician concerning an approximately 17 year old female with plantar warts since August 2005 who in August 2006, was vaccinated with fist dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. In September 2006, the patient received second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) 1 month after the first dose. The patient sought medical attention. The physician noted as of 16-NOV-2006, the patient's plantar warts resolved. The patient noticed that the plantar warts resolved (on an unspecified date in 2006) after the second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) was received. A different physician administered the HPV rL1 6 11 16 18 VLP vaccine (yeast). No other information was available at the time of reporting. Additional information was received from the physician who reported that is not an adverse event. The warts had been present for 2 years and were refractory to liquid nitrogen, imiquimod (ALDARA CREAM), and laser treatment. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** plantar warts

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272274-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.0	F	15-Dec-2006	15-Dec-2006	0	15-Feb-2007	16-Feb-2007	NC	WAES 0612USA02803	16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	
	HIBV	MERCK & CO. INC.	NULL		Unknown	Unknown	
	FLU	AVENTIS PASTEUR	427U7AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MMR	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Pyrexia, Wrong drug administered

**Symptom Text:** Initial and follow up information has been received from a physician and an office manager concerning a 12 month old white female patient with no past medical history who on 15-DEC-2006 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant vaccinations on the same day included a first dose of measles-mumps-rubella vaccine (MSD) SC into the left leg, Hib conj vaccine (OMPC) (manufacturer unknown) and a first dose of varicella virus vaccine live (MSD) SC into the left leg. Other concomitant vaccinations included a first dose of influenza virus split virion 3v vaccine inactivated (FLUZONE) (lot# 427U7AA) IM into the right leg. It was reported that the patient received HPV rL1 6 11 16 18 VLP vaccine (yeast) by accident. She was supposed to receive a dose of pneumococcal 4 6B 9V 14 18C 23F conj vaccine (CRM197) (PREVNAR). The reporter stated that the products were clearly labeled; there was not a confusion of products. It was "lack of education" of the medical assistant working on the office. The parents reported the patient had slight fever on 16-DEC-2006 (also reported as the 17-DEC-2006). Subsequently, the patient was seen in the office on 18-DEC-2006 and had recovered from slight fever. There were no there reported problems or "any other adverse events." Additional information is not expected.

**Other Meds:**

**Lab Data:** Test, Date, Value, Unit, Normal Range, Comment-body temp, 12/17/06, slight fever

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272275-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	27-Dec-2006	27-Dec-2006	0	15-Feb-2007	16-Feb-2007	--	WAES 0701USA00257	16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a nurse concerning her daughter, a 13 year old female who on 27-DEC-2006 was vaccinated with the second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On 27-DEC-2006 the patient developed dizziness and nausea. The patient's dizziness and nausea persisted. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 701

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272276-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	08-Dec-2006	08-Dec-2006	0	15-Feb-2007	16-Feb-2007	NH	WAES0701USA00266	16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	MNQ	AVENTIS PASTEUR	NULL	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fall, Feeling abnormal, Headache, Headache, Injury, Loss of consciousness, Pallor, Syncope

**Symptom Text:** Information has been received from a physician concerning a 12 year old female with no illness at the time of vaccination who on 08-DEC-2006 was vaccinated with a 0.5 ml first dose of Gardasil (yeast) (lot 653938/0954F). On 08-DEC-2006, the patient was concomitantly vaccinated with a first dose of Menatra, a dose of influenza virus vaccine (unspecified) and a dose of Boostrix. On 08-Dec-2006, the patient fainted shortly after vaccination. She fell from a standing position and hit the back of head on the floor. She was unconscious for approximately 30 seconds, and then was dazed and pale. The patient was "ok" after a few minutes. The patient complained of a headache, frontal to occipital. The patient was "ok" at home later that evening. The patient recovered with no sequelae on 08-DEC-2006. Additional information is not expected.

**Other Meds:**

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272277-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Nov-2006	21-Dec-2006	50	15-Feb-2007	16-Feb-2007	--	WAES0701USA00386	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Human papilloma virus test positive

**Symptom Text:** Information has been received from a female patient who in November 2006, was vaccinated with the second dose of Gardasil (yeast). It was reported that the patient received the first vaccination in September 2006. On 21-Dec-2006, the patient underwent an "HPV DNA" test. The results indicated that the patient tested positive for HPV type 16. The patient sought unspecified medical attention. The patient's outcome was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** diagnostic laboratory 12/21/06 - "HPV DNA" test positive for type 16

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272278-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	01-Dec-2006	01-Dec-2006	0	15-Feb-2007	16-Feb-2007	NH	WAES0701USA00406	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia, Sinus congestion

**Symptom Text:** Information has been received from a physician concerning a 24 year old female patient with NKDA who on 01-DEC-2006 was vaccinated into the left deltoid with a first dose of Gardasil (yeast) (lot#653978/0955F). At the time of vaccination the patient had "mild URI symptoms and a cold" with no fevers. In the week following vaccination, the patient developed a temperature of 101.5 and her URI progressed to sinus congestion and cough. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** body temperature 12/01?/06 101.5

**History:** NONE

**Prex Illness:** Cold; upper respiratory tract infection

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272279-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	01-Dec-2006	Unknown		15-Feb-2007	16-Feb-2007	WA	WAES0701USA00410	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypertension

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who in approximately December 2006, " a few weeks ago," was vaccinated with a dose of Gardasil (yeast) (lot#654885/1424F). Subsequently, "after her first shot" the patient developed hypertension. The patient sought unspecified medical attention. The patient's outcome was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272280-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	03-Jan-2007	03-Jan-2007	0	15-Feb-2007	16-Feb-2007	PA	WAES0701USA00415	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who on 03-Jan-2007 was vaccinated with a 0.5 ml dose of Gardasil (yeast). There was no concomitant medication. On 03-Jan-2007, after receiving the vaccination, the patient fainted. Unspecified medical attention was sought. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272281-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	24-Oct-2006	01-Nov-2006	8	15-Feb-2007	16-Feb-2007	--	WAES0701USA00441	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Amenorrhoea

**Symptom Text:** Information has been received from a nurse practitioner and healthcare worker concerning a 13 year old female who on 24-OCT-2006 was vaccinated intramuscularly with a first 0.5 mL dose of Gardasil (yeast) (lot# not reported). There was no concomitant medication. She was administered a second 0.5 ml dose of Gardasil (yeast), intramuscularly on 26-DEC-2006. It was reported that the patient, who has had her regular menses since the age of 10, had not had her regular menses in November 2006 or December 2006. The patient reported no other problems and was not reported to be pregnant. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272282-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA00481	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Pain

**Symptom Text:** Information has been received from a registered pharmacist, also the patient, via a company representative, concerning herself. The pharmacist reported that during her second dose of Gardasil (yeast), she experienced a tremendous amount of stinging. She also noted that the second day after vaccination she was still very sore. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272283-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA00488	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning four patients who were vaccinated with Gardasil (yeast). Subsequently the four patients experienced a fainting episode. At the time of the report, it was not reported if the four patients recovered. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272284-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	07-Dec-2006	07-Dec-2006	0	15-Feb-2007	16-Feb-2007	OH	WAES0701USA00569	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who on 07-DEC-2006 was vaccinated intramuscularly with a second dose of Gardasil (yeast). On 07-Dec-2006 the patient experienced significant arm pain, including through the passive motion. The physician reported that the patient was sent to see an orthopedic physician on 03-JAN-2007 because the patient was a dancer and could not dance with extreme pain. At the time of this report, the outcome was unknown. It was also reported that the patient was vaccinated with a first dose of Gardasil (yeast) on 12-OCT-2006 and there was no adverse experience with this initial dose. No product quality complaint involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272285-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA00596	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>		<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.		NULL		Unknown		Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Amenorrhoea

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who an unspecified date was vaccinated intramuscularly with a 0.5 ml dose of Gardasil (yeast) (lot number not reported). The nurse reported that the patient, after receiving the Gardasil (yeast), did not receive her next expected period. The patient sought unspecified medical attention. At the time of this report, the outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272286-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	02-Jan-2007	02-Jan-2007	0	15-Feb-2007	16-Feb-2007	AZ	WAES0701USA00601	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Subcutaneously		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Incorrect route of drug administration, Injection site bruising, Injection site reaction, Injection site swelling

**Symptom Text:** Information has been received from al licensed practical nurse concerning a 17 year old female with no pertinent medical history, who on 02-JAN-2007 was vaccinated with the first dose of Gardasil. There was no concomitant medication. The nurse reported that the patient received the vaccination via the subcutaneous route and on 02-JAN-2007, developed in injection site reaction. The reaction was described as being that of a swollen and bruised injections site on the patients shoulder. Unspecified medical attention was sought. The patient subsequently recovered on 03-JAN-2007.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272287-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	MI	WAES0701USA00616	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of Gardasil. subsequently, following vaccination, the patient loss consciousness. The patient regained consciousness after a few minutes. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272288-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	CA	WAES0701USA00621	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation irregular

**Symptom Text:** Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL. Subsequently, following the second vaccination, the patient experienced irregular periods. Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272289-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA00644	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with pertinent medical history and drug reactions/allergies not reported who on an unspecified date was vaccinated with the first dose of Gardasil, injection, 0.5ml. Concomitant medications was not reported. Subsequently on an unspecified date, the patient developed a rash on her chest and arm after receiving the first dose of Gardasil. The physician gave the patient an antihistamine (unspecified) and the rash on her chest and arm cleared in about 20 minutes. Subsequently the same day, the patient recovered from rash on her chest and arm. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272290-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	06-Sep-2006	06-Sep-2006	0	15-Feb-2007	16-Feb-2007	--	WAES0701USA00697	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female with pertinent medical history reported as none and allergic reaction to some antibiotics who on 06-SEP-2006 was vaccinated with the first dose of Gardasil. Concomitant medication was reported as none. On approximately 06-SEP-2006, the patient developed injection site pain that lasted 3 days following vaccination with Gardasil. On an unspecified date, the patient sought unspecified medical attention. On approximately 08-SEP-2006, the patient recovered from injection site pain. The patient had not received her second dose of Gardasil. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** Allergic reaction to antibiotics.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272291-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	30-Dec-2006	01-Jan-2007	2	15-Feb-2007	16-Feb-2007	WV	WAES0701USA00701	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pregnancy test negative, Uterine haemorrhage

**Symptom Text:** Information has been received from a registered nurse and physician assistant certified concerning a 16 year old female with on known drug allergies, no illness at time of being vaccinated, and no medical history who on 30-DEC-2006 was vaccinated with first dose of Gardasil (lot #654741/1208F) intramuscularly left deltoid at 1400 hours. There was no concomitant medication. On 01-JAN-2007, at 1400 hours the patient experienced abnormal uterine bleeding (Spotting) uncomplicated and sought medical attention. The patient already had her period (normal menses 27-DEC-2006) and had been "spotting all during this past week". They thought pregnancy was possible so they administered a urine pregnancy test (negative) and she was not pregnant. She had no abdominal pain and no previous history of abnormal uterine bleeding. The outcome of the uterine bleeding was not reported. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** Urine beta human 01/01/07 negative

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272292-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA00702	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning her niece a female (age not reported) with pertinent medical history and drug reactions/allergies not reported who in 2006 was vaccinated with the first and second doses of Gardasil, IM (1st and 2nd dose over a two month period). Concomitant medication was not reported. Subsequently on an unspecified date, the patient experienced vomiting and diarrhea after the first and second doses of Gardasil series. The patient sought unspecified medical attention. The nurse reported that the patient does not plan to have the third dose as recommended. Subsequently on an unspecified date, the patient recovered from vomiting and diarrhea. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272293-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	19-Dec-2006	28-Dec-2006	9	15-Feb-2007	16-Feb-2007	--	WAES0701USA00749	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Injection site rash, Tenderness

**Symptom Text:** Information has been received from a physician and the mother of a 12 year old female with pertinent medical history and drug reactions/allergies reported as none who on 19-DEC-2006 was vaccinated with the first dose of Gardasil (lot #655165/1425F). concomitant therapy included tetanus toxoid. On 28-DEC-2006, the patient experienced a rash at the injection site right after receiving the vaccination. The patient also experienced mild headaches almost immediately. A few days later the patient's headaches became more intense. The patient still experienced intermittent headaches but the severity has not decreased. On 31-DEC-2006, the patient presented to the physician office and complained that she had a headache for four days. The patient was told by the physician to increase the dosage of Motrin. On 01-JAN-2007, the patient presented to the physician office again and stated that she was not better and still had a headache. The physician stated when the patient pressed over her sinus area it seemed tender. The patient was treated with oral antibiotics. The patients headache persisted. Additional information has been requested.

**Other Meds:** Tetanus toxoid

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272294-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	04-Jan-2007	05-Jan-2007	1	15-Feb-2007	16-Feb-2007	--	WAES0701USA00770	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0689F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity, Paraesthesia

**Symptom Text:** Information has been received from a pharmacy intern concerning an 18 year old female with no pertinent medical history and no known adverse drug reactions and no known allergies reported. On 04-JAN-2007, the patient was vaccinated intramuscularly in the left arm with the first 0.5ml dose of Gardasil (lot #653736/0689F). There were no concomitant medications reported. On 05-JAN-2007, in the morning, the patient developed tingling in the fingers and her left hand with pain in the fingertips when touching anything. The patient sought unspecified medical attention. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272295-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Dec-2006	29-Dec-2006	7	15-Feb-2007	16-Feb-2007	NY	WAES0701USA00778	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1425F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Rash

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with a sulfonamide allergy and no other pertinent medical history reported. On 22-DEC-2006, the patient was vaccinated with 0.5ml of Gardasil ( Lot #655165/1425F). There were no concomitant medications reported. On 29-DEC-2006, one week after the injection, the patient developed a rash on her arms, legs and abdomen. The patient sought unspecified medical attention. It was reported that the rash had since cleared up but the date was unknown. At the time of this report, the patient had recovered from the event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272296-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	27-Dec-2006	Unknown		15-Feb-2007	16-Feb-2007	NY	WAES0701USA00786	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning a 25 year old female with no drug allergies who on 27-Dec-2006 was vaccinated with the first dose of Gardasil (yeast). Concomitant therapy included ZITHROMAX. Subsequently, on an unspecified date, the patient experienced nausea and dizziness. The patient did not seek medical attention. No diagnostic studies were performed. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** ZITHROMAX

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272297-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	KY	WAES0701USA00800	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a 15 year old female patient who was vaccinated with a first and second dose of Gardasil (yeast). Subsequently the patient fainted 15 minutes after each vaccination. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272298-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	CA	WAES0701USA00828	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a 23 year old female office employee in her office with drug reactions/allergies and pertinent medical history reported as unspecified who on an unspecified date was vaccinated with first dose of Gardasil (yeast) (lot# not reported) intramuscularly. Concomitant therapy was unspecified. On an unspecified date, the patient was vaccinated in the gluteal area and she experienced injection site pain. The patient sought medical attention. At the time of reporting, the outcome of the event was unspecified. No other information was provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272299-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA00832	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Influenza like illness, Stomach discomfort

**Symptom Text:** Information has been received from a nurse practitioner concerning her 18 year old daughter with drug reactions/allergies and medical history reported as unspecified who in approximately 2007 was vaccinated with second dose of Gardasil (yeast) (lot # not reported) 0.5 ml intramuscularly. Concomitant medication was unspecified. In approximately 2007, after the second dose of Gardasil (yeast), the patient experienced dizziness, and stomach upset. They were flu-like symptoms. The patient sought medical attention. At the time of reporting, the patient had recovered. No additional information was available at the time of reporting. Additional has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272300-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	13-Oct-2006	13-Oct-2006	0	15-Feb-2007	16-Feb-2007	KY	WAES0701USA00860	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a medical assistant concerning a 16 year old female with drug reactions/allergies to CECLOR and penicillin who on 13-OCT-2006 was vaccinated intramuscularly with the first 0.5 ml dose of Gardasil (yeast), (lot#653978/0955F). Concomitant therapy included OVRAL. It was reported the patient fainted with the first vaccination. On 13-DEC-2006, the patient was vaccinated intramuscularly with the second 0.5 ml dose of Gardasil (yeast) (lot#65389/0961F). The patient lay down for 25 minutes after the vaccination to prevent fainting. It was reported that the patient fainted again while she walked out to the waiting room. The patient recovered on the same day. Additional information has been requested.

**Other Meds:** OVRAL

**Lab Data:** NONE

**History:**

**Prex Illness:** allergic reaction to antibiotics; Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272301-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	05-Jan-2007	05-Jan-2007	0	15-Feb-2007	16-Feb-2007	KY	WAES0701USA00872	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 20 year old female who on 05-JAN-2007 was vaccinated intramuscularly with the first dose of Gardasil (yeast). Concomitant therapy included hormonal contraceptives (unspecified). The physician reported that the patient was extremely nervous about getting the shot. Later that evening, within 12 hours, the patient broke out in hives. The physician told the patient to go to the emergency room (ER). The patient went to the ER and was given BENADRYL for the hives. The physician reported that the patient was fine, but does not plan to give the patient anymore shots. There was no lot number provided. At the time of this report, it was noted that the patient was "fine after she had received BENADRYL. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** UNK

**History:**

**Prex Illness:** Nervousness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272302-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	20-Nov-2006	22-Nov-2006	2	15-Feb-2007	16-Feb-2007	MI	WAES0701USA00894	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Acne

**Symptom Text:** Initial information has been received from a physician via a company representative and follow-up information has been received from the physician concerning a 14 year old female student who, on 20-NOV-2006, was vaccinated with a 0.5 ml dose of Gardasil (yeast) (lot# not reported). There was no concomitant medication. Subsequently, on approximately 22-NOV-2006 or 23-NOV-2006, the patient developed a bad acne breakout. The physician reported that the patient developed "giant pimples" the likes of which she'd not experienced previously. The patient was reported to have been using over the counter acne wash which had been working well up to this point. The patient was put on oral antibiotics and given a topical wash for the breakout, which occurred on her face, chest and back. The patient's acne breakout was continuing at the time of the report. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272303-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	20-Oct-2006	05-Nov-2006	16	15-Feb-2007	16-Feb-2007	--	WAES0701USA00975	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0588F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea

**Symptom Text:** Information has been received from a physician concerning a 15 year old female patient with allergic rhinitis who on 20-OCT-2006 was vaccinated intramuscularly in the morning with a first dose of Gardasil (yeast) (lot#653735/0688F). Illness at the time of vaccination included pharyngitis. Concomitant therapy included amoxicillin. In the evening of 05-NOV-2006, three weeks after vaccination, the patient developed shortness of breath. The patient had no history of asthma. Subsequently, on an unspecified date, the patient recovered. Additional information is not expected.

**Other Meds:** amoxicillin

**Lab Data:** UNK

**History:**

**Prex Illness:** Pharyngitis, Rhinitis allergic

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 729

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272304-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	10-Nov-2006	10-Nov-2006	0	15-Feb-2007	16-Feb-2007	CA	WAES0701USA00990	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bronchospasm, Cough

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female with asthma and allergic eczema who on 10-NOV-2006 at 12:00PM, was vaccinated in the right arm intramuscularly with a first 0.5 ml dose of Gardasil (yeast) (lot#653978/0955F). Concomitant suspect vaccination included a dose of tetanus toxoid on 10-NOV-2004. Other concomitant therapy included albuterol and ZYRTEC. There was no illness at the time of vaccination. On 10-Nov-2006 the patient experienced bronchospasm 20 minutes after receiving Gardasil (yeast). It was also reported that the patient developed a cough but she did not vomit. The patient used her albuterol inhaler and then rested and was recovered on the same day, 10-NOV-2006. No vomiting and no other anaphylaxis type reaction was noted. Additional information is not expected.

**Other Meds:** albuterol, ZYRTEC, tetanus toxoid

**Lab Data:** UNK

**History:**

**Prex Illness:** Asthma, Allergic eczema

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272305-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Jan-2007	09-Jan-2007	1	15-Feb-2007	16-Feb-2007	MA	WAES0701USA01015	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1425F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female with asthma and no known allergies or adverse drug reactions reported. On 08-JAN-2007, the patient was vaccinated intramuscularly with the first 0.5 ml dose of Gardasil (yeast) (lot#655165/1425F). Concomitant therapy included hormonal contraceptives (unspecified) and albuterol. On 09-JAN-2007, the patient developed a rash on her back and chest. The patient sought unspecified medical attention. The patient was being treated with BENADRYL. At the time of this report, the patient had not recovered from the event.

**Other Meds:** albuterol, hormonal contraceptives

**Lab Data:** NONE

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272306-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	22-Dec-2006	22-Dec-2006	0	15-Feb-2007	16-Feb-2007	NY	WAES0701USA01016	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1424F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Malaise, Nausea, Syncope

**Symptom Text:** Information has been received from a physician concerning a 19 year old female with a penicillin allergy and no other pertinent medical history reported. On 22-DEC-2006, the patient was vaccinated intramuscularly with one dose of Gardasil (Lot #654885/1424F). Concomitant therapy included Ortho Tri Cyclen. On 22-DEC-2006, the patient felt nauseous shortly after administration. The patient then fainted for approximately 10 seconds while she was at the office. The patient remained in the office until she felt normal again. The patient then went home where later she felt sick again. The patient went to the emergency room and was then released. It was reported that there were no laboratory diagnostics performed at the physician's office and it was unknown if any were performed in the emergency room. At the time of this report, the patient had recovered from the events (date unknown). Additional information has been requested.

**Other Meds:** Ortho Tri Cyclen

**Lab Data:** NONE

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272307-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	09-Nov-2006	09-Nov-2006	0	15-Feb-2007	16-Feb-2007	--	WAES 0701USA01050	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 20 year old female patient with no allergies or medical history who on 09-NOV-2006, was vaccinated with the first 0.5 L, dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot unspecified). Concomitant therapy included penicillin. On 09-NOV-2006, at 1:30 P.M., the patient developed chills and fever of 102.7 degrees on 10-NOV-2006 at 7:00 P.M. The patient did not seek medical attention. The patient treated herself with acetaminophen (TYLENOL). The patient's symptoms lasted until noon on 11-NOV-2006. Additional information has been requested.

**Other Meds:** penicillin (unspecified)

**Lab Data:** test, date, value unit, normal range, comment body temp, 11/10/06, 102.7 degr

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272308-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	29-Dec-2006	29-Dec-2006	0	15-Feb-2007	16-Feb-2007	--	WAES0701USA01079	19-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning an 18 year old female with pertinent medical history and drug reaction/allergies not reported who on 29-DEC-2006 was vaccinated with the first dose of Gardasil (Lot #654885/1424F), injection, 0.5ml. Concomitant medication was not reported. ON 29-DEC-2006, the patient developed hives within hours of receiving the first dose of Gardasil. The physician reported that the hives became more generalized within 24 hours. On 29-DEC-2006, therapy with human papillomavirus vaccine was discontinued. Subsequently on an unspecified date, the patient recovered from hives. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272309-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	08-Jan-2007	08-Jan-2007	0	15-Feb-2007	16-Feb-2007	--	WAES0701USA01084	19-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Nausea

**Symptom Text:** Information has been received from a consumer through the pregnancy registry concerning a 15 year old daughter with pet allergies who on 08-JAN-2007 was vaccinated with the first dose of Gardasil. Concomitant therapy included prenatal medication (therapy unspecified) and erythromycin. On 08-JAN-2007, the patient was vaccinated with Gardasil and the patient was 14 weeks pregnant. The clinic administered the vaccine without confirming if her daughter was pregnant. The consumer stated that her daughter has experienced nausea since she received Gardasil. The physician did not administer the vaccine to the patient as she received the vaccination at a clinic. On 08-JAN-2007 therapy with Gardasil was discontinued. The outcome of the events was not reported. Additional information has been requested.

**Other Meds:** Therapy unspecified, erythromycin

**Lab Data:**

**History:** Pregnancy NOS (LMP Unknown) allergy to animal

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272310-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Jan-2007	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA01086	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Paraesthesia

**Symptom Text:** Information has been received from a physician's assistant concerning a female who on 08-JAN-2007 was vaccinated intramuscularly with a dose of Gardasil. Subsequently the patient passed out and experienced tingling sensation from her shoulder to her fingertips. It was reported that the patient did not seek medical attention. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272311-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	--	WAES0701USA01095	06-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy, Vaccine positive rechallenge

**Symptom Text:** Information has been received from a physician concerning a 14 year old female who was vaccinated with the first dose of Gardasil. Subsequently the patient experienced swollen lymph nodes on the same side as the injection two days after receiving the injection. The patient recovered from the swollen lymph nodes after the first injection with Gardasil. Two days after the second dose of Gardasil, the patient again experienced swollen lymph nodes on the same side as the injection. Clinical outcome related to the second occurrence of swollen lymph nodes in unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272312-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	02-Jan-2007	02-Jan-2007	0	15-Feb-2007	16-Feb-2007	--	WAES0701USA01236	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Oedema peripheral, Pain in extremity

**Symptom Text:** Information has been received from a health professional concerning a female pharmacist who on 02-JAN-2007 was vaccinated with a second dose of Gardasil. On 02-JAN-2007, the patient experienced a strong stinging sensation during vaccination. After vaccination, her arm swelled and was very sore. On 03-JAN-2007, the patient recovered. It was reported that the patient did not experience any of these symptoms with the first vaccination with Gardasil. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272313-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	27-Dec-2006	27-Dec-2006	0	15-Feb-2007	16-Feb-2007	PA	WAES0701USA01335	19-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse and a physician via a company representative concerning an 18 year old female who on 27-DEC-2006 was vaccinated intramuscularly with one dose of Gardasil (lot 653978/0955F). On 27-DEC-2006 the patient passed out after getting Gardasil. The patient sought unspecified medical attention. It was not reported if the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272314-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Nov-2006	27-Nov-2006	6	15-Feb-2007	16-Feb-2007	--	WAES0701USA01358	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Information has been received from a nurse practitioner concerning her daughter, a 20 year old female with possible human papilloma virus prior to May 2006 who had an abnormal Papanicolaou (PAP) smear and colposcopy, June 2006 who on 21-NOV2006 was vaccinated with a 0.5ml dose of Gardasil. Concomitant therapy included Yasmin. On 27-NOV-2006, the patient developed genital warts. The patient required laser surgery on 08-JAN-2007. Laboratory evaluation included hemoglobin. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** Yasmin

**Lab Data:** Hemoglobin

**History:** Papanicolaou smear abnormal

**Prex Illness:** Surgery

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272315-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	10-Nov-2006	Unknown		15-Feb-2007	16-Feb-2007	CA	WAES0701USA01378	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysmenorrhoea

**Symptom Text:** Information has been received from a physician concerning a 16 year old female patient with on pertinent medical history or drug reactions/allergies, who on 10-NOV-2006 was vaccinated intramuscularly with the first dose of Gardasil (lot #653937/0637F). There was no concomitant medication. Subsequently, on an unspecified, the patient experienced severe cramping during her menstrual cycle. Unspecified medical attention was sought. The physician stated that no further doses of Gardasil will be given until further information was received. At the time of this report, the patient was recovering. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 741

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272316-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	10-Nov-2006	12-Nov-2006	2	15-Feb-2007	19-Feb-2007	CA	WAES0701USA01392	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Contusion

**Symptom Text:** Information has been received from a physician and a certified medical assistant concerning a 14 year old female with no pertinent medical history who on 10-NOV-2006 was vaccinated IM with a first dose of Gardasil (lot #653937/0637F). There was no concomitant medication. On 12-NOV-2006 the patient developed "bad bruise". Unspecified medical attention was sought. On approximately 29-NOV-2006, the patient recovered. There were no laboratory or diagnostic tests performed. The physician reported that no further doses of Gardasil will be given until further information is received. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272317-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	22-Dec-2006	22-Dec-2006	0	15-Feb-2007	16-Feb-2007	--	WAES0701USA01401	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a 20 year old female who on 22-DEC-2006 was vaccinated with Gardasil (yeast) (lot number 653978/0955F). On 22-DEC-2006 the patient passed out after vaccination. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272318-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	08-Jan-2007	10-Jan-2007	2	15-Feb-2007	16-Feb-2007	--	WAES0701USA01402	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Pain, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 19 year old female who on 08-Jan-2007 was vaccinated with Gardasil (yeast) (lot number 655165/1425F) 0.5 ml intramuscularly. On 10-JAN-2007 the patient experienced 102 degrees F fever, chills and body aches for "the past 10 hours". The patient's 102 degrees F fever and chills and body aches persisted. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272319-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	08-Dec-2006	7	15-Feb-2007	16-Feb-2007	NJ	WAES0701USA01409	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Upper respiratory tract infection

**Symptom Text:** Information has been received from an office manager concerning a female patient who on 01-DEC-2006 was vaccinated with a dose of Gardasil (yeast). One week later the patient developed a rash and an upper respiratory tract infection. She was treated with BENADRYL and ORAPRED. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272320-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	04-Jan-2007	09-Jan-2007	5	15-Feb-2007	16-Feb-2007	PA	WAES0701USA01412	19-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness

**Symptom Text:** Information has been received from an R.N. concerning a 19 year old female patient who on 09-JAN-2007 was vaccinated IM with a dose of GARDASIL (lot #653978/0955F) and felt dizzy and lightheaded. Medical attention was sought. At the time of the report the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272321-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	08-Jan-2007	08-Jan-2007	0	15-Feb-2007	16-Feb-2007	NY	WAES0701USA01532	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female who on 08-JAN-2007 was vaccinated IM with a dose of Gardasil (yeast). It was noted that the patient fainted during the administration of the vaccine, the patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272322-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	TX	WAES0701USA01535	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with Gardasil (yeast). Subsequently the patient fainted. Unspecified medical attention was sought. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272323-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	04-Jan-2007	04-Jan-2007	0	15-Feb-2007	16-Feb-2007	OH	WAES0701USA01567	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling abnormal

**Symptom Text:** Information has been received from a registered nurse concerning a 26 year old female with no medical history or allergies, who on 04-JAN-2007 was vaccinated IM with a 0.5 ml dose of Gardasil (yeast). There was no concomitant medication. On 04-JAN-2007 the patient felt dizzy and had a sensation of hands being pressed down on her head. No other symptoms were noted. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. The symptoms lasted about 15 to 20 minutes and then resolved. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272324-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	TN	WAES0701USA01586	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female between 15 and 16 years old who was vaccinated with a 0.5 ml dose of Gardasil (yeast). After receiving the vaccine, the patient fainted. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272325-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	IA	WAES0701USA01747	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inflammation, Pain in extremity, Physiotherapy, Radiculitis brachial

**Symptom Text:** Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with the first dose of Gardasil (yeast). Subsequent following vaccination, the patient experiences extreme pain in the arm and inflammation. The patient underwent physical therapy and was diagnosed as having brachial neuritis. It was not specified if the series of Gardasil (yeast) would be completed. At the time of this report, the patient was recovering from the brachial neuritis. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** magnetic resonance - narrative

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272326-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	04-Oct-2006	07-Oct-2006	3	15-Feb-2007	21-Feb-2007	NY	WAES0701USA01772	06-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Vaccine positive rechallenge, Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning a 16 year old female with an aspirin allergy who on 04-OCT-2006 at 16:00 and 11-DEC-2006 at 14:30 was vaccinated IM into the right deltoid with a first and second dose of Gardasil (first dose lot #653736/0689F, second dose lot #654510/0962F). Concomitant therapy given on 04-OCT-2006 and 11-DEC-2006 included a dose of Havrix. Three days after the first dose, the patient vomited for 2 days and was out of school. Three days after the second dose the patient threw up a lot more for 2 days and was out of school. The nurse was concerned about this patient and considered her condition to be disabling since she missed school for two days after each dose. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. No product quality complaint was involved. Additional information is not expected.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:** Drug hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272327-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	21-Dec-2006	Unknown		15-Feb-2007	16-Feb-2007	FL	WAES0701USA01775	16-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0961F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Musculoskeletal pain

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female with no pertinent medical history and no known allergies who on 21-DEC-2006 was vaccinated into the right arm with a 0.5 ml first dose of Gardasil (yeast) (lot#654389/0961F). Concomitant therapy included unspecified over the counter vitamin supplements. Subsequently the patient experienced severe deep pain in her right shoulder. Unspecified medical attention was sought and there was no treatment given. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** vitamins (unspecified)

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272328-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	07-Jan-2007	07-Jan-2007	0	15-Feb-2007	16-Feb-2007	NY	WAES 0701USA01778	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 12 year old female with diabetes and eczema who on approximately 07-JAN-2007 was vaccinated with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) concomitantly with a dose of an unspecified vaccine. On approximately 07-JAN-2007, later in the night, the patient developed hives all over her body, mostly on her legs. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** diabetes, eczema

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272329-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	PA	WAES0701USA01779	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Syncope

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a first dose of Gardasil (yeast). Subsequently the patient complained of pain and then fainted within minutes of administration. Subsequently, the patient recovered without any additional treatment. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272330-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	02-Nov-2006	01-Dec-2006	29	15-Feb-2007	16-Feb-2007	PA	WAES 0701USA01810	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** HIV test false positive

**Symptom Text:** Information has been received from a physician concerning a 17 year old female with no medical history or allergies, who on 14-AUG-2006 on 02-NOV-2006 was vaccinated IM with a first and second 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. In December 2006, the patient had a false positive HIV result. It was noted that the physician stated that the patient had no risk factors for HIV. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** Serum HIV-1 p24, 12/06, false positive

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272331-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	WA	WAES 0701USA01889	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on an unknown date was vaccinated intramuscularly with the first dose of 0.5 mL of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently, it was reported that the patient felt faint post vaccination. The patient sought unspecified medical attention. At the time of this report, it was unknown if the patient had recovered from the event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272332-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	16-Feb-2007	WA	WAES 0701USA01890	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on an unknown date was vaccinated intramuscularly with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (Lot# not provided). Subsequently, it was reported that the patient felt faint post vaccination. The patient sought unspecified medical attention. At the time of this report, it was unknown if the patient had recovered from the event.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272333-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	12-Dec-2006	Unknown		15-Feb-2007	16-Feb-2007	--	WAES 0701USA01933	19-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female who on 12-DEC-2006 was vaccinated with her second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced pain down her arm one month after receiving her second dose. The patient's pain down her arm persisted. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272334-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	12-Jan-2007	Unknown		15-Feb-2007	16-Feb-2007	--	WAES 0701USA01947	19-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure, Syncope

**Symptom Text:** Information has been received from a physician concerning a 13 year old female who on 12-JAN-2007 was vaccinated with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) 0.5 ml intramuscularly. The patient fainted when she got outside in the parking lot of the physician's office (also reported as within 10 minutes). The patient was brought back into the physician's office and "let rest for a while". The physician checked the patient's blood pressure (no details provided). The physician noted that the patient is "fine now". Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272335-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	07-Dec-2006	08-Dec-2006	1	15-Feb-2007	16-Feb-2007	CA	WAES0701USA01976	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fluid retention, Weight increased

**Symptom Text:** Information has been received from a medical assistant concerning a 38 year old female with edema who on 07-DEC-2006 was vaccinated IM, into the deltoid, with a 0.5 ml first dose of Gardasil (yeast). Concomitant therapy included hormonal contraceptives (unspecified). On 08-Dec-2006 the patient "gained 13 pounds of water weight". Medical attention was sought and the patient was treated with unspecified diuretics. On approximately 29-Dec-2006, the patient recovered from "gained 13 pounds of water weight". Additional information has been requested.

**Other Meds:** Hormonal contraceptives

**Lab Data:** UNK

**History:**

**Prex Illness:** Edema

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272336-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	19-Sep-2006	Unknown		15-Feb-2007	16-Feb-2007	NJ	WAES 0701USA01977	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female who on 19-SEP-2006 was vaccinated IM with a first 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient experienced pain at the injection site. Unspecified medical attention was sought. It was reported that the patient did not return to complete the schedule. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272337-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	16-Nov-2006	16-Nov-2006	0	15-Feb-2007	16-Feb-2007	--	WAES0701USA02079	19-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Subcutaneously	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Discomfort, Dizziness, Incorrect route of drug administration

**Symptom Text:** Information has been received from a health professional concerning a 21 year old female patient with a history of anemia who on 16-NOV-2006 was vaccinated SC with a first 0.5 ml dose of Gardasil (yeast) (lot#653938/0954F). The patient reported feeling lightheaded and uncomfortable after the first dose was given. No further information was provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Anemia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272338-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	28-Dec-2006	01-Jan-2007	4	15-Feb-2007	16-Feb-2007	PA	WAES0701USA02086	19-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness, Paraesthesia

**Symptom Text:** Information has been received from a nurse concerning an 18 year old female with pertinent medical history and drug reactions/allergies unspecified who on 28-DEC-2006 was vaccinated with Gardasil (yeast) (lot# not reported) injection. Concomitant therapy unspecified. On 01-Jan-2007, the patient passed out. Medical attention was sought. The patient later reported that she was experiencing light headedness and tingling in her hands and feet on 02-JAN-2007. The patient was referred to a cardiologist. The patient had a carotid ultrasound and echocardiogram performed on 05-JAN-2007 and 11-JAN-2007, respectively (results not reported). At the time of reporting, the tingling in her hands and feet persisted. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** carotid artery 01/05/07 - result not reported, echocardiography 01/11/07 - result not reported

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272339-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	19-Feb-2007	CA	WAES0701USA02093	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysmenorrhoea

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated, intramuscularly with the first, 0.5 ml dose of Gardasil. The patient concomitantly received Menactra and Dtap. The patient complained that her subsequent menstrual period was "much more painful than usual" with severe menstrual cramping. The patient sought unspecified medical attention. At the time of the report, it was unknown if the patient recovered. Additional information has been requested.

**Other Meds:** Therapy unspecified, Menactra, Dtap

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272340-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	11-Oct-2006	11-Oct-2006	0	15-Feb-2007	20-Feb-2007	CA	WAES 0701USA0111	21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2455AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	652809/1008F		Unknown	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2002AC		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site anaesthesia, Injection site pain, Paraesthesia, Similar reaction on previous exposure to drug

**Symptom Text:** Information has been received from registered nurse concerning a 11 year old female who on 11-OCT-2006 at 15:30, was vaccinated with the first dose of Gardasil (yeast) (lot number 654540/0800F) intramuscularly in the left deltoid. Concomitant vaccinations included hepatitis A vaccine (inactive) (MSD) (lot number 652809/1008F) intramuscularly in the right deltoid, meningococcal ACYW conj vaccine (MENACTRA) (lot number U2002AC) intramuscularly in the right deltoid and (ADACEL) (lot number C2455AA) intramuscularly in the left deltoid. On 11-OCT-2006 the patient stated that her arm tingled and felt numb at the injection site (arm not specified). Tingling and numbness lasted one hour. After that the patient stated the arm was just sore at the injection site. On 27-DEC-2006 was vaccinated with the second dose of Gardasil vaccine (yeast). On 27-DEC-2006 the patient again experienced arm tingled at injection site, but it "just lasted a few minutes". Additional information is not expected.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272341-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	16-Nov-2006	16-Nov-2006	0	15-Feb-2007	20-Feb-2007	WA	WAES0701USA02175	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Pain in extremity

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on approximately 16-Nov-2006, about two months ago, was vaccinated with a 0.5 ml dose of Gardasil. On approximately 16-Nov-2006, the patient developed swelling of the arm (unspecified) after the injection and experienced pain in her whole arm. The patient sought unspecified medical attention. The patients arm pain persisted. although, the outcome of the patients arm swelling was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272342-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	11-Nov-2006	11-Nov-2006	0	15-Feb-2007	16-Feb-2007	WA	WAES 0701USA02181	16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Contusion, Injection site swelling, Tenderness

**Symptom Text:** Information has been received from an R.N. concerning a 22 year old female patient with an allergy to codeine who on 11-NOV-2006 was vaccinated with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast); and according to the nurse, developed severe swelling on the injection site arm after the first dose. The patient received the first vaccination at another office and no information was available on where the first vaccination was administered or the physician involved in the first vaccination. On 16-JAN-2007 the patient was seen in the office. She was breast feeding, and was reported to have been breast feeding when the first vaccination was administered. The patient reported that she had developed an egg shaped swelling at the injection site on the left upper arm that lasted for more than one week after the first vaccination. No timeline on the development of the swelling in relation to the vaccination was available. The arm was still bruised and tender 2 months after the first vaccination. The second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) has not been administered. At the time of the report, the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272343-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	15-Jan-2007	15-Jan-2007	0	15-Feb-2007	20-Feb-2007	FL	WAES0701USA02188	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site swelling, Oedema peripheral

**Symptom Text:** Information has been received from a RN concerning a 13 year old female patient who on 15-Jan-2007 was vaccinated IM with a dose of Gardasil, lot #6536978/0955F. Several hours later, the patient experienced pain and swelling at injection site and extending into her hand. There were no other symptoms noted. Medical attention was sought. At the time of the report the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272344-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	MI	WAES0701USA02260	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of Gardasil. Subsequently, following vaccination, the patient lost consciousness. The patient regained consciousness after a few minutes. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272345-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	20-Feb-2007	MI	WAES0701USA02261	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of Gardasil (0.5 ml). Subsequently, following vaccination, the patient lost consciousness. The patient regained consciousness after a few minutes. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272346-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	20-Feb-2007	MI	WAES0701USA02262	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of Gardasil (0.5 ml). Subsequently, following vaccination, the patient lost consciousness. The patient regained consciousness after a few minutes. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272347-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	27-Dec-2006	27-Dec-2006	0	15-Feb-2007	20-Feb-2007	OH	WAES0701USA02336	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a registered nurse concerning a 19 year old female who on 27-DEC-2006 was vaccinated in the arm (unspecified) with the first dose of Gardasil (lot #654885/1424F). There was no concomitant medication. On 24-DEC-2006, the patient developed a rash up and down both arms. The patient's rash was treated with Benadryl. Subsequently, after three days, the patient recovered from the rash. It was reported that the event did not require an emergency room/doctor visit. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272348-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES0701USA02347	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Amenorrhoea

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who on an unspecified date was vaccinated with a dose of Gardasil (lot number not reported). The nurse reported that the patient, after receiving the Gardasil, did not received her next expected period. The patient sought unspecified medical attention. At the time of this report. the outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272349-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	20-Feb-2007	--	WAES0701USA02348	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation delayed

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who on an unspecified date was vaccinated with dose (lot number not reported). The nurse reported that the patient, after receiving the Gardasil, did not received her next expected period. The patient sought unspecified medical attention. At the time of this report, the outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272350-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	01-Nov-2006	01-Nov-2006	0	15-Feb-2007	20-Feb-2007	VA	WAES0701USA02369	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site irritation, Loss of consciousness, Vomiting

**Symptom Text:** Information has been received from a 24 year old female with an unremarkable medical history and no known allergies or adverse drug reactions reported. In November 2006, the patient was vaccinated intramuscularly in the left arm with the first 0.5 ml dose of Gardasil. concomitant therapy included influenza virus vaccine (unspecified) and hormonal contraceptives (unspecified). In November 2006, right after she received her first injection of Gardasil, the patient vomited and the passed out. The patient developed burning at injection site. The patient sought unspecified medical attention. It was reported that the patient was alright after about 20 minutes after the injection. The patient plans to receive her second shot on 17-JAN-2007. In November 2006, the same day that the first dose of the vaccine was administered, the patient had recovered from the events. Additional information has been requested.

**Other Meds:** Hormonal contraceptives, influenza virus vaccine

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272351-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	08-Jan-2007	10-Jan-2007	2	15-Feb-2007	20-Feb-2007	NY	WAES0701USA02390	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 20 year old female with high blood pressure and an allergy to sulfa. On 08-Jan-2007, the patient was vaccinated intramuscularly with a first 0.5 ml dose of Gardasil (lot #655619/1427F). Concomitant therapy included Micronor. On 10-JAN-2007, the patient developed intermittent hives. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the event. Additional information has been requested.

**Other Meds:** Micronor

**Lab Data:** NONE

**History:** Blood pressure high, sulfonamide allergy.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272352-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	15-Jan-2007	15-Jan-2007	0	15-Feb-2007	20-Feb-2007	WA	WAES 0701USA02393	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a 26 year old female with a drug hypersensitivity to tetracycline, prochlorperazine maleate (COMPAZINE) and doxycycline and no other pertinent medical history reported. On 15-JAN-2007, the patient was vaccinated intramuscularly with HPV rL1 6 12 16 18 VLP vaccine (yeast). Concomitant therapy included a "steroid shot" and unspecified hormonal contraceptives. On 15-JAN-2007, the patient developed a terrible rash. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the event. Additional information has been requested.

**Other Meds:** corticosteroids, hormonal contraceptives

**Lab Data:** NONE

**History:** drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272353-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	01-Nov-2006	01-Nov-2006	0	15-Feb-2007	20-Feb-2007	MI	WAES 0701USA02404	06-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0702F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysgeusia, Vaccine positive rechallenge

**Symptom Text:** Information has been received from a licensed partner nurse concerning her 20 year old white daughter student with pertinent medical history and drug reactions/allergies reported as unspecified who on 01-NOV-2006 was vaccinated with first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 653650/0702F) IM left arm at 1500 hours. On approximately 17-JAN-2007, the patient was vaccinated with a second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # not reported). Following each dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), the patient experienced a metallic taste. The metallic taste was more pronounced after the first dose. The patient sought medical attention. Subsequently, the patient recovered. No other information was available at the time of reporting. Additional information was received from the licensed practical nurse. The patient complained of strong "metal" taste at the back of her tongue immediately after the first injection. This odd taste sensation lasted somewhere between 30 and 60 seconds and then slowly disappeared after 2 to 3 minutes. No additional information is expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272354-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	19-Feb-2007	PA	WAES0701USA02411	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site swelling, Syncope

**Symptom Text:** Information has been received from a physician concerning several females who on unspecified dates were vaccinated with Gardasil 0.5 ml by injection. Subsequently, several patients fainted after receiving Gardasil and several patients experienced pain and swelling at the injection site. Medical attention was sought. The outcome of the events was unspecified. No additional information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272355-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		15-Feb-2007	19-Feb-2007	--	WAES0701USA02415	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician's assistant concerning a 15 year old female who on unspecified dates was vaccinated intramuscularly in the arm with the first and second dose of Gardasil. Within 24 hours of receiving the first and second dose of Gardasil the patient developed a localized rash on the forearm. It was reported that the patient went to a dermatologist for the rash. It was reported that the events disappeared after a day or so. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272356-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	19-Feb-2007	--	WAES0701USA02455	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a 0.5 ml dose of Gardasil. Subsequently the patient developed a rash. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 782

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272357-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		15-Feb-2007	20-Feb-2007	--	WAES 0701USA02651	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site irritation, Injection site pain, Injection site swelling

**Symptom Text:** Information has been received from a registered nurse concerning "several" patients who were vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patients subsequently complained of a little arm soreness after the vaccination. All patients recovered from arm soreness. On unknown dates, patients were vaccinated with second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patients experienced pain, swelling and irritation at injection site. The nurse noted that she used 3 or 4 different lots, and the patients were complaining that "it hurt quite a bit when the medicine was being injected into the arm". The nurse further commented that the patients did not complain about this with the first dose. The patients went home after the office visit. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272366-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Feb-2007	09-Feb-2007	1	15-Feb-2007	16-Feb-2007	MA		16-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1161F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Vomiting

**Symptom Text:** Pt recived vaccine 5pm 2/8/07. Pt began vomiting and diarrhea 4am 2/9/07. Pt had no fever. Pt given IV fluids.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272384-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	03-Jan-2007	05-Jan-2007	2	15-Feb-2007	16-Feb-2007	CA		05-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1140F	1	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0651F		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0637F	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Induration

**Symptom Text:** Left upper, outer arm, 4 cm induration with erythema. Benadryl, Motrin RTC

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272387-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	15-Feb-2007	15-Feb-2007	0	15-Feb-2007	16-Feb-2007	--		16-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B009AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Heart rate increased, Tremor

**Symptom Text:** C/O dizziness "can't breath" observed tremor of hands states heart beating rapidly (AP=72/min)

**Other Meds:**

**Lab Data:**

**History:** Exercise induced asthma.

**Prex Illness:** URI and pharyngitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272399-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	01-Feb-2007	02-Feb-2007	1	16-Feb-2007	19-Feb-2007	MI		19-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1065F	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0962F	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B007AA	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1892AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Hypotension, Somnolence, Vomiting

**Symptom Text:** Early in the am of 2/2/2007, patient woke with sudden onset of vomiting, dizziness, and severe headaches. Seen by primary care physician later in the day with noticeable hypotension. Remained in bed over the weekend, sleeping most of the time and taking Motrin for headache.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 787

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272430-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	31-Oct-2006	30-Nov-2006	30	16-Feb-2007	19-Feb-2007	FL	WAES0702USA01168	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Pregnancy, Systemic lupus erythematosus

**Symptom Text:** Information has been received from a 26 year old female consumer with migraine headaches, who on approximately 31-OCT-2006 ("end of October or beginning of November 2006"), was vaccinated with the first dose of Gardasil (yeast). Concomitant therapy included propranolol HCL for migraine headaches. Subsequently, the patient "became pregnant at the end of November 2006," and reported " a normal pregnancy with no adverse side effects". The approximate LMP date was 30-NOV-2006, with an estimated due date of 06-SEP-2007. Additionally, on approximately 28-DEC-2006 ("approximately six weeks ago"), the patient was diagnosed with lupus (not further specified), and daily injections of LOVENOX were initiated as treatment. Unspecified blood tests were performed (results not reported). At the time of the report, the patient had not recovered. Upon internal review, the patient's diagnosis of lupus was considered to be an other important medical event. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Propranolol Hydrochloride

**Lab Data:** diagnostic laboratory 11/??/06 -

**History:**

**Prex Illness:** Pregnancy NOS (LMP= 11/30/2006), Migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 788

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272431-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	12-Jan-2007	13-Jan-2007	1	16-Feb-2007	19-Feb-2007	CA	WAES0702USA00888	19-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Brain scan normal, Condition aggravated, Dystonia, Pain, Tic, Torticollis

**Symptom Text:** Information has been received from a health professional concerning a 14 year old female with allergies to Prozac and Seroquel and a history of dystonic reaction involving the right arm, right leg and neck in 2006 caused by an allergic reaction to Seroquel who on 12-JAN-2007 was vaccinated IM with a first dose of Gardasil. Concomitant therapy included hormonal contraceptives (unspecified) and Prevacid. On 13-JAN-2007 the patient experienced a tic disorder involving her head and neck. The patient also had a rapid, involuntary, spasmodic dystonic reaction and torticollis like movement that appeared painful and continued during sleep. On 13-JAN-2007, the patient was examined in the emergency room and was given Benadryl and Ativan and was released. A CT scan of the brain was negative. On 15-JAN-2007, she was examined by her primary care physician and was given Benadryl IM. She was later examined on 15-JAN-2007 by a neurologist and was given Cogentin IM and was started on oral benztropine mesylate (MSD). ON 17-JAN-2007, 19-JAN-2007, and 05-FEB-2007, the patient was also examined by a neurologist. On 19-JAN-2007 the symptoms began to resolve and on 05-FEB-2007 completely resolved. The patient will continue with Cogentin until 19-FEB-2007. Tic disorder, rapid, involuntary, spasmic dystonic reaction and torticollis like movement were considered to be other important medical events and disabling. Additional information has been requested.

**Other Meds:** Hormonal contraceptives, Prevacid

**Lab Data:** head computed axial 01/13/07 - negative

**History:** Dystonic reaction

**Prex Illness:** Drug hypersensitivity

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272477-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	20-Feb-2007	OH	WAES 0701USA02867	21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site induration

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) concomitantly with a dose of MENACTRA and a dose of DTaP. Subsequently the patient developed knot at the injection site where she received DTaP. It was reported that the patient with a knot or "raised area" that was 1 and 1/2 inches long. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272478-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	17-Jan-2007	17-Jan-2007	0	15-Feb-2007	20-Feb-2007	CT	WAES 0701USA02982	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness, Malaise, Myalgia

**Symptom Text:** Information has been received from a physician concerning a female who on 17-JAN-2007 was vaccinated with a 0.5 ml first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On 17-JAN-2007 the patient experienced flu-like symptoms described as malaise and myalgia. Unspecified medical attention was sought. At the time of the report, the patient was recovering. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272479-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	21-Dec-2006	21-Dec-2006	0	15-Feb-2007	20-Feb-2007	NY	WAES 0701USA03006	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653735/0688F	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Flushing, Nausea

**Symptom Text:** Information has been received from a health professional concerning a 21 year old white female with no medical history, who on 21-DEC-2006 was vaccinated in the left deltoid with the second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot# 653735/0688F). There were no illnesses at the time of vaccination. On 21-DEC-2006, following vaccination, the patient felt faint and queasy and her face appeared flush. The patient's blood pressure was 102/60. The patient was given a cold drink of water and a cold compress and remained seated for 10 minutes and subsequently felt fine. The patient stated that "needles make her scared". No further information is expected.

**Other Meds:** UNK

**Lab Data:** blood pressure, 12/21/06, 102/60

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272480-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	08-Nov-2006	08-Nov-2006	0	15-Feb-2007	20-Feb-2007	VA	WAES0701USA03029	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653978/0955F		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site discolouration, Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female with no past medical history and no drug allergies who on 08-NOV-2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot# 653978/0955F) (0.5 ml), intramuscularly in the left deltoid. Concomitant therapy included minocycline HCl (MINOCIN). On 08-NOV-2006 the patient experienced skin discoloration around injection site. The discoloration was slightly lighter than her skin color and was shaped like a "C" to the other side was 20 mm. The area was not raised or sore. She mentioned that she had some mild soreness at the injection site for one to two days after the vaccine was initially administered. The patient had no other symptoms. There were no relevant diagnostic tests performed. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Minocin

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272482-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	14-Dec-2006	14-Dec-2006	0	15-Feb-2007	20-Feb-2007	--	WAES 0701USA03080	20-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fatigue

**Symptom Text:** Information has been received from a physician concerning a female who on 14-DEC-2006 was vaccinated by injection with the first dose of HPV vaccine (yeast). On 14-DEC-2006 the patient experienced fatigue after HPV vaccine (yeast) was administered. The patient received the second dose of HPV vaccine (yeast) on 15-JAN-2007 and did not experience any further symptoms. The patient sought unspecified medical attention. At the time of the report, it was unknown if the patient had recovered. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272483-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	18-Jan-2007	18-Jan-2007	0	15-Feb-2007	20-Feb-2007	HI	WAES 0701USA03099	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia

**Symptom Text:** Information has been received from a physician concerning a 17 year old female with no pertinent medical history and no drug reactions/allergies who on approximately 18-JAN-2007 was vaccinated with HPV vaccine (yeast) (lot # not reported) injection, 0.5 ml, in her left upper arm. There was no concomitant medication. On 18-JAN-2007, the patient developed pain and soreness in both sides of her hips. The patient sought medical attention. No lab diagnostic tests were performed. The patient stated that as of 18-JAN-2007, she only feels pain when she touches the side of her hips. At the time of reporting the outcome was unspecified. No other information was provided by the physician. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272484-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	21-Dec-2006	21-Dec-2006	0	15-Feb-2007	20-Feb-2007	AL	WAES 0701USA03182	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site induration

**Symptom Text:** Information has been received from an office manager concerning a 16 year old female who on 21-DEC-2006 was vaccinated in the arm (unspecified) with the first dose of HPV vaccine (yeast). There was no concomitant medication. On approximately 21-DEC-2006, after receiving the vaccination, the patient developed a "knot" at the injection site. The patient sought unspecified medical attention. The "knot" at the patient's injection site persisted. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272485-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	22-Dec-2006	22-Dec-2006	0	15-Feb-2007	20-Feb-2007	MI	WAES 0701USA03195	20-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2141AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	653938/0954F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling hot

**Symptom Text:** Information has been received from a registered nurse concerning a 14 year old white female (weight 118#, height 60.75") with otitis, sore throat, congestion, runny nose, amoxicillin and erythromycin allergy who on 22-DEC-2006 was vaccinated with the first dose of HPV vaccine (yeast) (lot # 653938/0954f), IM. Concomitant therapy included MENACTRA (lot # U2141AA), IM. On 22-DEC-2006 after the vaccine while at the check out window, the patient stated that she felt hot, felt her vision was fading and felt faint. The registered nurse held her arm and walked with her back to an exam room where she had her lay down and elevated her legs on two pillows for 15 minutes. The patient's feeling passed. When the patient first returned to the exam room the physician checked her and then checked her when she felt better. After 15 minutes of lying down. Subsequently, the patient recovered from the events that same day. Additional information has been requested.

**Other Meds:**

**Lab Data:** blood pressure, 12/22/06, 98/60, normal

**History:** otitis; sore throat; nasal congestion; runny nose; penicillin allergy; allergic reaction to antibiotics

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272486-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	05-Jan-2007	05-Jan-2007	0	15-Feb-2007	20-Feb-2007	--	WAES 0701USA03348	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urinary tract infection

**Symptom Text:** Information has been received from a physician concerning a 14 year old female patient who on approximately 05-JAN-2007 was vaccinated at another physicians office with HPV vaccine (yeast) (lot # not provided). On an unspecified date in January 2007, the patient was seen by the reporting physician for a suspected urinary tract infection (lab results not provided). The patient sought unspecified medical attention. At the time of this report it was unknown if the patient had recovered from the event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272487-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	15-Jan-2007	15-Jan-2007	0	15-Feb-2007	20-Feb-2007	--	WAES 0701USA03429	20-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a 14 year old female who on 15-JAN-2007 was vaccinated, intramuscularly with the first dose of HPV vaccine (yeast), (lot # not reported). On 15-JAN-2007 the patient fainted after receiving the vaccination. The patient was seen in the Emergency Room (ER) following vaccination and "no problems were found". At the time of the report, it was unspecified, if the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272488-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	22-Nov-2006	Unknown		15-Feb-2007	21-Feb-2007	IN	WAES 0701USA03430	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Papilloma viral infection

**Symptom Text:** Information has been received from a registered nurse concerning a 19 year old female with allergy to cefaclor (CECLOR) who on 22-NOV-2006 was vaccinated with the first dose of HPV vaccine (yeast). Concomitant therapy included ethinyl estradiol (+) etonogestrel (NUVARING), lansoprazole (PREVACID) and minocycline HCl. On 03-JAN-2007, the patient had a cervical (PAP) smear. The patient tested positive for Papilloma viral infection (HPV). On 11-JAN-2007, the patient was vaccinated with the second dose of HPV vaccine (yeast). (Lot # 655617/1447F). The patient sought unspecified medical attention. At the time of the report, it was unknown if the patient recovered. Additional information has been requested.

**Other Meds:** Nuvaring, Prevacid, minocycline hydrochloride

**Lab Data:** cervical smear, 01/03/07 (+), positive for HPV

**History:** Allergic to antibiotics

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272489-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Jan-2007	01-Jan-2007	0	15-Feb-2007	20-Feb-2007	CA	WAES 0701USA03436	20-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injury, Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse via a company representative concerning a 16 year old female who, "the other night", was vaccinated with a first dose of HPV vaccine (yeast) (lot# not reported). The nurse reported that girl passed out in the office and hit her head after receiving a first dose of vaccine. The girl was unconscious in the office waiting room 3 to 4 minutes. It was reported that the patient was "revived" by using ammonia inhalant, and "seemed to take longer than expected to regain consciousness." The patient was administered an office neurological exam which was "ok and the patient was sent home", reported as recovered. The nurse also reported that it was unclear if this injection was painful. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** neurological, 01/07, comment: "was ok"

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272490-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Nov-2006	29-Nov-2006	0	15-Feb-2007	20-Feb-2007	MI	WAES 0701USA03460	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	653938/0954F	0	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope vasovagal

**Symptom Text:** Information has been received from a registered nurse concerning a 16 year old female student with emotional issues (in counseling) who on 29-NOV-2006, at 4:00 PM, was vaccinated IM into the left arm with a first dose of HPV vaccine (yeast) (lot# 653938/0954F). There was no illness at the time of vaccination. It was reported that the vaccination was given while the patient was sitting. A few second after the injection, the patient said "oh", and leaned to the right slowly to a reclined position and remained conscious but stiffened. She was awake. The doctor checked on her and stated that she was having a vagal response. After reclining 5-10 minutes, she said she was ok. Her blood pressure was 112/78 and temperature was 100.1F. The nurse noted that the patient was dressed in multiple layers and a hat and she had no had lunch. The patient was considered recovered on the same day, 29-NOV-2006. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** blood pressure, 11/29/06 112/70; body temp, 11/29/06 100.1f

**History:** emotional problems

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272491-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Nov-2006	01-Dec-2006	2	15-Feb-2007	20-Feb-2007	IN	WAES 0701USA03483	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Erythema, Flushing, Hot flush, Nausea, Syncope

**Symptom Text:** Information has been received from a mother of a 16 year old female patient with "cysts in her ovaries", and allergies to penicillin, sulfa, cefaclor (CECLOR) and erythromycin ethylsuccinate (+) sulfisoxazole acetyl (PEDIAZOLE) who on 29-NOV-2006 was vaccinated with HPV vaccine (yeast), "in her hip". There was no concomitant medication. Subsequently, "within 2 to 3 days after receiving the injection." the patient developed "hot flushes", fainted, felt dizzy, and nausea. The patient was also "red and flushed" in her face since receiving the injection. The patient was experiencing the "hot flushes" almost every day. It was also reported that the patient had been vaccinated with Tdap "whooping cough" injection (manufacturer unknown) on 05-JAN-2007 and the patient experienced swelling, itching and "a knot" at the injection site for the last "two to three weeks." At the time of the report, the patient was reportedly not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** ovarian cyst; penicillin allergy; sulfonamide allergy; drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272492-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	20-Feb-2007	CA	WAES 0701USA03485	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Pain

**Symptom Text:** Information has been received from a registered nurse concerning an adolescent female (age not reported) who on an unspecified date was vaccinated with the first dose of HPV vaccine (yeast). Subsequently, the patient passed out or was unconscious (date unknown). It was reported that the vaccination was "somewhat painful". The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the event (date unknown). The nurse reported that there were a total of 4 cases of adolescent females that passed out or were unconscious after receiving the first dose of HPV vaccine (yeast) out of 130 total doses administered by the office. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272493-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		01-Feb-2007	20-Feb-2007	TN	WAES 0701USA03497	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female between 15 and 16 years old who was vaccinated with a 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). After receiving the vaccine, the patient fainted. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272494-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		15-Feb-2007	20-Feb-2007	TX	WAES 0701USA03498	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female between 15 and 16 years old who was vaccinated with a 0.5 ml dose of HPV vaccine (yeast). After receiving the vaccine, the patient fainted. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272495-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	TN	WAES 0701USA03499	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female between 15 and 16 year old who was vaccinated with a 0.5 ml dose of HPV vaccine (yeast). After receiving the vaccine, the patient fainted. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272496-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	TN	WAES 0701USA03500	21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female between 15 and 16 years old who was vaccinated with a 0.5 ml dose of HPV vaccine (yeast). After receiving the vaccine, the patient fainted. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272497-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	04-Dec-2006	04-Dec-2006	0	15-Feb-2007	21-Feb-2007	--	WAES 0701USA03503	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site discolouration

**Symptom Text:** Information has been received from a clinical trial coordinator concerning a female health care worker (age not reported) at a study site. On 04-DEC-2006, the patient was vaccinated in the left deltoid with the first dose of HPV vaccine (yeast) outside of the study. Subsequently, the patient developed discoloration. A band aid was placed over the injection site. As of 12-JAN-2007, there was still obvious discoloration to the area with visible outline of the band aid. The patient stated that she had never had this happen with a band aid before. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272498-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	CO	WAES 0701USA03511	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pruritus, Oedema peripheral, Oedema peripheral

**Symptom Text:** Information has been received from a nurse in a doctor's office concerning a female who was vaccinated with a first dose of HPV vaccine (yeast). Subsequently the patient's hands and feet swelled and had itchiness at the injection site. The patient refused to come in for the second vaccine. The patient recovered. Unspecified medical attention was sought.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272499-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Nov-2006	29-Nov-2006	0	15-Feb-2007	21-Feb-2007	IL	WAES 0701USA03514	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hot flush, Nausea

**Symptom Text:** Information has been received from a medical assistant concerning a 16 year old female with a penicillin, sulfonamide and cefaclor (CECLOR) allergy who on 29-NOV-2006 was vaccinated with a dose of HPV vaccine (yeast). It was reported that ever since she was given the vaccine, the patient experienced hot flashes and nausea. Unspecified medical attention was sought. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** penicillin allergy; sulfonamide allergy; allergic reaction to antibiotics

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272500-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	18-Jan-2007	Unknown		15-Feb-2007	21-Feb-2007	WA	WAES 0701USA03531	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy, Pain

**Symptom Text:** Information has been received from a immunization coordinator nurse concerning a 26 year old female nurse in her office who on 18-JAN-2007 was vaccinated in the arm with a second dose of HPV vaccine (yeast). Subsequently the patient experienced "general achiness" throughout her body and swollen lymph glands. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. It was reported that the patient "did not respond like this" after her first dose of HPV vaccine (yeast). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272501-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Dec-2006	Unknown		15-Feb-2007	21-Feb-2007	TX	WAES 0701USA03620	21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Epistaxis

**Symptom Text:** Information has been received from a nurse concerning her 16 year old daughter who in approximately December 2006, was vaccinated with her first dose of HPV vaccine (yeast). Subsequently, the patient developed three nosebleeds. Medical attention was sought. The patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272502-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	18-Jan-2007	18-Jan-2007	0	15-Feb-2007	21-Feb-2007	--	WAES 0701USA03757	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	655165/1425F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Nausea, Vomiting

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female on contraception, and supplements with iron deficiency anaemia and no allergies, who on 18-JAN-2007 was vaccinated IM with a first dose of HPV vaccine (yeast) (lot# 655165/1425F). Concomitant therapy included ethinyl estradiol/norethindrone acetate (LOESTRIN) and iron (unspecified). Two hours after, the patient called the office and complained of nausea and vomiting. The patient came into the office the next day because her vomiting lasted throughout the night and she stated that she passed out. By the time she came to the office she was doing better. No diagnostic studies were performed. At the time of this report, the patient was recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Loestrin, iron (unspecified)

**Lab Data:** NONE

**History:** contraception; routine health maintenance; iron deficiency anaemia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272503-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	23-Jan-2007	23-Jan-2007	0	15-Feb-2007	21-Feb-2007	FL	WAES 0701USA03883	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Pallor

**Symptom Text:** Information has been received from a nurse concerning a 14 year old female who on 23-JAN-2007 was vaccinated with the first dose of HPV vaccine (yeast) (lot number not provided). The nurse reported that after the patient received the vaccination she turned pale "within 10 minutes of vaccination". The nurse reported that the patient's blood pressure was 120/80 prior to vaccination and her blood pressure dropped to 90/50 about ten minutes after the patient was vaccinated. The nurse reported that the patient was sent to the Emergency Room (ER) at the hospital nearby for treatment and observation. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** blood pressure, 01/23/07, 120/8; blood pressure 01/23/07, 90/50

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272504-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	05-Jan-2007	06-Jan-2007	1	15-Feb-2007	21-Feb-2007	FL	WAES0701USA03895	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0961F	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain of skin, Pruritus, Rash

**Symptom Text:** Information has been received from an L.P.N. concerning a 13 year old female student with a congenital heart defect and allergy to contrast dye who on the morning of 05-JAN-2007 between approximately 9-11 a.m. was vaccinated in the left upper arm with her second dose of Gardasil (yeast), lot#654389/0961F. In the p.m. of 06-JAN-2007 the patient developed skin tender and some skin "bumps" with pruritis X 2 days. It was reported that on 09-JAN-2007, the patient recovered. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Unspecified congenital anomaly of heart; Hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272505-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	FL	WAES0701USA03908	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a female (demographics not reported) who on an unspecified date was vaccinated with Gardasil (yeast) (Lot# not provided). Subsequently the patient developed hives. At the time of this report it was unknown if the patient had recovered from the hives. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272506-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Oct-2006	01-Oct-2006	0	15-Feb-2007	21-Feb-2007	PA	WAES0701USA03939	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vaginal haemorrhage

**Symptom Text:** Information has been received from two nurses at a physician's office concerning a female (age not reported) who in October 2006 was vaccinated with the first dose of Gardasil (yeast). In October 2006, the patient developed excessive vaginal bleeding (during her period). The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272508-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	NY	WAES0701USA03959	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypokinesia, Malaise, Pain in extremity, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with Gardasil (yeast). Subsequently the patient developed malaise and fever, also had a sore arm such that she felt she couldn't move it for 24 hours. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 819

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272509-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	16-Jan-2007	18-Jan-2007	2	15-Feb-2007	21-Feb-2007	NY	WAES0701USA03962	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Epigastric discomfort

**Symptom Text:** Information has been received from the father of an 18 year old female with a penicillin allergy noted as rash and fever. On 16-JAN-2007, the patient was vaccinated intramuscularly in the deltoid, with the first dose of Gardasil (yeast). There were no concomitant medications reported. On 18-JAN-2007, the patient developed epigastric pressure and discomfort. On 19-JAN-2007, the patient was examined by her physician and was prescribed famotidine. On 21-JAN-2007, the patient complained of difficulty and discomfort breathing which worsened on 22-JAN-2007. On 23-JAN-2007, the patient was planning to seek medical attention, at her local school infirmary. At the time of this report, the patient had not recovered from the events. Additional information has been requested.

**Other Meds:** PEPCID

**Lab Data:** NONE

**History:**

**Prex Illness:** Penicillin allergy; Rash; Fever

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272510-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	19-Jan-2007	21-Jan-2007	2	15-Feb-2007	21-Feb-2007	VA	WAES0701USA03965	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus

**Symptom Text:** Information has been received from a physician concerning a 26 year old female who on 19-JAN-2007 was vaccinated intramuscularly with the first dose of Gardasil (yeast). On approximately 21-JAN-2007, "within about three days", the patient reported that both her arms were itchy and red. The patient sought unspecified medical attention. The physician reported that she told the patient to take some Benadryl to treat the symptoms. The physician reported that she did not plan to re-vaccinate the patient with Gardasil (yeast). No lot number was provided. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272511-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Nov-2006	18-Dec-2006	40	15-Feb-2007	21-Feb-2007	--	WAES0701USA03968	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Pelvic pain

**Symptom Text:** Information has been received from a licensed visiting nurse through the pregnancy registry concerning a 18 year old female who became pregnant during the 3-dose of Gardasil (yeast). On 08-NOV-2006, the patient was vaccinated with the first dose of Gardasil (yeast). It was reported that the patient was not pregnant when she received her first dose of Gardasil (yeast). On 18-DEC-2006, the patient developed pelvic pain. The patient was seen in the emergency room. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272512-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES0701USA03978	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash generalised

**Symptom Text:** Information has been received from a Pharm D healthcare student concerning a female (age not reported) who on an unspecified date was vaccinated with her first dose of Gardasil (yeast). Two weeks post vaccination, the patient developed a full body rash with tiny, erythematous papules. The patient sought unspecified medical attention. The pharmacist stated that the he has no other information, as the nurse had the chart. At the time of this report, the outcome of the event was unknown. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272513-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Nov-2006	01-Nov-2006	0	15-Feb-2007	21-Feb-2007	CA	WAES0701USA04026	05-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site swelling

**Symptom Text:** Information has been received from a physician concerning a 16 year old female who "about 2 months ago" in approximately. November 2006, was vaccinated, intramuscularly (IM), into the deltoid muscle with the first 0.5 ml, dose of Gardasil (yeast). "About 2 months ago". in approximately, November 2006, on the same day of injection, the patient developed swelling at the site of injection. The patient reported that the swelling at the injection site subsided (date not reported). The patient sought unspecified medical attention. The patient received the 2nd dose recently without incident. The latter dose was administered (IM) in the thigh. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272514-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES 0701USA04058	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with HPV vaccine (yeast). Subsequently, following vaccination, the patient fainted. The patient fully recovered. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272515-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	PA	WAES 0701USA04068	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Syncope

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a first dose of HPV vaccine (yeast). Subsequently the patient complained of pain and then fainted within minutes of administration. Subsequently, the patient recovered without any additional treatment. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272516-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	PA	WAES 0701USA04069	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Syncope

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a first dose of HPV vaccine (yeast). Subsequently the patient complained of pain and then fainted within minutes of administration. Subsequently, the patient recovered without any additional treatment. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 827

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272517-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Nov-2006	01-Dec-2006	30	15-Feb-2007	21-Feb-2007	OR	WAES 0701USA04101	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** HIV test negative, HIV test positive

**Symptom Text:** Information has been received from a health professional concerning a 17 year old female who in November 2006, was vaccinated with a first dose of HPV vaccine (yeast). In December 2006, the patient tested positive for human immunodeficiency virus (HIV). The HIV test was performed in December 2006 when the patient donated blood. Unspecified medical attention was sought. The patient had 2 subsequent HIV tests. The first test was "equivocal" and the second test was negative. It was reported that the patient was not sexually active and did not use intravenous (IV) drugs. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** serum HIV-1 gag, 12/06, positive; serum HIV-1 gag, equivocal; serum HIV-1 gag, negative

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272518-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
36.0	F	11-Dec-2006	12-Dec-2006	1	15-Feb-2007	21-Feb-2007	WI	WAES 0701USA04136	05-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Information has been received from a 36 year old female with sulfonamide allergy and irritable bowel syndrome who on 11-DEC-2006 was vaccinated with a second 0.5 mL of HPV vaccine (yeast). Concomitant therapy included escitalopram oxalate (LEXAPRO). In December 2006, " few days after" receiving the vaccination, the patient broke out in hives and a rash on her chest. The patient sought unspecified medical attention. Subsequently, after three weeks, the patient recovered from the hives and rash. It was reported that the patient did not have a reaction after vaccination with the first dose of HPV VLP vaccine (yeast). Additional information has been requested.

**Other Meds:** Lexapro

**Lab Data:** NONE

**History:** sulfonamide allergy; irritable bowel syndrome

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272519-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	17-Jan-2007	21-Jan-2007	4	15-Feb-2007	21-Feb-2007	--	WAES 0701USA04160	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Confusional state, Disorientation

**Symptom Text:** Information has been received from a physician concerning a "15 year 11 months" old female who on 17-JAN-2007 was vaccinated with her first dose of HPV vaccine (yeast). Concomitant therapy included Citalopram hydrobromide (CELEXA). On 21-JAN-2007 the patient was disoriented and confused about her surroundings. The patient was seen in an Emergency Department. Blood work. Computed axial tomography scan (CT) and drug screening were all normal. Additional information has been requested.

**Other Meds:** Celexa

**Lab Data:** Diagnostic test: computed axial, 01/21/07, normal; diagnostic laboratory, 01/21/07, normal Lab Results: blood drug screen, 01/21/07, normal

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272520-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES0701USA04212	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypersensitivity

**Symptom Text:** Information has been received from a nurse practitioner concerning a female who was vaccinated with a 0.5 ml dose of Gardasil (yeast). Subsequently the patient developed an "allergic reaction". Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272521-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES0701USA04254	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site reaction

**Symptom Text:** Information has been received from a licensed practical nurse concerning approximately 14 patients who was vaccinated with Gardasil (yeast). Subsequently the patients experienced injection site reaction including pain. The reactions resolved "after a couple of days". Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272522-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES 0701USA04279	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral

**Symptom Text:** Information has been received from a health professional concerning a female patient who was vaccinated IM with a 0.5 ml "recent" dose of HPV vaccine (yeast). Subsequently the patient called the practice and reported swelling in both arms and she wanted to be seen by the physician. No further information was provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272523-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	05-Jan-2007	05-Jan-2007	0	15-Feb-2007	21-Feb-2007	--	WAWS 0701USA04282	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Hypertension, Tachycardia

**Symptom Text:** Information has been received from a physician concerning a 20 year old female with a history of collapse of left lung (September 2006 for which she recovered) who on 05-JAN-2007 was vaccinated with a first IM dose of HPV vaccine (yeast). Concomitant therapy on 05-JAN-2007 included a dose of medroxyprogesterone acetate (DEPO-PROVERA). On 05-JAN-2007 the patient experienced dizziness, tiredness, tachycardia and high blood pressure. The patient has been on medroxyprogesterone acetate since July 2006 and has not experienced any of these symptoms. Her pulse rate has been as high as 145 at rest and blood pressure was 138/85 and an EKG showed tachycardia. Blood work was done and results not provided. She is scheduled to have pulmonary function tests on 07-FEB-2007 and will be seeing a cardiologist "in the future." The patient's dizziness and tiredness and tachycardia and high blood persisted. Additional information has been requested.

**Other Meds:** Depo-Provera

**Lab Data:** Diagnostic test: blood pressure, 01/05/07, 138/6; electrocardiogram, 01/05/07, tachy; Lab Results: total heartbeat count, 01/05/07, 145

**History:** collapse of lung

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272524-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
32.0	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	IL	WAES0701USA04404	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Inappropriate schedule of drug administration, Pruritus, Rash

**Symptom Text:** Information has been received from a physician concerning a 32 year old female with no pertinent medical history or drug reactions/allergies, who on an unspecified date was vaccinated with Gardasil (yeast) (0.5 ml). There was no concomitant medication. Subsequently, 30 minutes after vaccination, the patient developed redness and itchiness on the palms of her hands, soles of her feet, and in a "band around her waist". The patient also developed "8 red spots on the left side of her trunk". The redness, itchiness, and red spots lasted for approximately 5 days and then disappeared. It was reported that nothing occurred at the injection site. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272525-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	OH	WAES0701USA04413	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of Gardasil (yeast) (0.5 ml). Subsequently, following vaccination, the patient lost consciousness. It was reported that the patient regained consciousness after a "couple of minutes". Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272526-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	01-Jan-2007	01-Jan-2007	0	15-Feb-2007	21-Feb-2007	--	WAES0701USA04415	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Heart rate increased

**Symptom Text:** Information has been received from a nurse practitioner concerning a 14 year old female with no pertinent medical history and no history of drug reactions/allergies in January 2007 was vaccinated with the first dose of Gardasil (yeast) (Lot # not reported) 0.5 ml injection. There was no concomitant medication. In January 2007, the evening she received her first dose of Gardasil (yeast), she experienced rapid heart beat. Medical attention was sought. She had the same experience 24 hours later. The patient has not had another experience since then. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272527-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES0701USA04429	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia

**Symptom Text:** Information has been received from a registered nurse concerning a couple of females with unspecified pertinent medical history and unspecified drug reactions/allergies who on an unspecified date were vaccinated with first dose of Gardasil (yeast) (lot # not reported), 0.5 ml, IM. Concomitant therapy was not specified. On an unspecified date, the patients experienced tingling in their fingers of the arm being injected while getting the injection. The tingling resolved within a couple of minutes of receiving the shot. Medical attention was sought. At the time of reporting, the patients had recovered. The patients plan on getting was sought. At the time of reporting, the patients had recovered. The patients plan on getting their second and third doses of Gardasil (yeast). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272528-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	18-Jan-2007	18-Jan-2007	0	15-Feb-2007	21-Feb-2007	MI	WAES0701USA04447	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus generalised

**Symptom Text:** Information has been received from a physician concerning a 26 year old female with hypothyroidism and a history of papanicolaou smear abnormal and no history of drug reactions/allergies who on 06-NOV-2006 was vaccinated with first dose of Gardasil (yeast) 0.5 ml IM. On 18-JAN-2007, the patient was vaccinated with a second dose of Gardasil (yeast) (lot # not reported). Concomitant therapy included SYNTHROID and LO/OVRAL. On 18-JAN-2007, forty-five minutes after receiving the second dose, the patient experienced generalized itching. No additional symptoms were noticed. Medical attention was sought. The physician prescribed BENADRYL and the symptoms resolved. The patient fully recovered on 18-JAN-2007. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** LO/OVRAL, SYNTHROID

**Lab Data:** NONE

**History:** Papanicolaou smear abnormal

**Prex Illness:** Hypothyroidism

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272530-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Oct-2006	01-Oct-2006	0	15-Feb-2007	21-Feb-2007	--	WAES 0701USA04475	06-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vaccine positive rechallenge, Vertigo

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female with no medical history who in October 2006 or November 2006 was vaccinated with her second dose of HPV VLP vaccine (yeast) (0.5 mg), intramuscularly. There was no concomitant medication. Subsequently, the patient experienced intermittent vertigo 5 days later. The patient was "recently" administered her third dose of HPV VLP vaccine and was "now" experiencing constant vertigo. It was noted that the patient had a family history of vertigo. There were no laboratory or diagnostic tests performed. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272531-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	31-Dec-2006	31-Dec-2006	0	15-Feb-2007	21-Feb-2007	--	WAES 0701USA04481	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Meningism, Musculoskeletal stiffness

**Symptom Text:** Information has been received from a nurse concerning a 17 year old female who at the "end of December" was vaccinated with a second dose of HPV VLP vaccine (yeast) (0.5 ml). Subsequently, the patient experienced meningitis like symptoms and cervical neck stiffening. Unspecified medical attention was sought. At the time of the report, th patient was recovering. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272532-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	15-Jan-2007	15-Jan-2007	0	15-Feb-2007	21-Feb-2007	--	WAES0701USA04509	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a laboratory technician concerning a 26 year old female who on 15-JAN-2007 was vaccinated with a first dose of HPV vaccine (yeast). Ten minutes after the vaccination, the patient passed out at the check out for an unspecified time. The patient said that she always passes out after she gets an injection. Unspecified medical attention was sought. On 15-JAN-2007, the patient recovered without incident. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** loss of consciousness

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272533-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	24-Jan-2007	24-Jan-2007	0	15-Feb-2007	21-Feb-2007	TX	WAES 0701USA04530	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injected limb mobility decreased, Paraesthesia, Skin discolouration, Skin warm

**Symptom Text:** Information has been received from a registered nurse concerning her 22 year old daughter with no allergies who on 24-JAN-2007 was vaccinated with HPV VLP vaccine (yeast). Concomitant therapy included methylphenidate HCl (RITALIN) and "pregnancy shot" (name unknown). On 24-JAN-2007 the patient immediately "felt her fingers tingle and her arm got hot." Later that evening her "fingers turned white and blue." She then went back to the physician who instructed her to "wrap it in warm packs." The patient also took diphenhydramine HCl (BENADRYL). The nurse stated that her daughter's arm was getting better, but she still had trouble picking up her arm to her shoulder area. At the time of the report, the patient was recovering. Additional information has been requested.

**Other Meds:** therapy unspecified, Ritalin

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272534-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	01-Nov-2006	01-Nov-2006	0	15-Feb-2007	21-Feb-2007	--	WAES 0701USA04532	22-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site swelling

**Symptom Text:** Information has been received from a consumer concerning a 38 year old female with sulfa allergy who "about two months ago" in approximately November 2006 was vaccinated with HPV VLP vaccine (yeast). There was no concomitant medication. Subsequently, "about two months ago" in approximately November 2006, the patient experienced "swelling in upper left arm where the (HPV vaccine) was administered." The site was immediately sore. The swelling increased at first and subsided after about a month. Unspecified medical attention was sought. The patient recovered "about one month ago." There were no relevant diagnostic tests or laboratory data. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 844

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272535-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	TX	WAES 0701USA04555	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration, Nerve injury

**Symptom Text:** Information has been received from a nurse concerning a 19 year old female who, on an unspecified date, was vaccinated intramuscularly with a second dose of HPV VLP vaccine (yeast). The patient developed immediate redness at the injection site and a knot was noticed at the injection site 1 to 2 days post injection. The nurse reported that the patient did not see her family physician and the family physician suspected "nerve damage." It was not specified whether or not the patient had a reaction the first time she was vaccinated with HPV VLP vaccine (yeast). The nurse reported that they were following up with the patient to make sure she was okay. Unspecified medical attention was sought. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272536-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	03-Jan-2007	03-Jan-2007	0	15-Feb-2007	21-Feb-2007	PA	WAES 0701USA04565	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Syncope

**Symptom Text:** Information has been received from a physician concerning his 15 year old daughter who on 03-JAN-2007 was vaccinated with a first dose of HPV VLP vaccine (yeast). On 03-JAN-2007 the patient fainted and experienced soreness at the injection site. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272537-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Jan-2007	22-Jan-2007	0	15-Feb-2007	21-Feb-2007	MA	WAES 0701USA04582	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female patient who in "the week of 22-JAN-2007" was vaccinated IM with a 0.5 ml dose of HPV VLP vaccine (yeast). After vaccination, the patient fainted. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272569-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	25-Jan-2007	27-Jan-2007	2	19-Feb-2007	21-Feb-2007	NH		21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Right arm	Intramuscular	
	FLUN	MEDIMMUNE, INC.	500438P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0960F		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vaginal haemorrhage

**Symptom Text:** pt recieved HPV #1 on 1/25/07 since vaccine has had period for past 22 days. has not had issues with vaginal bleeding between period before vaccine.

**Other Meds:**

**Lab Data:** will be getting tsh, ferritin, and cbc

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272578-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	13-Dec-2006	13-Dec-2006	0	15-Feb-2007	21-Feb-2007	FL	WAES 0701USA04602	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Mass, Tenderness

**Symptom Text:** Information has been received from a 25 year old female office manager who on 13-DEC-2006 was vaccinated with a first 0.5 mL dose of HPV VLP vaccine (yeast). On 13-DEC-2006, the patient developed a small bump under the skin that was tender after receiving the vaccination. The patient sought unspecified medical attention. At the time of this report, the patient's small, tender bump under the skin persisted. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272579-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	29-Nov-2006	29-Nov-2006	0	15-Feb-2007	21-Feb-2007	WA	WAES 0701USA04623	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		654540/0800F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Pharyngeal hypoaesthesia, Throat tightness

**Symptom Text:** Information has been received from a registered nurse concerning a 20 year old female with an allergy to amoxicillin (AUGMENTIN) who on 29-NOV-2006 was vaccinated IM, into the deltoid, with a first dose of HPV VLP vaccine (yeast) (lot # 654540/0800F). Concomitant therapy included ORTHO EVRA. Approximately 1 minute after the vaccination, the patient reported that her "throat felt constricted." Subsequently, the patient recovered after 5 minutes. On 25-JAN-2007 the patient was vaccinated with a second dose of dose of HPV VLP vaccine (yeast). Five seconds after the vaccination, the patient experienced "numbness in the throat" that lasted a short duration. The patient reported that she developed an intense headache 30 minutes after the vaccination that lasted until she went to bed. On 26-JAN-2007, the patient recovered from the headache. Unspecified medical attention was sought. There were no laboratory or diagnostic tests performed. Additional information has been requested.

**Other Meds:** Ortho Evra

**Lab Data:** UNK

**History:** drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272580-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	25-Aug-2006	Unknown		15-Feb-2007	23-Feb-2007	WI	WAES 0701USA04643	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy

**Symptom Text:** Information has been received from a registered nurse through a Merck Pregnancy Registry concerning a 23 year old female with allergies to sulfamethoxazole (+) trimethoprim (BACTRIM) and nitrofurantoin (MACROBID) high blood pressure but no current blood pressure medication. Rhesus antibodies (RH) negative, and a history of cervical dysplasia, urinary tract infections and Caesarian (C) section for first child, year 2006, who on 25-AUG-2006 was vaccinated with HPV vaccine (yeast). The nurse reported that the patient was scheduled for a leep procedure, due to cervical dysplasia on 20-SEP-2006 and before the procedure a blood serum pregnancy test was taken, and result was positive for pregnancy. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** serum beta-human, 09/20/06, (+), positive for pregnancy

**History:** Cervical dysplasia, Caesarean section; Urinary tract infection; blood pressure high, sulfonamide allergy, drug hypersensitivity

**Prex Illness:** pregnancy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272581-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	18-Jan-2007	Unknown		15-Feb-2007	23-Feb-2007	GA	WAES 0701USA04649	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Syncope

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who approximately 18-JAN-2007 was vaccinated by injection with a 0.5 mL dose of HPV vaccine (yeast). Lot # unspecified by reporter). There was no concomitant medication. Subsequently, it was reported that five minutes after the injection the patient fainted. The patient was taken to the emergency room (ER) but no admitted to the hospital. The physician did not think the HPV vaccine (yeast) caused the patient to faint, as much as severe anxiety from the shot. At the time of the report, the patient had recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272582-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	PA	WAES 0701USA04667	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a dose of HPV vaccine (yeast). Subsequently, the patient fainted. Her outcome was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272583-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	WA	WAES 0701USA04672	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Herpes zoster, Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning an 18 year old female patient who was vaccinated with her first dose of HPV vaccine (yeast) and had no adverse side effects. Subsequently, she was vaccinated with her 2nd dose of HPV vaccine (yeast) and within 24 hours broke out in hives, which developed into shingles. Medical attention was sought. As of the report date, the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272584-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	--	WAES 0701USA04679	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site haemorrhage

**Symptom Text:** Information has been received from a registered nurse concerning an approximately 23 year old female who was vaccinated with HPV vaccine (yeast). The registered nurse reported that she had another nurse had given "numerous" Gardasil vaccinations. Subsequently this patient experienced a "trickle of blood down her arm she the needle withdrawn". The nurse further commented that there was "nothing wrong with the patient, she didn't even notice" and, "there was no blood in the syringe when the plunger was pulled back before injecting the patient". Bleeding resolved and the patient was sent home. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272585-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	25-Jan-2007	25-Jan-2007	0	15-Feb-2007	23-Feb-2007	--	WAES 0701USA04682	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Bone pain

**Symptom Text:** Information has been received from a pharmacist concerning a 20 year old female who on 25-JAN-2007 was vaccinated with a second dose of HPV vaccine (yeast) 0.5 ml intramuscularly. Subsequently the patient experienced joint and bone pain. The patient sought unspecified medical attention. The patient is recovering from joint and bone pain. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272586-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	19-Jan-2007	19-Jan-2007	0	15-Feb-2007	23-Feb-2007	--	WAES 0701USA04690	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site cyst

**Symptom Text:** Information has been received from a registered nurse concerning an "18 or 19" year old female who on 19-JAN-2007 was vaccinated with the first dose of HPV vaccine (yeast). On 19-JAN-2007, the patient developed a cyst at the injection site. The patient sought unspecified medical attention. The patient was referred to a dermatologist. At the time of this report, the outcome of the event was unknown. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272587-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES001USA04694	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a licensed practical nurse concerning approximately 75 female patients who were vaccinated IM with 0.5ml doses of Gardasil. Subsequently the patients experienced pain at the injection site. Unspecified medical attention was sought. Subsequently, the patients recovered. Attempts are being made to obtain additional identifying information regarding the patients mentioned in this report. Additional information will be provided when available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272588-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	CA	WAES0701USA04695	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Pain

**Symptom Text:** Information has been received from a registered nurse concerning an adolescent female (age not reported) who on an unspecified date was vaccinated with the first dose of Gardasil vaccine. Subsequently, the patient passed out or was unconscious (date unknown). It was reported that the vaccination was "somewhat painful". The patient sought unspecified medical attention. At the time of this report, the patient has recovered from the event (date unknown). The nurse reported that there were total of 4 cases of adolescent females that passed out or were unconscious after receiving the first dose of Gardasil out of 130 total doses administered by the office. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272589-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	CA	WAES0701USA04696	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Pain

**Symptom Text:** Information has been received from a registered nurse concerning an adolescent female (age not reported) who on an unspecified date was vaccinated with the first dose of Gardasil. Subsequently, the patient passed out or was unconscious (date unknown). It was reported that the vaccination was "somewhat painful". The patient sought unspecified medical attention. At the time of this report, the patient has recovered from the event (date unknown). The nurse reported that there were total of 4 cases of adolescent females that passed out or were unconscious after receiving the first dose of Gardasil out of 130 total doses administered by the office. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272590-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	CA	WAES0701USA04697	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation irregular

**Symptom Text:** Information has been received from a physician concerning a female who on an unspecified date was vaccinated intramuscularly with the second dose of Gardasil. Subsequently, following the second vaccination, the patient experienced irregular periods. Unspecified medical attention was sought. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272591-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	PA	WAES0701USA04698	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vaginal haemorrhage

**Symptom Text:** Information has been received from two nurses at a physician's office concerning one of the nurses' daughter (age not reported). On an unspecified date, the patient was vaccinated with the first dose of Gardasil. Subsequently, the patient developed excessive vaginal bleeding (during her period). At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272592-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	15-Jan-2007	Unknown		15-Feb-2007	01-Mar-2007	CA	WAES0701USA04758	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fungal infection, Immune system disorder, Pharyngolaryngeal pain, Rash, Sinusitis

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) on approximately 15-JAN-2007 was vaccinated with Gardasil. Subsequently, the patient developed a weakened immune system, yeast infection, sore throat, sinusitis and had a rash on her leg that was lasting several days. At the time of this report, the outcome of the events were unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272593-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	29-Jan-2007	25-Jan-2007	-4	15-Feb-2007	01-Mar-2007	GA	WAES0701USA04778	09-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 21 year old female on antibiotics for condition unspecified, and pertinent medical history and drug reactions/allergies unspecified who on approximately 29-JAN-2007 was vaccinated with first dose of Gardasil (lot # not reported) IM. Concomitant suspect therapy included Antimicrobial (unspecified). The physician reported that the patient sought medical attention (called the office) to report that she had hives (on approximately 25-JAN-2007). The patient had been on antibiotics for a couple of days prior to receiving Gardasil. The physician felt the hives may be related more to the antibiotics than the vaccine. The outcome of the hives was unspecified. no further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272594-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	25-Jan-2007	28-Jan-2007	3	15-Feb-2007	01-Mar-2007	KY	WAES0701USA04781	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0011U	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a certified medical assistant concerning a 21 year old female with penicillin allergy who on 25-JAN-2007 was vaccinated with first dose of Gardasil (lot #654702/0011U), 0.5 ml IM in the deltoid. Concomitant therapy included Yasmin and Wellbutrin. On 28-JAN-2007, three days later, the patient woke up with a rash on her entire body. The patient sought medical attention. The patient took Benadryl, but it had not improved. The medical assistant reported that the patient stated the rash is the same over her entire body, the injection site is not any worse than the rest of her body. At the time of reporting, the patient's rash persisted. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** Yasmin, Wellbutrin

**Lab Data:** UNK

**History:** Penicillin allergy.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272595-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	16-Jan-2007	27-Jan-2007	11	15-Feb-2007	23-Feb-2007	NY	WAES0701USA04794	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 24 year old female with no pertinent medical history and no known adverse drug reactions or allergies reported. On 16-JAN-2007, the patient was vaccinated with the first dose of Gardasil (yeast). There were no concomitant medications reported. On 27-JAN--2007, the patient developed a rash on her arms and legs. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272596-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Dec-2006	16-Dec-2006	15	15-Feb-2007	23-Feb-2007	IN	WAES0701USA04857	26-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema nodosum

**Symptom Text:** information has been received from a physician concerning a 17 year old female with amenorrhea, hirsutism and a CECLOR allergy who on 01-DEC-2006 was vaccinated IM with a first dose of Gardasil (yeast). The patient received Menactra concomitantly. Other concomitant therapy included Ovcon 50. On 16-DEC-2006 the patient developed erythema nodosum. The patient sought unspecified medical attention. The patient was treated with a course of steroids and has fully recovered. No laboratory diagnostic tests were performed. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** OVCON 50

**Lab Data:** NONE

**History:**

**Prex Illness:** Amenorrhea, Hirsutism, Allergic reaction to antibiotics

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272597-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	18-Jan-2007	28-Jan-2007	10	15-Feb-2007	23-Feb-2007	CA	WAES0701USA04897	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymphadenopathy

**Symptom Text:** Information has been received from a physician concerning his 20 year old female daughter with no other pertinent medical history reported. On 18-JAN-2007, the patient was vaccinated IM with the first 0.5 ml dose of Gardasil (yeast). There were no concomitant medications reported. On 28-JAN-2007, the patient developed unilateral supraclavicular lymphadenopathy. There were no other symptoms reported. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272598-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	25-Jan-2007	27-Jan-2007	2	15-Feb-2007	23-Feb-2007	GA	WAES0701USA04926	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female patient who on 26-JAN-2007 was vaccinated with a dose of Gardasil (yeast). On 27-JAN-2007 the patient developed a rash on her arm, chest and back. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272599-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	29-Jan-2007	29-Jan-2007	0	15-Feb-2007	23-Feb-2007	SD	WAES0701USA04931	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Malaise, Nausea

**Symptom Text:** Information has been received from a healthcare provider concerning her 20 year old daughter with a penicillin allergy who on 29-JAN-2007, in the morning, was vaccinated with a second IM dose of Gardasil (yeast). Concomitant therapy included Ortho Tri Cyclen, Advair. On 29-JAN-2007 "later in the day" the patient was driving and developed dizziness and nausea. She could no longer drive so the passenger took over driving. As of 29-JAN-2007 she still did not feel well when she got back to school. A first dose of Gardasil (yeast) was given IM on 22-NOV-2006. Additional information has been requested.

**Other Meds:** albuterol, ORTHO TRI-CYCLEN, ADVAIR

**Lab Data:** UNK

**History:** Ovarian cyst, Asthma

**Prex Illness:** Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272600-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	13-Nov-2006	01-Dec-2006	18	15-Feb-2007	23-Feb-2007	PA	WAES0701USA04984	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspnoea, Muscle spasms, Vaginal haemorrhage

**Symptom Text:** Information has been received from a 22 year old female certified medical assistant who on 12-SEP-2006 was vaccinated IM with the first dose of Gardasil (yeast) (Lot#653735/0688F). On 13-NOV-2006 the patient received the second dose of Gardasil (yeast) (Lot#653735/0688F). Concomitant therapy included Depo-Provera. On an unspecified date in December 2006, the patient began with vaginal bleeding "on and off for several weeks. On 13-JAN-2007 the patient started with a flow that was very heavy lasting seven days, with cramping and shortness of breath. At the time of this report it was unknown if the patient had recovered from the events. Additional information has been requested.

**Other Meds:** DEPO-PROVERA

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272601-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	18-Jan-2007	18-Jan-2007	0	15-Feb-2007	23-Feb-2007	VA	WAES0701USA04996	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with pertinent medical history and drug reactions/allergies unspecified who on approximately 18-JAN-2007 was vaccinated with Gardasil (yeast) (lot # not reported). On approximately 18-JAN-2007, the patient experienced a rash all over her body. The outcome of the rash was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272602-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	29-Jan-2007	29-Jan-2007	0	15-Feb-2007	23-Feb-2007	--	WAES0701USA05003	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Disturbance in attention, Feeling abnormal

**Symptom Text:** Information has been received from a 23 year old female emergency medical attention with a penicillin allergy who on 29-JAN-2007 was vaccinated IM with a second 0.5 ml dose of Gardasil (yeast). On 29-JAN-2007 the patient reported feeling "weird or slow in the head" and "can not concentrate or think clearly". The patient received a first IM 0.5 dose of Gardasil (yeast) on 12-DEC-2006. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272603-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
10.0	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	PA	WAES0701USA05006	26-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a pharmacist concerning a 10 year old female vaccinated with a first 0.5 ml dose of Gardasil (yeast). Two days later, the patient developed a rash behind her knees and on her chest. Unspecified medical attention was sought. At the time eof this report, the patient's outcome was unknown. No product quality was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272604-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	NJ	WAES0701USA05007	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient who was vaccinated with Gardasil (yeast), (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272605-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		15-Feb-2007	23-Feb-2007	--	WAES0701USA05035	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dry mouth

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with Gardasil (yeast). Subsequently the patient experienced dry mouth. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272606-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	28-Dec-2006	26-Jan-2007	29	15-Feb-2007	21-Feb-2007	PA	WAES 0701USA05041	21-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653735/0688F	0	Unknown	Intramuscular	VARCEL

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysmenorrhoea, Dyspnoea, Groin pain, Menorrhagia

**Symptom Text:** Information has been received from a health professional concerning a 12 year old white female who on 28-DEC-2006 was vaccinated intramuscularly with the first dose of HPV vaccine (yeast) (lot# 653735/0688F). Concomitant therapy included varicella virus vaccine live (MSD) received on 08-DEC-2006 and Menactra vaccine received on 27-NOV-2006. On approximately 26-JAN-2007 the patient experienced an extremely heavy menstrual cycle with more cramps than previous cycles, one episode of pain in the groin area and shortness of breath while at basketball practice. At the time of this report it was unknown if the patient had recovered from these events.

**Other Meds:**

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272607-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	26-Jan-2007	28-Jan-2007	2	15-Feb-2007	23-Feb-2007	--	WAES0701USA05044	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration, Injection site swelling

**Symptom Text:** Information has been received from a nurse concerning a female with diabetes who on 26-JAN-2007 was vaccinated with the second dose of Gardasil (yeast). On 28-JAN-2007 the patient experienced a big knot, redness and puffiness at the injection site. The patient sought medical attention. The patient is recovering from a big knot, redness and puffiness at the injection site. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:**

**Prex Illness:** Diabetes

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272608-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	29-Jan-2007	29-Jan-2007	0	15-Feb-2007	23-Feb-2007	RI	WAES0701USA05047	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Nausea, Panic attack, Vomiting

**Symptom Text:** Information has been received from a Certified Nurse Midwife concerning a 20 year old female who is "prone to panic attacks" who on 29-JAN-2007 at 11:15 am was vaccinated IM with the first dose of Gardasil (yeast) (Lot # not provided). At 7:30 pm that same evening the patient experienced a panic attack with severe nausea, vomiting and difficulty breathing and went to the emergency room. The patient was not admitted to the hospital. At the time of this report it was unknown if the patient had recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:**

**Prex Illness:** Panic attack

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272609-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	WA	WAES0701USA05074	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Information has been received from a receptionist at a physician's office concerning a 23 year old female who "about a month ago" in approximately December 2006 was vaccinated with a first dose of Gardasil. Subsequently, the patient developed a sore arm. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272610-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	26-Jan-2007	26-Jan-2007	0	15-Feb-2007	23-Feb-2007	--	WAES0702USA00039	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Information has been received from a physician concerning a female patient who on 26-JAN-2007 was vaccinated with a first dose of Gardasil (yeast). On 26-JAN-2007 the patient experienced itching and a rash around the area of the arm and the back of the knee. The rash continued to worsen and medication was ordered to treat the rash. At the time of this report, the patient's outcome was unknown. It was noted that the patient will not receive the second and third dose of the vaccine. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272611-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		15-Feb-2007	23-Feb-2007	--	WAES0702USA00126	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site haemorrhage

**Symptom Text:** Information has been received from a registered nurse concerning an approximately 23 year old female (patient 2 of 4) who was vaccinated with Gardasil (yeast). The registered nurse reported that she another nurse had given "numerous" Gardasil vaccinations. Subsequently this patient experienced a "trickle of blood down her arm when the needle withdrawn". The nurse further commented that there was "nothing wrong with the patient, she didn't even notice" and, "there was no blood in the syringe when the plunger was pulled back before injecting the patient". Bleeding resolved and the patient was sent home. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272612-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	--	WAES0702USA00127	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site haemorrhage

**Symptom Text:** Information has been received from a registered nurse concerning an approximately 23 year old female (patient 3 of 4) who was vaccinated with Gardasil. The registered nurse reported that she and another nurse had given "numerous" Gardasil vaccinations. Subsequently this patient experienced a "trickle of blood down her arm when the needle withdrawn". The nurse further commented that there was "nothing wrong with the patient, she didn't even notice" and, "there was no blood in the syringe when the plunger was pulled back before injecting the patient". Bleeding resolved ant the patient was sent home. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272613-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		15-Feb-2007	28-Feb-2007	--	WAES 0702USA00128	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site haemorrhage

**Symptom Text:** Information has been received from a registered nurse concerning an approximately 23 year old female (patient 4 of 4) who was vaccinated with HPV vaccine (yeast). The registered nurse reported that she and another nurse had given "numerous" Gardasil vaccinations. Subsequently this patient experienced a "trickle of blood down her arm when the needle withdrawn". The nurse further commented that there was "nothing wrong with the patient, she didn't even notice" and, "there was no blood in the syringe when the plunger was pulled back before injecting the patient". Bleeding resolved and the patient was sent home. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272614-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Jan-2007	22-Jan-2007	0	15-Feb-2007	28-Feb-2007	MA	WAES 0702USA00129	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female patient who in "the week of 22-JAN-2007" was vaccinated IM with a 0.5 ml dose of HPV vaccine (yeast). After vaccination, the patient fainted. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272615-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	22-Jan-2007	22-Jan-2007	0	15-Feb-2007	28-Feb-2007	MA	WAES 0702USA00130	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a female patient who in "the week of 22-JAN-2007" was vaccinated IM with a 0.5 ml dose of HPV vaccine (yeast). After vaccination, the patient fainted. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272616-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Jan-2007	29-Jan-2007	7	15-Feb-2007	28-Feb-2007	NY	WAES 0702USA00144	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		655617/1447F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pain

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with no past medical history who on 22-JAN-2007 was vaccinated IM with a second 0.5 ml dose of HPV vaccine (yeast) (lot #655617/1447F). There was no concomitant medication. On 29-JAN-2007 the patient developed erythema and mild tenderness at the site of injection. There was no fever. She sought unspecified medical attention. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272617-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	11-Jan-2007	21-Jan-2007	10	15-Feb-2007	28-Feb-2007	MA	WAES 0702USA00147	09-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lymph node pain, Malaise

**Symptom Text:** Information has been received from a physician concerning an approximately 20 year old female, with no medical history, who on 11-JAN-2007 was vaccinated intramuscularly with a first dose of HPV vaccine (yeast). Concomitant therapy included hormonal contraceptives (unspecified). On approximately 21-JAN-2006 the patient developed bilateral tender lymph nodes and malaise. Unspecified medical attention was sought. At the time of the report, the patient's bilateral tender lymph nodes and malaise persisted. There were no laboratory or diagnostic tests performed. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272618-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	23-Jan-2007	26-Jan-2007	3	15-Feb-2007	28-Feb-2007	--	WAES 0702USA00149	23-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	654702/0011U	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a 19 year old female who on 23-JAN-2007 was vaccinated with a 0.5 ml first dose Gardasil (lot #654702/011U). On 26-JAN-2007 the patient developed a rash on her stomach. Medical attention was sought and the patient was told to take diphenhydramine hydrochloride (BENADRYL). There were no laboratory or diagnostic tests performed. Subsequently, the patient recovered from rash on her stomach. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272619-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	26-Jan-2007	27-Jan-2007	1	15-Feb-2007	28-Feb-2007	PA	WAES 0702USA00160	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		655619/1427F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Pain in extremity, Paraesthesia

**Symptom Text:** Information has been received from a registered nurse from a hospital infusion center concerning a 22 year old female with sulfa allergy and no pertinent medical history who on 26-JAN-2007 was vaccinated with first dose of Gardasil (lot# 655619/1427F), 0.5 ml, IM in left deltoid. There was no concomitant medication. On 27-JAN-2007, Saturday morning, the patient called and reported she experienced pain at the injection site and the pain had increased. The patient sought medical attention. No diagnostic tests were performed. On 31-JAN-2007, the patient experienced pain and tingling down her left arm. At the time of reporting, the patient had no recovered. The patient was referred to her primary physician for follow-up. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272620-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	28-Jan-2007	28-Jan-2007	0	15-Feb-2007	28-Feb-2007	--	WAES 0702USA00167	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site erythema, Paraesthesia

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) with pertinent medical history and drug reactions/allergies reported as unspecified who on 28-JAN-2007 was vaccinated with Gardasil (lot# not reported), 0.5 ml IM. Concomitant therapy was unspecified. On approximately 28-JAN-2007, the patient experienced redness at the injection site with tingling in her arms. The condition progressed to tingling in her fingers with numbness in both arms and fingers. The patient sought medical attention. At time of reporting, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272621-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	17-Jan-2006	Unknown		15-Feb-2007	01-Mar-2007	--	WAES0702USA00193	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a consumer concerning her 19 year old daughter who on approximately 17-JAN-2006 was vaccinated with a dose of Gardasil. Subsequently the patient developed a "rash from head to toe." It was reported that the patient had followed up with her physician. At the tiem of the report, the patient's rash persisted. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272622-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	MD	WAES07002USA00197	01-Mar-2007
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Injection site pain, Similar reaction on previous exposure to drug

**Symptom Text:** Information has been received from a nurse practitioner concerning a 21 year old female who on unspecified dates was vaccinated intramuscularly with the first and second doses of Gardasil. Subsequently, the patient experienced dizziness and injection site stinging following the first vaccination and injection site stinging following the second vaccination. It was reported that the events occurred immediately after vaccination and resolved after about 5 minutes. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272623-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	MD	WAES0702USA00207	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Loss of consciousness

**Symptom Text:** Information has been received from a nurse practitioner concerning a 16 year old female who on an unspecified date was vaccinated intramuscularly with the first dose of Gardasil. Concomitant therapy included a tetanus toxoid shot. Immediately with vaccination, the patient developed injection site stinging and the patient passed out for a few seconds. The patient sought unspecified medical attention. The nurse practitioner reported that the patient was fine after a few seconds and was able to drive home. There was no lot number provided. Additional information has been requested.

**Other Meds:** Tetanus toxoid

**Lab Data:** UNK

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272624-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	PA	WAES0702USA00208	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Nervous system disorder, Pain in extremity

**Symptom Text:** Information has been received from a nurse practitioner concerning a 17 year old female who was vaccinated, intramuscularly with HPV vaccine. The nurse reported that the patient was having "neurological problems" after receiving the vaccine. The reporter stated that the patient explained she was having "pain and numbness" in her extremities. The reporter stated the patient was going to see a neurologist. At the time eof the report, it was unknown, if the patient recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272625-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	--	WAES0702USA00262	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with HPV vaccine. Subsequently, following vaccination, the patient fainted. The patient fully recovered. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272626-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	--	WAES0702USA00263	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with HPV vaccine. Subsequently, following vaccination, the patient fainted. The patient fully recovered. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272627-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	--	WAES0702USA00264	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on unspecified dates was vaccinated with the first and second doses of HPV vaccine. Subsequently, following each vaccination, the patient vomited. The patient fully recovered. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272628-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	12-Jan-2007	14-Jan-2007	2	15-Feb-2007	01-Mar-2007	--	WAES0702USA00274	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Skin lesion

**Symptom Text:** Information has been received from a physician concerning a female patient who on 12-JAN-2007 was vaccinated with a dose of HPV vaccine. On 14-JAN-2007 the patient experienced painful raised lesions on the arm where the vaccine was administered. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272629-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	12-Jan-2007	14-Jan-2007	2	15-Feb-2007	01-Mar-2007	CA	WAES0702USA00304	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		655619/1427F	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Skin lesion

**Symptom Text:** Information has been received from a physician concerning a 25 year old female who on 12-JAN-2007 was vaccinated IM in the right deltoid, with a first 0.5 ml dose of HPV vaccine (lot#655619/1427F). There was no concomitant medication. On 14-JAN-2007 the patient developed skin eruptions, lesions, on the axilla of the right arm. It was reported that the patient was treated with Benadryl. The patient reported the patient's lesions continued for two weeks and were worsening. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272630-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	24-Jan-2007	24-Jan-2007	0	15-Feb-2007	01-Mar-2007	TX	WAES0702USA00307	01-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site, Injection site rash, Rash

**Symptom Text:** Information has been received from the mother of a 22 year old female, via a consumer (friend), who on approximately 24-JAN-2007 was vaccinated in the buttock with the first dose of HPV vaccine. On approximately 24-JAN-2007 the patient developed an initial rash at the injection site, which went away. A few days later, approximately 27-JAN-2007 the patient developed a rash on her entire trunk, spreading form her crotch to her shoulders. The patient's mother was thought to be a nurse, who administered the injection to her daughter at home after she picked up the vaccine from her daughter's physician. It was also reported that the mother of the patient had picture of her daughter's rash. At the time of the report the patient had not recovered from the rash on her trunk. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272631-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	30-Jan-2007	31-Jan-2007	1	15-Feb-2007	01-Mar-2007	--	WAES0702USA00321	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who on 30-JAN-2007 was vaccinated with the second 0.5 mL dose of HPV vaccine. Concomitant therapy included unspecified hormonal contraceptives. On 31-JAN-2007, the patient developed a rash under skin that covered entire body except her legs. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the event. The nurse did mention that the patient "did not have a reaction to the first injection of HPV vaccine. Additional information has been requested.

**Other Meds:** hormonal contraceptive

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272632-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	26-Jan-2007	26-Jan-2007	0	15-Feb-2007	01-Mar-2007	CA	WAES0702USA00348	01-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a 22 year old female healthcare worker who on 26-JAN-2007 was vaccinated with HPV vaccine. The patient stated that the "HPV stung a lot as it was being administered." Unspecified medical attention was sought. The patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272633-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES0702USA00596	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated by HPV vaccine, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272634-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES0702USA00597	01-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injections. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272635-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES0702USA00598	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272636-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES0702USA00599	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272637-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES0702USA00600	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272638-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	01-Mar-2007	NJ	WAES0702USA00601	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272639-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	NJ	WAES0702USA00602	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the tiem of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272640-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	NJ	WAES0702USA00603	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272641-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		15-Feb-2007	21-Feb-2007	--	WAES0702USA00604	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** Information has been received from a registered nurse concerning a female, pediatric patient, who was vaccinated with Gardasil, (lot not reported). Subsequently the patient experienced severe injection site pain. It was reported that the pain was in the muscle and started at the time of injection. The pain lasted for 2 days and then resolved. The patient was treated with warm compresses. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 912

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272718-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	29-Oct-2006	29-Oct-2006	0	20-Feb-2007	21-Feb-2007	FR	WAES0612AUS00040	21-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0444F		Unknown	Intramuscular			

**Seriousness:** LIFE THREATENING, SERIOUS

**MedDRA PT** Bronchospasm, Dizziness, Dizziness, Dyspnoea, Oxygen supplementation, Pallor, Palpitations, Syncope

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 29-OCT-2006 was vaccinated with Gardasil (lot No 654672/0444F, batch no NE01680, Expiry date 23-FEB-2009) on her left deltoid muscle. The patient is needle phobic and had nothing to eat on 29-OCT-2006 until the patient received vaccination on 12:02pm. On 29-OCT-2006 the patient experienced syncope and bronchospasm. Four minutes after injection, the patient had syncope. The symptoms included light headedness, pallor, feeling like fainting and palpitation. The patient had no chest pain but had bronchospasm with dyspnoea. The patient's sitting blood pressure was 110/67 mmHg and pulse rate was 55. Glasgow Coma Score was 15/15. The patient had oxygen mask. The patient was not hospitalized. The physician considered her diagnosis as phobia, syncope vs drug reaction. Subsequently the patient recovered from syncope and bronchospasm. The physician considered syncope and bronchospasm were related to therapy with Gardasil and asked the patient to reconsider about continuing the next dose of Gardasil. Syncope and bronchospasm were considered to be life threatening by the reporting physician. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** blood pressure 29Oct06 110/67 mmHg Comment: sitting BP, physical examination 29Oct06 Comment: Pulse rate 55, Glasgow come scale 29Oct06 Comment: 15/15

**History:**

**Prex Illness:** Phobic anxiety

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272720-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	01-Feb-2007	01-Feb-2007	0	20-Feb-2007	21-Feb-2007	--	WAES0702USA02439	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Contusion, Haemorrhage, Rectal haemorrhage

**Symptom Text:** Information has been received from a health professional concerning her 13 year old female cousin with pertinent medical history and drug reactions/allergies not specified who in approximately February 2007, was vaccinated with Gardasil (Lot # not reported) 0.5 ml. Concomitant therapy was unspecified. In approximately February 2007, the patient experienced "internal bleeding throughout her body" after being vaccinated with Gardasil. The bleeding presented initially as bruising and most recently as rectal bleeding. Medical attention was sought. On an unspecified date, the patient was hospitalized. At the time of reporting, the patient had not recovered. The patient's internal bleeding, bruising, and rectal bleeding were reported as immediately life threatening and disabling events. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272739-1      **Related reports:** 272739-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.8	F	10-Feb-2007	11-Feb-2007	1	20-Feb-2007	21-Feb-2007	PA		21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Nausea and vomiting 4:30 am 2-11-07 to 5:00 pm

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:** high Fever~DTaP (unknown mfr)~2~0~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272739-2      **Related reports:** 272739-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	01-May-2007	--	WAES0703USA00617	01-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Information has been received from a health professional concerning a female who was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient vomited the day after receiving HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient sought medical attention. Subsequently, the patient recovered. Additional information is not expected.

**Other Meds:** unknown

**Lab Data:**

**History:** unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272740-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Feb-2007	08-Feb-2007	0	20-Feb-2007	21-Feb-2007	KY		21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperaesthesia, Pruritus, Urticaria

**Symptom Text:** Generalized itching started the evening of vaccine. Increased in sensitivity, esp in scalp over next 3 days. Broke out in hives 3 days after vaccine-both arms and face. Given po Benadryl with improvement. Hives gone after 2 doses of Benadryl. Rx for Zyrtec started.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272771-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	07-Feb-2007	09-Feb-2007	2	20-Feb-2007	21-Feb-2007	FL		21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash papular, Rash pruritic

**Symptom Text:** AFEBRILE ERYTHEMATOUS FINE PAPULAR PRURITIC RASH ON CHEST, LEGS, BACK AND ABDOMEN BEGINNING 2 DAYS POST VACCINATION. PRURITITS AND ERYTHEMA RESPONDED TO ORAL BENADRYL.

**Other Meds:** NONE

**Lab Data:** THROAT CULTURE TO RULE OUT STREP PN 2/13/07. RESULTS WERE NEGATIVE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272785-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	19-Feb-2007	19-Feb-2007	0	21-Feb-2007	21-Feb-2007	PA		21-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	0942R	1	Left arm	Subcutaneously	
	TDAP	AVENTIS PASTEUR	C2644AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0954F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness, Loss of consciousness, Syncope

**Symptom Text:** 5 minutes after Pt received vaccines, fainted LOC lasted about 5 seconds then pt dizzy and lightheaded for about 5-10 min and relieved by 10 min resting supine then 5 min sitting and drinking gatorade/eating cheese crackers.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Keartosis Pilaris

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 919

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272792-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	11-Feb-2007	11-Feb-2007	0	21-Feb-2007	22-Feb-2007	ME	WAES0702USA02702	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dysstasia, Feeling drunk, Incoherent, Lethargy

**Symptom Text:** Information has been received from a licensed practical nurse concerning an 18 year old female with a penicillin allergy and allergy to BENADRYL who on 11-FEB-2007 was vaccinated at another practice with a first dose of Gardasil. There was no concomitant medication. On 11-FEB-2007, 30 minutes after the vaccination, the patient "felt lethargic and could not stand on her own". "She looked like she was drunk and she did not make any sense when she spoke". The patient went to an emergency department and was released. She was reported to have no rash or breathing problems. It was also reported that a urinalysis was clear and drug test was normal. She was reported to have recovered 12 hours after the vaccination./ The reporter felt that the patient's symptoms were disabling. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** urinalysis 02/11/07 clear, urine drug screen 02/11/07 normal

**History:**

**Prex Illness:** Penicillin allergy, Drug hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272793-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Aug-2006	Unknown		21-Feb-2007	22-Feb-2007	PA	WAES0702USA01359	07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Foetal disorder, Pregnancy

**Symptom Text:** Information has been received from a medical assistant concerning her 18 year old daughter with family history free from abnormalities who in August 2006, was vaccinated with Gardasil (lot # not reported) injection, IM. Concomitant therapy included varicella virus vaccine live (lot # not reported) given in September 2006). The patient sought medical attention. At the time of reporting, the patient was 4 months pregnant (estimated last menstrual period 03-NOV-2006 and estimated date of delivery 10-AUG-2007). Her unborn child has fetal abnormalities which were detected shortly after vaccination with Gardasil and varicella virus vaccine live. On an unspecified date, the patient had ultrasounds and amniocentesis performed. Additional information was received from the patient's mother via telephone call who reported that her daughter is currently under the care of perinatologist. Additional information has been requested.

**Other Meds:**

**Lab Data:** Amniocentesis, Ultrasound

**History:**

**Prex Illness:** Pregnancy NOS (LMP = 11/3/2006)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272821-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	05-Feb-2007	06-Feb-2007	1	21-Feb-2007	22-Feb-2007	CA		22-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness, Nausea, Tremor

**Symptom Text:** Pt received Gardasil on Feb 5 2007 in pm. She went home the next day she woke up 6:00 am with dizziness, legs shaking, nauseated, feeling faint lasting 3 days unable to go to school. The fourth day she felt better.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** came in for lump on stomach, was hit while playing basketball

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272847-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	15-Feb-2007	18-Feb-2007	3	21-Feb-2007	23-Feb-2007	CO		26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0962F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site rash, Urticaria

**Symptom Text:** HPV vaccine given 2/15/07. PT called office 2/20/07 with reports of "breaking out from vaccine". States on 2/18 she had hives on waist up, dry and flaky. Only "pain and pimple" at injection site (R arm). Pt denied any other changes in detergents, soap, food, perfume, lotion, etc. Pt told to take Benadryl.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** Routine Pap smear

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272851-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
8.0	F	21-Feb-2007	Unknown		21-Feb-2007	22-Feb-2007	KS		22-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1301F	1	Left arm	Subcutaneously	
	FLU	AVENTIS PASTEUR	U2272AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration

**Symptom Text:** The HPV vaccine was given to a 7 yr. old girl.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272865-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	11-Jan-2007	12-Jan-2007	1	22-Feb-2007	23-Feb-2007	MI		09-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vaginal haemorrhage

**Symptom Text:** Vaginal bleeding started day after receiving Gardasil vaccine. Bleeding is persistent (Moderate-severe) and still present LMP 12/28/02 ended 01/02/07. Onset menses 10 year age.

**Other Meds:**

**Lab Data:** Denies sexual activity, PG test neg.

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272876-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	08-Feb-2007	08-Feb-2007	0	22-Feb-2007	23-Feb-2007	--		26-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00134		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Burning sensation, Incorrect dose administered, Injection site erythema, Injection site pain, Injection site rash, Vaccination complication

**Symptom Text:** Patient received partial dose of vaccine in left deltoid due to defective syringe. Pt immediately complained of a burning sensation on her arm where the medication ran (down her arm) I cleansed her entire upper arm with alcohol-pt relieved little relief. The she stated it was sore at about a 2 inch radius from the injection site. Pt was discharged in mother's care to monitor her. Pt's mother was contacted around 10:00 am the next day-stated-evening of 02/08/07, pt had severe pain at site and gave 2 500mg doses of Acetaminophen to relieve pain. Mother stated site looked red and raised-similar to a bee sting reaction. She also stated it was gone upon waking and pt now only complaining of moderate site pain with little swelling and redness. Pt to return in 3 days for reevaluation.

**Other Meds:** Ortho-tricyclen, Synthroid

**Lab Data:** NONE

**History:** egg allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272889-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	12-Feb-2007	12-Feb-2007	0	22-Feb-2007	23-Feb-2007	--	WAES0702USA02754	23-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 17 year old female with penicillin allergy who on 12-FEB-2007 was vaccinated with Gardasil 0.5ml intramuscularly (lot number 653736/0014U). There was no concomitant medication. On 12-FEB-2007, 45 to 60 minutes post vaccination, the patient called the physician's office stating that she had hives on her arms and legs. The treatment was Benadryl. On 13-FEB-2007, the patient was seen at the physician's office and still had hives on her arms and legs but no shortness of breath. No other treatment was given. The hives were improving. Hives on arms and legs were considered an other important medical event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:**

**Prex Illness:** Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 927

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272893-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	17-Jan-2007	29-Jan-2007	12	22-Feb-2007	23-Feb-2007	PA		26-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1046F	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Papilloedema, Rash generalised, Varicella

**Symptom Text:** This was a second varicella immunization. She received her first 6/9/97. She recieved both varicella and Gardacil on 1/17/07 about 10 days later she developed a rash consistant with varicella. The rash was over her entire body with greater than 20 sites. The rash followed the course of varicella and has dried up. She also developed papilledema and needed to be placed on prednisone by an ophthalmologist. The rash is resolving but she is still being treated for papilledema by another physician

**Other Meds:** Asmanex, Nasonex, albuterol inhaler,

**Lab Data:** None

**History:** allergies, asthma, Eczema

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 928

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272895-1      **Related reports:** 272895-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	20-Feb-2007	20-Feb-2007	0	22-Feb-2007	23-Feb-2007	MD		26-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	02634	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arrhythmia, Dyspnoea, Dysstasia, Fall, Feeling hot, Fluid replacement, Hyperhidrosis, Hyperventilation, Injury, Loss of consciousness, Nausea, Paraesthesia

**Symptom Text:** I received the vaccination at approximately 8:20 AM and felt nothing (my arm slightly ached where the vaccine had been injected, but I felt nothing out of the ordinary post-injection). I walked over to the check-in counter to schedule my third a final injection in the series and put on my jacket. I remember the nurse saying 8:00 AM on Wednesday, June 20 and then the next thing I remember is being surrounded by people on the floor of the office. I blacked out while standing up and hit the left side of my body (mainly my lower jaw, neck, and clavicle) and when my body hit the floor the center, back of my head slammed to the floor. No one actually saw what parts of my body hit where during the fall because the nurse was behind the counter sitting at the computer (below eyesight of my fall) and patients in the waiting room were seated behind a wall. Based on where I remember standing before blacking out and where my body hurt after waking up, I think I am pretty certain I know what was hit. After waking up the doctor and several nurses helped me sit up and recommended calling an ambulance to have my head checked out. At first I declined because I did not think I had any serious problems, but after I tried standing and could not, I agreed to the ambulance. My face was tingly, I had trouble breathing (when I first woke up I was hyperventilating), I was sweating, and my legs were not stable. The EMT arrived and took my blood pressure and decided I should go to the emergency room for a check-up. When we arrived at the ER my head and lower jaw were throbbing from the fall. The ER staff gave me an IV for hydration and ran the typical tests (blood pressure, heart rate, etc.), an EKG, and later received a CAT scan. After returning from the CAT Scan I was still a bit shaken but was breathing normal. My left arm ached from the injection (my right arm ached after the first injection in series, so I ignored that aches). After being in the hospital for at least two hours I suddenly blacked out again. My sister was sittin

**Other Meds:** I take Ortho Try Cyclen Lo, daily and a multi-vitamin

**Lab Data:** CAT Scan, EKG, blood pressure, heart rate

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272895-2      **Related reports:** 272895-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	20-Feb-2007	20-Feb-2007	0	16-Mar-2007	21-Mar-2007	MD	WAES0702USA03759	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Syncope

**Symptom Text:** Information has been received from a health professional concerning a 23 year old female who on 19-DEC-2006 was vaccinated with a first dose of Gardasil. On 20-FEB-2007, the patient was vaccinated IM, into the right deltoid, with a second 0.5 ml dose of Gardasil (lot #655849/0263U). There was no concomitant medication. On 20-FEB-2007, approximately 2 to 3 minutes after the vaccination, the patient fainted for 30 to 45 seconds. It was reported that the rescue squad was called because the patient developed leg numbness spreading to the shoulders after recovering from the fainting spell. It was reported that the numbness lasted from a few minutes. The patient was transported to the emergency room of a local hospital. At the emergency room, the patient had a second episode of syncope at 12:20 p.m. At the time of the report the patient was in the emergency room and had not recovered from the second event of syncope. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272911-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.1	F	17-Feb-2007	17-Feb-2007	0	22-Feb-2007	23-Feb-2007	NY		09-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1948AA	0	Right arm	Unknown	
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC14B008AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1447F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** No adverse effect, Wrong drug administered

**Symptom Text:** none-realized Dtap was given instead of Tdap

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272940-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Dec-2006	22-Dec-2006	0	23-Feb-2007	26-Feb-2007	FL	WAES0702USA03448	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Intramuscular			

**Seriousness:** PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Insomnia, Medical device complication, Musculoskeletal pain, Pain, Physiotherapy

**Symptom Text:** Information has been received from a physician and an office manager concerning a 17 year old female with asthma who on 22-DEC-2006 was vaccinated IM, into the left arm, with a 0.5 ml first dose of Gardasil (lot#654540/0800P). It was reported that at the end of the administration the "safety spring plunger snapped back and caused the patient pain." The office manager explained that this incident was due to human error, the physician was unfamiliar with safety mechanism. On 22-DEC-2006, the patient experienced left shoulder pain and difficulty sleeping on her left arm. On approximately 12-FEB-2007, the patient saw an orthopedic surgeon. The patient underwent an X-ray which revealed no bony abnormality. The orthopedic surgeon recommended that the patient go to physical therapy. At the time of the report, the patient had not recovered. The physician considered the left shoulder pain and difficulty sleeping on her left arm to be disabling events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** X-ray 02/12??/07 - No bony abnormalities

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 932

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272941-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Feb-2007	09-Feb-2007	1	23-Feb-2007	26-Feb-2007	KS	WAES0702USA01732	26-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity, Pruritus, Urticaria

**Symptom Text:** Information has been received from a certified registered nurse anesthetist concerning her daughter, a 16 year old female on contraceptive therapy, who on 08-FEB-2007 was vaccinated with the first dose of Gardasil, 0.5 ml, IM in the left arm. Concomitant therapy included Yasmin for birth control. On approximately 09-FEB-2007 (within 24 hours), the patient experienced a sore arm and itching. By 11-FEB-2007 the patient developed "huge hives crawling up both arms and hives to the jaw down around the face." Treatment included Benadryl, 50mg. The patient's mother called the hospital triage nurse, "but child was not hospitalized." A second dose of Benadryl, 25 mg was administered on the evening of 11-FEB-2007. The patient was reported to be recovering. The reporter considered the hives, sore arm and itching to be an other important medical event. Additional information has been requested.

**Other Meds:** Yasmin

**Lab Data:** NONE

**History:**

**Prex Illness:** Contraception

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272942-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		23-Feb-2007	26-Feb-2007	PA	WAES0702USA02738	26-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Immune system disorder

**Symptom Text:** Information has been received from a nurse concerning her niece (age not reported) who on an unspecified date was vaccinated with Gardasil injection. Concomitant therapy was unspecified. Subsequently, the patient experienced "immune system shut down" after receiving the vaccination. The patient had sought medical attention. On an unspecified date, the patient was hospitalized and at the time of reporting it was unknown how long the patient was hospitalized or if she was still in the hospital. It was unspecified if the patient had recovered. The nurse felt that the "immune system shut down" was considered to be immediately life-threatening. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272976-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	15-Feb-2007	16-Feb-2007	1	23-Feb-2007	26-Feb-2007	MD		27-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Nausea, Pain in extremity

**Symptom Text:** 2-22-07 pt reported feeling dizzy and tired, nauseous, and arm just stopped hurting yesterday, symptoms started day after injection, no lump, no bump at site

**Other Meds:** Yasmin

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** cold

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272978-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	16-Feb-2007	16-Feb-2007	0	23-Feb-2007	26-Feb-2007	VA		27-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Muscular weakness, Nausea, Paraesthesia, Photophobia

**Symptom Text:** Approx. 2 hours after receiving HPV vaccine pt. developed tingling in left arm (vaccine given in left arm) and then in left leg. At times both extremities felt slight "weak". Pt developed severe right sided headache with nausea and photophobia

**Other Meds:** Mircette-28

**Lab Data:**

**History:** NONE

**Prex Illness:** mild viral URI

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272983-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	19-Feb-2007	20-Feb-2007	1	23-Feb-2007	28-Feb-2007	NY		28-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00116	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Nausea, Syncope, Vomiting

**Symptom Text:** Patient received Gardasil vaccine in P.M. during night, nausea, vomited x 1, then fainted. Temperature 100.7

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 272989-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	31-Jan-2007	Unknown		23-Feb-2007	28-Feb-2007	VA		28-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pregnancy test positive

**Symptom Text:** Patient has positive pregnancy test on 2-22-07. Cancel all future doses.

**Other Meds:** Prenatal vitamin

**Lab Data:** (+) pregnancy

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273013-1      **Related reports:** 273013-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	20-Feb-2007	22-Feb-2007	2	26-Feb-2007	27-Feb-2007	CT		27-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	?	0	Right arm	Intramuscular	HPV4

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Herpes zoster, Pain, Paraesthesia, Pruritus, Rash

**Symptom Text:** ON 2/22/07 PATIENT STARTED WITH TINGLY,ITCHY AREA ON BACK THAT BECAME A RAISED ,RED RASH ON BACK. IT IS MOSTLY ON ONE SIDE MORE THAN THE OTHER AND IS VERY PAINFUL AND CAUSES HER LEFT SIDE TO BE TINGLY. SHE WENT TO THE WALK-IN BECAUSE IT WAS THE WEEKEND AND THEY DIAGNOSED HER WITH SHINGLES. SHE WAS STARTED ON A COURSE OF VALTREX TO TAKE TID FOR ONE WEEK. SHE IS FOLLOWING UP WITH HER PRIMARY CAE M.D. WHO IS POSSIBLY TO DO LAB WORK.

**Other Meds:** LOOVRAL

**Lab Data:**

**History:** NONE KNOWN

**Prex Illness:** NONE KNOWN

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273013-2      **Related reports:** 273013-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	20-Feb-2007	22-Feb-2007	2	16-Mar-2007	29-Mar-2007	CT	WAES0702USA04416	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Herpes zoster, No adverse effect, Paraesthesia, Rash

**Symptom Text:** Information has been received from a Licensed Practical Nurse (L.P.N.) concerning a 16 year old female patient with a possible allergy to AUGMENTIN who on 20-FEB-2007 was vaccinated with her second dose of Gardasil. She was seen at Urgent care on 22-FEB-2007, with a raised red tingling rash on her back, and side. The diagnosis was shingled. Patient was treated with VALTREX TID for a week. She had no adverse symptoms after the first dose of Gardasil. The patient was reported as not recovered at the time of this report. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 940

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273026-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	12-Feb-2007	12-Feb-2007	0	26-Feb-2007	27-Feb-2007	TN	WAES0702USA02831	28-Feb-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Fall, Loss of consciousness

**Symptom Text:** Information has been received from a physician and a nurse in the physician's office concerning a 14 year old female who on 12-FEB-2007 was vaccinated with the first 0.5ml dose of Gardasil. within two minutes of receiving the shot, the patient passed out. it was reported that as she was falling to the ground, it was observed that she was having a seizure. The seizure was described as a "drawing of the right arm". The patient did not have full body tremors. The seizure lasted approximately one minute. The patient was sent to the emergency room, however, was reported as being "Fine" when she left the office. The patient was not admitted to the hospital. The nurse did not know of any treatment given in the ER and believed that the patient was just observed and released. The physician reported that the patient was fine after being released from the emergency room. On 12-FEB-2007, the patient has recovered from the events. It was reported that the patient had no history of seizures and the nurse stated that the patient will continue with the Gardasil series. Upon internal reviews, seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273065-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	08-Feb-2007	10-Feb-2007	2	26-Feb-2007	28-Feb-2007	ND		28-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1822AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1282F	0	Right arm	Intramuscular	
	FLU	CHIRON CORPORATION	72004	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cervix disorder, Contusion, Discomfort, Myalgia, Myalgia, Pain

**Symptom Text:** 2 days after receiving vaccines started having sharp, stabbing pain, and bruising in cervix area. Muscles ache and burn also inner thighs. No fever, no vaginal discharge. Still having discomfort 12 days afterwards. No sexually active.

**Other Meds:**

**Lab Data:**

**History:** Depression, low back pain

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273098-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		27-Feb-2007	28-Feb-2007	FR	WAES0702USA03743	28-Feb-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Condition aggravated, Juvenile arthritis

**Symptom Text:** Information has been received from a hospital physician concerning an 18 year old female with rheumatism who was vaccinated with a first dose of Gardasil. Subsequently the patient experienced juvenile arthritis, which was assumed to be an acute exacerbation of pre existing rheumatism. Beforehand she had been uncomplaining for a long time. She was admitted to the hospital where a joint puncture was carried out. At the time of the report, the symptoms were ongoing. No further information is available. Other business partner numbers included E2007-01082.

**Other Meds:** UNK

**Lab Data:** Arthrocentesis

**History:**

**Prex Illness:** Rheumatism

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273099-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	22-Feb-2007	22-Feb-2007	0	27-Feb-2007	28-Feb-2007	NY		05-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B007AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1426F	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB141AA	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2158AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Chest discomfort, Cough, Dyspnoea, Dyspnoea, Hypersensitivity, Tremor, Wheezing

**Symptom Text:** None Stated 03/05/07-records received from facility: seen in ED for allergic reaction to vaccines. HX of cough, wheezing and SOB few hours prior to ED visit, symptoms began 30 minutes after vaccines. Initially returned to PCP with c/o chest tightness, difficulty breathing, treated with epipen and benadryl and sent to ED. No swelling of mouth, lips or tongue. Allergies to cat (owns a cat). Uses nasonex for nasal congestion. VS P: 141, resp 20 BP 130/91. Treated with solu medol and ranitidine. Tremors, difficulty breathing. PE unremarkable. Lungs clear, no rhonchi, no wheezes. Admitted for IV steroid treatment.

**Other Meds:**

**Lab Data:** records received 4/5/07-CBC:66 neutrophils. 24.6 lymphocytes.

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273103-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	08-Feb-2007	Unknown		27-Feb-2007	28-Feb-2007	TX		28-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Rash on shoulders, chest and back

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273112-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Dec-2006	02-Feb-2007	43	27-Feb-2007	28-Feb-2007	IN		13-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blister, Herpes virus infection, Hordeolum

**Symptom Text:** 2/2/07 Vesicles near eyebrow, sty in eyelid - found to be possible herpes. Treated with Valtrex.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273116-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	20-Feb-2007	20-Feb-2007	0	27-Feb-2007	28-Feb-2007	MN		28-Feb-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Right arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2168CA	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Rash, Urticaria

**Symptom Text:** symptoms started 2-20-07 at 7pm. 1st noticed bumps on arms. She now has hives on her abdomen, face, neck and arms. She also felt faint at times.

**Other Meds:** Metronidazole 100 mg/day

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 947

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273177-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
31.0	F	12-Dec-2006	12-Dec-2006	0	28-Feb-2007	01-Mar-2007	--	WAES0702USA03479	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Amnesia, Convulsion, Dyspnoea, Headache, Incoherent, Influenza like illness, Malaise, Nausea

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 31 year old female with type II diabetes mellitus, sulfa, morphine, DEMEROL and penicillin allergy and a history of gastric bypass (1994), reverse gastric bypass (1996) and mild asthma who on 12-DEC-2006 was vaccinated with her first dose of Gardasil (lot #653978/0955F), 0.5 ml, IM. Concomitant therapy included metformin HCL (GLUCOPHAGE). On 12-DEC-2006 less than one hour after receiving her first dose of Gardasil, the patient developed "Flu-Like" symptoms. The patient stated that she had a headache and nausea but was not sure if she had a fever. About ten hours after the initial vaccine was administered the patient had a convulsive seizure. The seizure lasted about 2 minutes. The patient was not coherent and was breathing heavy. After the seizure, the patient continued to fell ill and had no memory of the seizure. The patient did not go to the hospital. The patient's husband was an EMT, so he attended to her but did not given her any medication. The patient had no prior history of seizures. The next day the patient felt better. Upon internal review, convulsive seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** GLUCOPHAGE

**Lab Data:**

**History:** Gastric bypass, gastric stapling reversal, asthma

**Prex Illness:** Type II diabetes mellitus, Sulfonamide allergy, Drug hypersensitivity, Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273185-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	23-Feb-2007	23-Feb-2007	0	28-Feb-2007	01-Mar-2007	MA		01-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hyperhidrosis, Oxygen supplementation, Pallor, Paraesthesia

**Symptom Text:** Pt was leaving office c/o being dizzy, extreme pallor, perspiring, tingling both hands, 118-70, P116, O2 Sat 98%, O2 given, kept 45 min color improved. Tingling of fingers subsided.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273206-1      **Related reports:** 273206-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	22-Jan-2007	29-Jan-2007	7	28-Feb-2007	01-Mar-2007	UT		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Left arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	U2177AA		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Aphthous stomatitis, Asthenia, Blepharospasm, Dysaesthesia, Fatigue, Fatigue, Headache, Hypoaesthesia, Hypoaesthesia, Hypoaesthesia facial, Mouth ulceration, Muscular weakness, Myalgia, Pain

**Symptom Text:** Patient had myalgias at day 7 post vaccine. Severe headache global x <24 hours. Severe muscle weakness. Severe fatigue, symptoms routine except headache which disappeared in 24 hours. 03/07/8/07-records received from rheumatology consultation for DOS 03/02/07-Impression: Myalgias, dysethesias hands and feet, increased fatigability, oral ulceration/cankers;possible rare reaction to either flu or Gardasil. Rule out vasculitis, lupus and other connective tissue disease. C/O severe body pain, weakness, headache lasted 1 day but has had persistent generalized muscle pain. Transient numbness in hand, face and feet. Eyes feel sore, some twitching of eyelids. PMH: Seizure as infant after pertussis vaccine and never completed the series. No recurrence of seizure and did not appear to be febrile seizure. Mother has multiple sclerosis. PE:Muscles tender to palpation pretty uniform throughout body, not so much in hands as in forearms, arms, trunks, legs, calves.

**Other Meds:**

**Lab Data:** Severe reaction Gardasil and Influenza vaccine given. Labs:WNL. Rheumatoid factor negative. CK 64 repeat CK 65.

**History:** Pertussis vaccine. 3/7/07 records received Seizure as infant after pertussis vaccine and never completed the series. Mononucleosis at age 16. Migraines.

**Prex Illness:**

**Prex Vax Illns:** seizure~Vaccine not specified~1~0~In Patient|aeizure~Vaccine not specified~1~0~In Sibling

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 950

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273206-2      **Related reports:** 273206-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	22-Jan-2007	22-Jan-2007	0	16-Mar-2007	29-Mar-2007	UT	WAES0702USA04702	29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Erythema, Fatigue, Headache, Rash, Rash macular

**Symptom Text:** Information has been received from a consumer concerning her daughter, a 19 year old female with a history of a seizure response to pertussis vaccine as an infant, who on 11-OCT-2006 was vaccinated with the first dose of Gardasil and on 22-JAN-2007 was vaccinated with the second dose of Gardasil. The mother reported that her daughter "had no adverse experiences" with that vaccination. Concomitant suspect therapy included influenza virus vaccine (unspecified), also administered on 22-JAN-2007. On 29-JAN-2007 the mother stated that her daughter experienced "severe systemic arthritic response," and further explained, "she woke up with severe joint pain, severe fatigue, headaches and a red, blotchy facial rash." The mother reported that her daughter had "multiple lab work" performed, however specific tests or results were not provided. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Convulsion

**Prex Illness:** Allergy to vaccine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273207-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	28-Dec-2006	28-Dec-2006	0	28-Feb-2007	01-Mar-2007	PA		01-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus

**Symptom Text:** 2-27-07 Patient stated "I had redness in my right arm that went down to right hand and knuckles, then it started in left arm and hand it was very itchy. Started 30-45 min after injection given.

**Other Meds:** Yaz birth control

**Lab Data:**

**History:** NKDA; no birth defects; no medical conditions

**Prex Illness:** NONE reported

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273209-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	16-Feb-2007	20-Feb-2007	4	28-Feb-2007	01-Mar-2007	SC		01-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2689AA	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1968AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	01874	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Sensation of heaviness, Skin burning sensation

**Symptom Text:** Legs burning and hurt next a.m. Tuesday, arms heavy was better on Wednesday, still with something that was gone on Thursday, burning feeling was gone on Wednesday p.m.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 953

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273223-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	17-Feb-2007	17-Feb-2007	0	01-Mar-2007	02-Mar-2007	FR	WAES0702POL00004	23-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	36970		Unknown	Intramuscular	

**Seriousness:** LIFE THREATENING, SERIOUS

**MedDRA PT** Apnoea, Asthenia, Blood pressure decreased, Disorientation, Fall, Head injury, Headache, Hypotension, Retrograde amnesia, Syncope

**Symptom Text:** Information has been received from a physician concerning a 19 year old female who on 17-FEB-2007 was placed on therapy with human papillomavirus vaccine, 0.5 ml, 0.5 ml prophylaxis. On 17-FEB-2007 the human papillomavirus was administered intramuscular in deltoid muscle according to manufacturer's recommendation. The reporter felt that the injection was made properly. Immediately after taking human papillomavirus vaccine the patient experienced weakness. At that moment the blood pressure was 100/70, total heartbeat count was 76/min, temperature was 97.6 deg F. Dyspnoe and changes on the skin were not observed. The patient was laid down in horizontal position with her legs elevated for 5 minutes. After 4 minutes the regression of symptoms was observed. Approximately after 20 minutes the patient fell down. The syncope was observed. Head injury and apnoe were observed. Restoring of respiratory patency by deviation of head and removing of collapsed tongue was performed. Regression of apnoe was observed. The patient experienced disorientation and retrograde amnesia. The patient remembered only the weakness before syncope, but she did not remember what happened later. Then the patient regained consciousness. After that the headache was observed in the injured place and later in whole head. At that moment the blood pressure was 100/60. total heartbeat count was 79/min, temperature was 97.6 deg F, Meningeal signs were negative. After 2 hours no abnormalities were observed. Subsequently, the patient recovered from syncope, hypotension, weakness, apnoe, disorientation, retrograde amnesia, head injury and headache. The reporter felt that syncope, hypotension, weakness, apnoe, disorientation, retrograde amnesia, head injury and headache were related to therapy with Gardasil. Syncope and apnoe were considered by the doctor to be immediately life-threatening. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** blood pressure 17Feb07 100/70 mmHg Comment: low, blood pressure 17Feb07 100/60 mmHg, total heartbeat count 17Feb07 76/min, total heartbeat count 17Feb07 79/min, temperature measurement 17Feb07 97.6 deg F

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273263-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	27-Feb-2007	28-Feb-2007	1	01-Mar-2007	02-Mar-2007	NY		02-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2136AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1426F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Pain, Pyrexia, Rhinorrhoea, Vomiting

**Symptom Text:** FEELING ACHY AND FEVER (101.0) 48HRS AFTER ADMINISTRATION ALONG WITH VOMITTING X6 THAT NIGHT AND TWICE THE FOLLOWING MORNING. MILD RUNNY NOSE, NO COUGHING, NO WHEEZING, NO HIVES,NO DIARRHEA, MILD ABDOMINAL CRAMPING. NO LETHARGY, NO BEHAVIORAL CHANGES, NO JOINT PAIN OR MUSCLE WEAKNESS. ADMINISTERED IBUPRIFEN 400 MG PO AT 11AM ON 03-01-07. ADVISED SYMPTOMATIC CARE AND SEEK EMERGENCY SERVICE IF SYMPTOMS PERSIST OR WORSEN.

**Other Meds:** SINGULAIR 5 MG QHS AND ALBUTEROL MDI 2 INHALATIONS PRN AMD ASMANEX INHALER 1 INHALATION A DAY

**Lab Data:** TEMP= 101.0

**History:** BRONCHIAL ASTHMA; NO ALLERGIES

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273294-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
67.0	F	30-Jan-2007	03-Feb-2007	4	02-Mar-2007	05-Mar-2007	NY		05-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0011U	0	Right arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blister, Erythema, Rash, Skin warm

**Symptom Text:** 4 days after receiving Gardasil vaccine 1st injection patient c/o red, hot rash on both hands and upper thighs, rash on thighs with small blisters lasted approx 1 hour then subsided this went on daily for the next 10 days each time lasting 1 hour.

**Other Meds:** Combivent inhaler, Advantage inhaler, Spiriva inhaler.

**Lab Data:** NONE

**History:** Asthma, Emphysema

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273305-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	16-Feb-2007	16-Feb-2007	0	02-Mar-2007	05-Mar-2007	TX		09-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	0	Right arm	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Fall, Head injury, Injury, Syncope

**Symptom Text:** Pt received Gardasil and within a minute, pt fainted while sitting on table, fell of and hit her head on a drawer handle, pt began to seize. Called 911, she was stabilized by EMS. 03/05/07-records received from PCP:Five minutes after administration of vaccine episode of eyes rolling back, fell off exam table and struck neck and head on cabinet drawers. Unresponsive to voice with stiffening of all extremities. Event lasted 30 seconds, afterwards alert oriented and recalled speaking to urse prior to event. Glucose 76, O2 sats 99% on RA. BP after episode 99/52, pulse 49. Transported to ER. 03/09/07-records received from facility for DOS 2/16/07-DX:Syncope. Post syncopal seizure.

**Other Meds:**

**Lab Data:** UNK labs received 3/9/07.CT head:normal C Spine unremarkable

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273357-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	05-Jan-2007	05-Jan-2007	0	02-Mar-2007	05-Mar-2007	NY	WAES0702USA04223	05-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Malaise, Pallor, Somnolence, Syncope

**Symptom Text:** Information has been received from physician concerning a 16 year old female patient who on approximately 05-JAN-2007 ("7 weeks ago") was vaccinated with the first dose, 0.5ml, IM, of Gardasil. There was no concomitant medication. The physician reported that the patient stated she "did not feel well when checking out and turned white and fainted when being taken back into the examining room." The physician clarified that the patient "did not lose consciousness or hit her head because he caught the patient." He confirmed the patient fainted "within 5 minutes" of the vaccination, and remained "groggy for up to 30 minutes" after the vaccination. The patient was then "considered recovered," and left the office. The physician considered the events to be disabling. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273362-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
10.7	F	19-Feb-2007	19-Feb-2007	0	02-Mar-2007	05-Mar-2007	CA		05-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0186U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bradycardia, Chills, Pyrexia, Vomiting

**Symptom Text:** Fever, chills, bradycardia, vomiting.

**Other Meds:**

**Lab Data:**

**History:** NKA

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 959

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273382-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Feb-2007	01-Feb-2007	0	05-Mar-2007	06-Mar-2007	FR	WAES0702USA04752	06-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0859F		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Anaphylactic reaction, Anxiety, Dyspnoea

**Symptom Text:** Information has been received from a health authority concerning a 16 year old female who on 01-FEB-2007 was vaccinated with the first dose of Gardasil (lot #654740/0859F, batch #NE25270), IM into the left deltoid muscle. It was reported that previous vaccinations were well tolerated. On 01-FEB-2007 at 6:15 pm, the patient experienced anaphylactic reaction with dyspnoea and anxiety reaction and the patient was hospitalized. Subsequently after 75 minutes, the patient recovered from anaphylactic reaction. Anaphylactic reaction was considered to be immediately life-threatening. Case is closed. Other business partner numbers include E2007-01238. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273390-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	21-Dec-2006	21-Dec-2006	0	05-Mar-2007	07-Mar-2007	MA		07-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Pallor

**Symptom Text:** Mom states patient was fine right after shot #1, but felt faint, looked pale on way out of office - came back to exam room and laid down x 20 minutes then was fine. Mom reports this today when returning for shot #2.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273415-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Nov-2006	Unknown		05-Mar-2007	06-Mar-2007	CO		06-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	
	DTP	AVENTIS PASTEUR	C2609AA	0	Right arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2255AAA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site reaction, Pigmentation disorder

**Symptom Text:** Received first vaccine on 11/08/2006 never reported it until 03/01/. Area where she got Gardasil injection and tender and Hypo-pigmented. Left Arm 32mm x 24 mm 11/08/2006 Right Arm 22 x 25 mm 01/08/2007

**Other Meds:** Yaz, Celexa

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273426-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	12-Feb-2007	04-Mar-2007	20	05-Mar-2007	06-Mar-2007	PA		26-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1111R	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0961F	0	Right arm	Intramuscular	

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Arrhythmia, Cardiac disorder, Cough, Nasopharyngitis, Oxygen supplementation, Respiratory arrest, Somnolence, Viral myocarditis, Vomiting

**Symptom Text:** Vaccine administration date 2/12/2007, varicella dose #2 and Gardasil dose #1 administered concurrently. No symptoms until March 4th when in AM noted by mother to have a cold/URI symptoms with cough. Emesis at 11 after soup at 10, napping when mom at home at 3 PM but difficult to arouse. Called 911 and started rescue breathing. Paramedics initially called in stable VS's but required active CPR on gurney by time came into ED. In disorganized vfib in ER-resusc'd with PALS then consulted cardiology for ECMO. Cannulated for VA ECMO - on full flow support after 1.5 hours. Heart completely akinetic. Went to cath lab to get biopsies, CAD's and assessment of integrity of heart with very poor tone/strength to heart muscle noted; presumed acute viral myocarditis. Has gotten IVIG. Can't assess neurologic function due to significant drug load. Remains with very disorganized rhythm today; to consider EPS study; also studying family for possible inherited rhythm disturbances. 03/20/07-partial records received from facility, patient remains in hospital. Received ECMO support for cardiac arrest secondary to myocarditis. Endomyocardial biopsy: acute lymphocytic myocarditis with scattered eosinophils. 04/25/07-DC Summary received for DOS 03/04-03/23/07-DC DX: Cardiac arrhythmia. Myocarditis.

**Other Meds:** None

**Lab Data:** Echocardiogram:dilated right ventricle. severely decreased biventricular systolic function. mild tricuspid/mitral insufficiency. atrial septum bulges. small pleural effusion right.

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273430-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Mar-2007	02-Mar-2007	1	05-Mar-2007	06-Mar-2007	MI		07-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2340AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1860AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Headache, Injection site pain, Injection site swelling, Musculoskeletal stiffness, Nausea, Pyrexia

**Symptom Text:** Patient awakened early 3/2/07 with fever, chills, nausea and headache. L arm at injection site was tender and puffy. Temperatures ranged from 100.8 to 102.0 throughout the day. 3/3/07-c/o nausea, headache and temp of 100.0 3/4/07- c/o headache and stiff neck. 3/5/07-c/o headache

**Other Meds:** NONE

**Lab Data:**

**History:** none

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273433-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Feb-2007	02-Mar-2007	4	05-Mar-2007	06-Mar-2007	MO		07-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Burning sensation, Musculoskeletal pain, Pain

**Symptom Text:** The 2nd injection in November nearly caused my daughter to pass out. She had to lie down & drink some water. The third injection on Feb. 26 was the most painful, with a burning sensation flowing down her arm toward her hand. Approximately 5 days after the injection, she began experiencing very sharp pain in the shoulder she received the injection in. Continues to be in moderate pain, especially with movement of shoulder.

**Other Meds:** birth control pill

**Lab Data:** No medical treatment sought at this time. If doesn't resolve, will seek attention.

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273453-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	05-Mar-2007	05-Mar-2007	0	05-Mar-2007	06-Mar-2007	CA		07-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01884	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Patient fainted.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 966

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273469-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Jan-2007	01-Jan-2007	0	06-Mar-2007	07-Mar-2007	CA	WAES0702USA04695	07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Grand mal convulsion

**Symptom Text:** Information has been received from a physician, via a company representative, concerning a 16 year old female patient who in January 2007 ("last month"), was vaccinated with the first dose, 0.5ml, of Gardasil. The physician reported that in January 2007 ("last month"), the patient experienced a grand mal seizure after receiving her first dose. In addition, the physician reported that the "patient has no history of seizures and was taken to the ER. The physician did not know if the patient was admitted. It was unknown if the patient recovered. Upon internal review, grand mal seizure was determined to be an other medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273472-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	27-Feb-2007	28-Feb-2007	1	06-Mar-2007	07-Mar-2007	IL		07-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01874	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site mass, Injection site pain, Myalgia, Neuralgia

**Symptom Text:** pain of muscle/nerve, neck, arm, and upper back. Very tender arm at injection site and knot at injection site. Put on Prednisone and Mobic by doctor after exam of site and pain.

**Other Meds:** BCP (YAZ)

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273475-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	20-Nov-2006	01-Dec-2006	11	06-Mar-2007	12-Mar-2007	MD		12-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Amenorrhoea

**Symptom Text:** Patient states she missed her menses the month after administration of her first Gardasil injection. Another nurse says she heard another patient say the same thing happened to her, but she couldn't remember the second patient's name in order to fill another report.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273503-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	26-Feb-2007	26-Feb-2007	0	06-Mar-2007	07-Mar-2007	OR		09-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHAVB113AA	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHBVB261AA	2	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Throat tightness

**Symptom Text:** Ct c/o feeling of throat tightening up and difficulty breathing approx 3 1/2-4 hrs of receiving vaccinations. Went to bed and next am awake with throat tightness and breathing trouble, but left eye was swollen shut, right eye puffy, hands and arms swollen bilat., temp 100.9, earlobes also swollen, rash with red blotchness right hand. No local reaction, no arthralgia, ct saw pcp on 2/27/07. Treated with Benadryl 50mg a 6 hour x 2-3 days. Improved substantially by 3/27

**Other Meds:** Stratera, Yazmine, 25 mg diphenhydramine QHS prn

**Lab Data:** ABN CBC-WBC; Monocytes 12.8%; Lymphocytes 50.7; granulocytes 365; other values WNL

**History:** NONE

**Prex Illness:** poss. slight CAD

**Prex Vax Illns:** hives, swelling~~~10~In Sibling

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273505-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	23-Feb-2007	23-Feb-2007	0	06-Mar-2007	07-Mar-2007	MA		07-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1426F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** Aftershot, patient developed pain on the side of the body (left) that shot was administered, over left arm, left trunk, and left leg. There was no local redness, swelling, or pain at site of vaccine itself. The patient was treated with Motrin and ice and resolved after 24 hours.

**Other Meds:** NONE

**Lab Data:**

**History:** allergic to strawberries

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 971

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273513-1 (S)    **Related reports:** 273513-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	14-Dec-2006	14-Dec-2006	0	07-Mar-2007	08-Mar-2007	NY	WAES0703USA00049	08-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Back pain, Neck pain, Pain in extremity, Pain in jaw

**Symptom Text:** Information has been received from a physician concerning a 17 year old female patient with a history of rash after taking amoxicillin, who on 14-DEC-2006 was vaccinated with the first dose, 0.5 ml, in the right arm, of Gardasil. Concomitant therapy included (ORTHO TRI-CYCLEN). In December 2006 (date not specified), the patient "experienced pain at left angle of jaw, neck pain and mid back pain. "The physician reported that the "mother treated daughter with ibuprofen and within 36 hours symptoms improved. The physician stated "the client did not report this reaction at the time. "On 20-FEB-2007 a second dose , 0.5ml, in the left arm, of Gardasil was administered. On 25-FEB-2007, the patient called the office, "complaining of pain at left angle of jaw, mid back pain, and pain in the right deltoid, upper aspect of the right arm, the opposite arm" of where she received the vaccination. At the time of this report it was unknown if the patient had recovered. The physician considered the events to be significantly disabling. Additional information has been requested.

**Other Meds:** ORTHO TRI-CYCLEN

**Lab Data:** NONE

**History:** Drug rash

**Prex Illness:** Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273513-2      **Related reports:** 273513-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	20-Feb-2007	20-Feb-2007	0	15-Mar-2007	16-Mar-2007	NY		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Back pain, Drug hypersensitivity, Mobility decreased, Pain in extremity, Pain in jaw

**Symptom Text:** Gardasil given Left upper arm on 2/20/07 experienced pain within 24 hours starting at Left angle of jaw and extending down to mid low back, accompanied by right upper outer arm/deltoid pain with shoulder movement and inability to raise Right arm past 90 degrees home prescribed Ibuprofen seen here 2/26/07 and right arm pain persisted. 1st dose Gardasil 12/14/06 given GYN office, also experienced Left neck/jaw pain down to mid back and Right deltoid pain however 1st dose given in Right arm.

**Other Meds:** ORTHO TRI-CYCLEN

**Lab Data:** NONE

**History:** Hx rash on amoxicillin in past

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273514-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	06-Feb-2007	14-Feb-2007	8	07-Mar-2007	08-Mar-2007	FR	WAES0703USA00122	08-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Abnormal behaviour, Hallucination, auditory, Mental disorder

**Symptom Text:** Information has been received from a health professional concerning an 18 year old female patient with no past medical history who on 06-FEB-2007 was vaccinated with a first dose of Gardasil (dosage not provided). There was no concomitant medication. On 14-FEB-2007 the patient developed bizarre philosophical outlook and claimed to hear the voice of a good entity called "it" which could "redress unbalance in her family." She also described the Gardasil as poison coursing through her body. The patient was seen by the reporter who described her behavior as overtly sexual by throwing herself back in the chair with her legs wide open. The reporter stated it was a major psychiatric breakdown and her parents were unable to cope with her at home. The patient was sectioned to be admitted to the hospital. The patient had not recovered as of 23-FEB-2007. Other business partner numbers included E2007-01291. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273519-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	Unknown	08-Feb-2007		07-Mar-2007	08-Mar-2007	FR	WAES0702HUN00008	08-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** Information ahs been received from a physician concerning a 38 year old female who was vaccinated with Gardasil. On 08-FEB-2007 about two weeks after vaccination, the patient experienced numbness and was hospitalizes. At the time of vaccination patient had chlamydial infection and had taken Botox (botullinum injection used for cosmetic reasons).The action taken with regards to therapy with Gardasil was none. The patient is recovering and the causality reported by treating physician is "possible". No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Chlamydial infection

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273522-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	09-Feb-2007	09-Feb-2007	0	07-Mar-2007	07-Mar-2007	OH		08-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Injection site anaesthesia, Injection site pain, Tenderness

**Symptom Text:** Teen reports today pain at injection site for 1 week, then pain resolved and noticed numbness at site, which then went down to fingers, and involving entire arm. Transient, sometimes causing weakness. Site today tender to touch but location varies during exam. Full ROM

**Other Meds:** NONE

**Lab Data:** sent to ped neurology at clinic

**History:** possible migraines-not diagnosed yet by neuro. says right arm numbness with migraines

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273538-1      **Related reports:** 273538-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Feb-2007	24-Feb-2007	1	07-Mar-2007	08-Mar-2007	MA		05-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01874	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Myalgia, Pharyngolaryngeal pain, Swelling

**Symptom Text:** Pt developed arthralgia, swelling and myalgia involving hands, fingers, elbow joint, toes and ankle joints in 2x hrs after vaccination. Also pt developed sore throat 4 days after immunization.

**Other Meds:** NONE

**Lab Data:** Strep culture

**History:** asthma

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273538-2      **Related reports:** 273538-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Feb-2007	24-Feb-2007	1	09-Apr-2007	01-May-2007	--	WAES0703USA00619	02-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	656049/0187U		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Myalgia, Pharyngolaryngeal pain

**Symptom Text:** Information has been received from a registered nurse concerning a 17 year old female, with no pertinent medical history who on 23, Feb 2007 was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 656049/0187U). On 24, Feb 2007. the patient experienced arthralgia, myalgia and sore throat. Patient outcome was unknown. Additional information has been requested.

**Other Meds:** unknown

**Lab Data:** unknown

**History:** none

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273547-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	21-Feb-2007	22-Feb-2007	1	07-Mar-2007	12-Mar-2007	VA		12-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature decreased, Headache, Influenza like illness, Neck pain

**Symptom Text:** Headaches, low grade temp 100 degrees, neck pain, flu-like symptoms. Patient was treated by her family.

**Other Meds:**

**Lab Data:**

**History:** Amoxicillin, PCN

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273553-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	13-Feb-2007	20-Feb-2007	7	07-Mar-2007	08-Mar-2007	NC		08-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** C/0 rash/hives starting on arms, wrists spread to face and legs 7-9 days post injection. Treatment prescribed by primary care MD, ----->, Medrol pack --->, -----> rash/hives disappeared within 24 hours of start of treatment.

**Other Meds:** (Loestrin 24)

**Lab Data:** NONE

**History:** NONE - NKDA, NKA

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273565-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	07-Mar-2007	07-Mar-2007	0	07-Mar-2007	08-Mar-2007	IN		09-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, LIFE THREATENING, SERIOUS

**MedDRA PT** Chest discomfort, Urticaria, Urticaria

**Symptom Text:** Within 1 hour of receiving vaccination she developed diffuse urticaria. responded to injected benadryl and depomedrol. 03/09/07-records received. for DOS 3/7/07-developed whole body hives and itching, chest felt heavy. Current medication Ketek. PE: WNL except for confluent hives on arms

**Other Meds:** demulen, ketek, aquatab

**Lab Data:** none

**History:** allergy Tetracycline record received 3/9/07-prior HX tetracycline allergy.

**Prex Illness:** dry skin

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273578-1      **Related reports:** 273578-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	26-Feb-2007	26-Feb-2007	0	07-Mar-2007	08-Mar-2007	OR		03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	9187U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pruritus, Urticaria

**Symptom Text:** 15 minutes after vaccine - had generalized "itching" feeling every where. She rubbed, hives bright red presented. Took liquid 50 mg Benadryl 1 hr later, no hives, no itchiness but a bad headache.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Sulfa, noreo, Prednisone

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273578-2      **Related reports:** 273578-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	26-Feb-2007	26-Feb-2007	0	09-Apr-2007	01-May-2007	OK	WAES0703USA00992	01-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 20 year old female who on 26, Feb 2007 was vaccinated IM with a 0.5 mL first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). There was no concomitant medication. The nurse reported that 15 minutes after she had her first vaccination. she came back to the office with generalized hives all over the body where she touched and scratched. The nurse confirmed that there was no reaction at the injection site and she had no problems breathing. The patient was given diphenhydramine hydrochloride and the reaction was gone, but then she had headaches. The patient was reported to have gone home, recovered, after an hour of observation on 26, Feb 2007. Additional information has been requested.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273583-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	21-Feb-2007	22-Feb-2007	1	07-Mar-2007	08-Mar-2007	CT		08-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0013U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus, Rash

**Symptom Text:** Pt developed rash over torso following day after vaccine administered. Rash worsened over week (red patches, itching). Referred to dermatologist given RX clobetasol Propionate and Zyrtec.

**Other Meds:**

**Lab Data:**

**History:** Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273631-1      **Related reports:** 273631-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	26-Dec-2006	23-Jan-2007	28	08-Mar-2007	09-Mar-2007	--	WAES0702USA04566	09-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Balance disorder, Clumsiness, Coordination abnormal, Demyelination, Diplopia, Hemiparesis, Hypoaesthesia, Hypoaesthesia facial

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with no pertinent medical history and no drug reactions or allergies, who on 26-DEC-2006 was vaccinated with a 0.5 mL dose of Gardasil (Lot not reported). There was no concomitant medication. On 23-Jan-2007 the patient developed numbness of her face which eventually spread to her hands and legs. The patient was treated with prednisone and acyclovir. The numbness partially cleared but she then developed double vision, weakness of her right side, unbalance, decreased coordination and clumsiness of her hands. The patient sought unspecified medical attention. On 23-FEB-2007 the patient had a magnetic resonance imaging (MRI), which revealed demyelination and a spinal tap (results not available yet). The physician stated that the patient was starting to get better but was told the patient's parents stopped the Gardasil vaccine series. The dose of Gardasil vaccine was administered by the patient's primary care physician (PCP). The reporter considered the patient's numbness of her face, hands and legs, double vision, weakness of her right side, imbalance, decreased coordination, clumsiness of her hands and demyelination to be other important medical events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** magnetic resonance 02/23/07 - revealed demyelination (other results not available), spinal tap 02/23/07 - (other results not available)

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273631-2 (S)    **Related reports:** 273631-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	20-Dec-2006	18-Jan-2007	29	12-Mar-2007	13-Mar-2007	--	WAES0703USA00100	20-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dysgraphia, Hypoaesthesia facial, Mobility decreased, Paraesthesia

**Symptom Text:** Information has been received from a Nurse practitioner concerning her daughter who on 20-DEC-2006 was vaccinated with her first dose of Gardasil. 4 weeks later, on 18-JAN-2007 the patient developed numbness and tingling on her face, she could not use her right hand to write and had limited mobility with her right leg. The patient was seeing a neurologist. Her outcome was unknown. The reporter considered that the event to be disabling. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273640-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	26-Feb-2007	26-Feb-2007	0	08-Mar-2007	08-Mar-2007	ME		08-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	PPV	MERCK & CO. INC.	0889F		Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1932AB		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0011U		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Nausea, Pain, Pyrexia, Swelling

**Symptom Text:** Right arm red, swollen, has fever, nausea, body aches, no rash or hives.

**Other Meds:**

**Lab Data:**

**History:** NKDA-Eczema

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273677-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	12-Jan-2007	12-Jan-2007	0	08-Mar-2007	09-Mar-2007	TX		09-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Subcutaneously	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypokinesia, Injection site pain

**Symptom Text:** At one month post injection pt was having continued pain at injection site. At two months, not much improvement. Difficulty moving arm. Refused 2nd and 3rd injection because of this reaction.

**Other Meds:** Yasmin, Zyrtec prn

**Lab Data:** NONE

**History:** seasonal allergies

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273691-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	11-Dec-2006	21-Dec-2006	10	08-Mar-2007	09-Mar-2007	NY		09-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1163F	0	Left arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2166MA	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** First seizure 10 days after first gardasil vaccine. Two months later, second seizure episode 16 days after second gardasil.

**Other Meds:**

**Lab Data:** MRI and EEG.

**History:** Developmental delay

**Prex Illness:**

**Prex Vax Illns:** seizure~Human Papillomavirus Recombinant Vaccine, Quadrivalent (Gardasil)~2~12~In Patient



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273705-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	31-Dec-2006	15-Feb-2007	46	09-Mar-2007	12-Mar-2007	--	WAES0702USA04624	12-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Blood test, Infectious mononucleosis

**Symptom Text:** Information has been received from the mother of a 18 year old female consumer who in late December 2006, was vaccinated 0.5 mL IM with her first dose of Gardasil. The patient came down with mononucleosis on 15-FEB-2007. Unspecified Blood work was performed. The patient was reported as recovered on 19-FEB-2007. No further information is available.

**Other Meds:** Unknown

**Lab Data:** NONE

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273706-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	24-Nov-2006	24-Nov-2006	0	09-Mar-2007	12-Mar-2007	--	WAES0703USA00022	12-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Condition aggravated, Contusion, Idiopathic thrombocytopenic purpura, Infectious mononucleosis, Injection site haematoma, Injection site haematoma, Petechiae

**Symptom Text:** Information has been received from a physician at health conference, concerning her 15 year old daughter with a history of bleeding gums (attributed to orthodontic braces) previous 7 days, menstruation heavier 7 days earlier, slight sore throat approximately 1 week prior, and infectious mononucleosis showed possible acute infection, but seroconversion did not occur until 05-FEB-2007, possibly delayed by prolonged steroid treatment. On 03-OCT-2006, the patient was vaccinated with first dose of HPV vaccine. No reaction occurred. On 24-NOV-2006, the patient was vaccinated with second dose of HPV vaccine (lot # not reported), one month after the first dose. No reaction occurred. On 12-DEC-2006, poliovirus vaccine boosterix injection was given. A 5cm bruise developed within 4 hours. On 12-DEC-2006, the patient was hospitalized with a platelet count greater than 5. Signs included: 4 cm hematoma at the site of immunization left upper arm, few petechiae on lower abdomen, no hepato-splenomegaly. Provisional diagnosis of immune thrombocytopenia (ITP) was made. The patient was treated with Prednisone 75 mg stat, 3 weeks of 50 mg Prednisone, followed by decreasing dose over the next month. By 29-JAN-2007, the patient's platelet count slowly returned to normal. The physician commented: "This is case of ITP, probably due to infectious mononucleosis, but diagnosed 18 days after the second dose of HPV vaccine (symptoms started approximately 10 days after the vaccine). I am hopeful it was due to Glandular fever but an interesting co-incidence and an unusual presentation of "IW." Additional information has been requested.

**Other Meds:**

**Lab Data:** platelet count 12/12/06 >5 150-400, platelet count 01/29/07 150-400 normal

**History:**

**Prex Illness:** Gingival bleeding; Heavy periods; Sore throat; Steroid therapy; infectious mononucleosis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273722-1      **Related reports:** 273722-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	29-Jan-2007	Unknown		09-Mar-2007	09-Mar-2007	AZ		12-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Hypotrichosis, Loss of consciousness, Malaise, Night sweats

**Symptom Text:** 1 hour after injection, pt passed out in class x 15 seconds. Felt "sick and exhausted" rest of the day. Coordination was off. Has experienced night sweats since injection and feels hair is thinning.

**Other Meds:** Tricycline Lo

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273722-2      **Related reports:** 273722-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	29-Jan-2007	29-Jan-2007	0	16-Mar-2007	20-Mar-2007	NJ	WAES0702USA00378	20-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Circulatory collapse, Dizziness, Nausea

**Symptom Text:** Information has been received from a physician concerning his 22 year old female cousin with no known drug allergies, who on 29 Jan 2007 was vaccinated IM into the arm with a first dose of Gardasil. There was no concomitant medication. On 29 2007, the patient became dizzy, nauseous and collapsed about 1 hour after vaccination. The patient recovered rapidly and went home to bed. It was noted that the patient's weakness continued for 24 hours. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. On 31 Jan 2007 the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273740-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	05-Mar-2007	05-Mar-2007	0	09-Mar-2007	12-Mar-2007	CO		12-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1062F	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB143BK	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Injection site vesicles, Oedema peripheral, Pain in extremity, Skin warm

**Symptom Text:** Right upper arm red, hot, swollen 18 cm x 18 cm the circumference of arm. 5 small fluid filled vesicles around injection site. Patient c/o pain in effected arm. No systemic s/s. Doctor name reported examined patient and recommended Advil for pain ice to effected area. Advised to go to E.R. if symptoms worsened or systemic involvement occurs and contact PCP.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273750-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	08-Mar-2007	08-Mar-2007	0	09-Mar-2007	12-Mar-2007	ID		12-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1249F	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0012U	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus generalised, Rash maculo-papular

**Symptom Text:** Patient started itching, mostly on trunk, last night; woke up itching all over and has rash (fine maculopapular rash) all over; given hydroxyzine for itching;

**Other Meds:** Orthocyclen

**Lab Data:** N/A

**History:** Allergy to sulfa

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273751-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
0.3	M	02-Mar-2007	03-Mar-2007	1	09-Mar-2007	12-Mar-2007	NC		12-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NA	0	Right leg	Intramuscular	
	DTAPH	UNKNOWN MANUFACTURER	NA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia, Rash macular, Vomiting, Wrong drug administered

**Symptom Text:** Wrong Vaccination was give. My son was given the HPV vaccine which is for women 18-26 years old. So far just normal post vaccine responses. Some blotching of skin, fever, and vomiting. Pediatric office contacted me on March 8th to report the wrong vaccination administration

**Other Meds:**

**Lab Data:**

**History:** n/a

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273768-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	05-Mar-2007	05-Mar-2007	0	09-Mar-2007	12-Mar-2007	CA		12-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0181U	0	Left arm	Intramuscular	MNQ

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Dizziness, Nausea

**Symptom Text:** Patient complained of abdominal pain about 3 hours after receiving vaccines then the next day had nausea and dizziness.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273789-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	09-Mar-2007	10-Mar-2007	1	12-Mar-2007	13-Mar-2007	MI		13-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1968AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00130	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Chills

**Symptom Text:** Elevated temp and chills approx. 16 hours after vaccine given

**Other Meds:** Prevacid 30mg Q day / Allegra

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 998

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273808-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	19-Jan-2007	20-Jan-2007	1	12-Mar-2007	13-Mar-2007	MI	M12007004	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Confusional state, Dehydration, Diplopia, Headache, Hypersomnia, Hypoaesthesia, Hypokinesia, Musculoskeletal pain, Nasal congestion, Orthostatic hypotension, Pain in extremity, Paraesthesia, Pharyngolaryngeal pain, Sensory disturbance, Stress, Vision blurred

**Symptom Text:** 1/31/07 tc from mother-states patient had HPV vaccine 1/19/07 on 1/20/07 c/o achy arms. Developed headache that comes and goes and blurred vision the comes and goes. On 1/26/07 c/o weakness-couldn't move-went to hosp ER-was in ER for 8 hours. No convulsion for use of symptoms. Able to move now but has charge of sensation of left side. Mom states had been sleeping a lot. 2/21/07-Return call from mom. Completed form with available info, lasted 6 days-numbness/tingling. 03/30/07-records received from reporter. PE:WNL Pain when walking able to walk with some poor effort on examination but grossly normal musculoskeletal exam. Dehydration, musculoskeletal pain. Orthostatic blood pressure mostly likely due to poor oral intake. Sore throat and nasal congestion. Numbness in toes and feel and intermittent blurring of vision and seemed confused. Tired. Mother concerned about possible bipolar disorder. Multiple stressors in home life. Recommended mental health care provider

**Other Meds:**

**Lab Data:** all tests came back normal records received 3/30/07-EKG normal. CXR normal.

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273813-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	20-Feb-2007	20-Feb-2007	0	12-Mar-2007	13-Mar-2007	WI		13-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB129AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** Adult dose of Hepatitis A given (1440 elu) instead of pediatric dose of Hepatitis A (720 elu)

**Other Meds:** Adderall XR 20 mg daily ADD, Tetracycline 500 mg BID acne

**Lab Data:** NONE

**History:** left elbow cracking

**Prex Illness:** ADD, Right ankle sprain, Acne

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273817-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	26-Feb-2007	26-Feb-2007	0	12-Mar-2007	14-Mar-2007	VA		15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Burning sensation, Erythema, Pruritus

**Symptom Text:** Within 1/2 hr of receiving injection pt complained of face itching. Within 1 hour face and neck burning red and itchy. Given Benadryl at school. Slept several hours, still complaining of itching when she woke up. Resolved without further treatment.

**Other Meds:**

**Lab Data:** NONE

**History:** Psoriasis

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273848-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	28-Feb-2007		13-Mar-2007	14-Mar-2007	--	WAES0703USA00274	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion, Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a registered nurse through a pregnancy registry concerning a female (age not reported) who on an unspecified date was vaccinated intramuscularly with a 0.5 ml first dose of Gardasil. The patient was pregnant, and on 28-FEB-2007 the patient had a miscarriage or abortion after receiving the first dose of Gardasil. The patient sought unspecified medical attention. At the time of this report, the nurse was unsure if the patient had a miscarriage or abortion. Upon internal review, the patient's miscarriage or abortion was considered an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Pregnancy NOS (LMP = unknown).

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273849-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	02-Jan-2007	16-Jan-2007	14	13-Mar-2007	14-Mar-2007	FR	WAES0703USA00872	15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Fatigue, Headache

**Symptom Text:** Information has been received from a physician concerning a 25 year old female who on 02-JAN-2007 was vaccinated with the first dose of Gardasil (lot # not reported), IM in the left arm. Concomitant medication was not reported. On approximately 16-JAN-2007, two to three weeks post vaccination, the patient experienced extreme fatigue. On approximately 06-FEB-2007, five weeks post vaccination, the patient experienced cephalgia. The patient was hospitalized for check-up, but no diagnosis could be established. The patients extreme fatigue and cephalgia persisted. Other business partner numbers included E2007-01394. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273852-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Feb-2007	27-Feb-2007	1	13-Mar-2007	14-Mar-2007	FL		15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00116	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Patient had Gardasil (1st injection of series) on 2/26/07 10:00 am, 24 hours later developed pink rash on arms. torso and neck. Patient complain of itching, denies using any new meds or products. Patient came in for OV with doctor, was given Medrol dose pack.

**Other Meds:** Yasmin

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273861-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Feb-2007	02-Mar-2007	2	13-Mar-2007	14-Mar-2007	PA		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2172AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling

**Symptom Text:** Approximately 10 cm local reaction of redness and swelling Left arm. Treatment: warm soaks.

**Other Meds:** Imipramine

**Lab Data:**

**History:** Enuresis

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273907-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	22-Jan-2007	22-Jan-2007	0	14-Mar-2007	15-Mar-2007	VA	WAES0701USA04414	15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion induced, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a licensed practical nurse, for the Pregnancy Registry for Gardasil concerning a 25 year old female with drug hypersensitivity to ENTEX, erythromycin, codeine, LORTAB, and IMITREX and a history of pregnancy who on 21-NOV-2006 was vaccinated with first dose of Gardasil (lot # 654702/0011U) IM. On 22-JAN-2007, the patient was vaccinated with second dose of Gardasil (lot # 654702/0011U), IM. Concomitant therapy included amitriptyline hydrochloride. The patient sought medical attention. On an unspecified date, urine beta-human chorionic gonadotropin test was positive for pregnancy. The patient's last menstrual period was December 2006 (gestation: first trimester), expected date of delivery is approximately September 2007. No other information was available at the time of reporting. Additional information was received from a health professional from the physician's office via telephone. It was reported that the patient terminated her pregnancy (date not reported), not because of Gardasil but for other reasons. The outcome of the induced abortion was not reported. Upon internal review, abortion induced was determined to be an Other Important Medical Event. No additional information is expected.

**Other Meds:** amitriptyline hydrochloride

**Lab Data:** urine beta-human - positive for pregnancy

**History:** Pregnancy

**Prex Illness:** Pregnancy NOS (LMP = Unknown) Drug hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273908-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	03-Jan-2007	11-Feb-2007	39	14-Mar-2007	15-Mar-2007	IL	WAES0703USA00867	15-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Eosinophil count increased, Headache, Neck pain

**Symptom Text:** Information has been received from a registered nurse concerning a 16 year old female who on 03-JAN-2007 was vaccinated with Gardasil (lot # not reported). On 11-FEB-2007, the patient experienced neck pain, and headache. Medical attention was sought. The patient was hospitalized. The patient had an "eosinophil type reaction" also. Laboratory evaluation revealed elevated eosinophils. The outcome of the neck pain, headache, and eosinophil type reaction was snot reported. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** eosinophil count 02/11/07 - elevated

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273909-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	05-Mar-2007	05-Mar-2007	0	14-Mar-2007	15-Mar-2007	OH	WAES0703USA01199	15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Eye infection, Eye swelling, Swelling face

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 05-MAR-2007 was vaccinated IM with the first dose of Gardasil. Concomitant therapy included hormonal contraceptives (unspecified). On 05-MAR-2007, two hours post-vaccination, the patient developed swollen eyes and face and went to an emergency room. The patient underwent sinus films, which were noted to be negative, and was administered BENADRYL and unspecified antibiotics for a possible eye infection. The patient was released that same evening. On 07-MAR-2007, the physician contacted the patient and reported that there was "not much improvement." The patient's swollen eyes and face persisted. Eye and face swelling were reported as other important medical events. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** nasal sinus X-ray 03/05/07 - negative

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273915-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	05-Mar-2007	05-Mar-2007	0	14-Mar-2007	15-Mar-2007	FL		15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	02634	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperhidrosis, Pallor, Syncope

**Symptom Text:** Appeared patient fainted just after vaccine was given, sl diaphoretic pale, recovered quickly after ammonia inhaler was used. Patient rested water was given, left office feeling well.

**Other Meds:** LOESTRIN 24

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

<b>Vaers Id:</b> 273916-1		<b>Related reports:</b> 273916-2; 273916-3							
<b>Age</b>	<b>Gender</b>	<b>Vaccine Date</b>	<b>Onset Date</b>	<b>Days</b>	<b>Received Date</b>	<b>Status Date</b>	<b>State</b>	<b>Mfr Report Id</b>	<b>Last Edit Date</b>
16.0	F	31-Aug-2006	31-Aug-2006	0	14-Mar-2007	15-Mar-2007	ND		20-Apr-2007
<b>VAX Detail:</b>	<b>Type</b>	<b>Manufacturer</b>		<b>Lot</b>	<b>Prev Doses</b>	<b>Site</b>	<b>Route</b>	<b>Other Vaccine</b>	
	HPV4	MERCK & CO. INC.		0640F	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Tremor

**Symptom Text:** Patient walked to lobby after shot and passed out, then body shook. She was helped back to exam room and observed. She hit back of head and no bump forward. Iced area for 30 minutes. She left in 45 minutes in good condition. Ct scan normal next day.

**Other Meds:** NONE

**Lab Data:** CT- brain - normal

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273916-2      **Related reports:** 273916-1; 273916-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	31-Aug-2006	31-Aug-2006	0	16-Mar-2007	19-Mar-2007	ND		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Computerised tomogram, Convulsion, Diplopia, Dizziness, Dizziness, Injection site pain, Loss of consciousness, Musculoskeletal stiffness, Nausea, Syncope, Vision blurred

**Symptom Text:** Patient fainted and went into a seizure in the reception area of the clinic 10 minutes after the 1st Gardasil shot was administered. The seizure lasted approximately 2-3 minutes. Several nurses and doctor propped her in a wheelchair at which time she woke up for a few seconds and replaced her shoe that had fallen off. She immediately went into another seizure, losing consciousness, stiffened out like a board raising out of the seat of the wheelchair. The nurses and doctor hurried her back to the exam room and lifted her, still stiff and unconcious, onto the exam table. My best estimate is that this second seizure lasted a minimum of 3-4 minutes. Patient continued to feel week and slightly nauseated for several hours, also experiencing extreme pain at the sight of the injection and dizziness and double or blurred vision for 2-3 days later. When she told us about her dizziness and blurred vision the day after the 1st shot, we called doctor and he had us come to the emergency room to give her a CT scan. The 2nd Gardasil shot was administered with patient reclining on the exam table. She again complained of the painfulness at the site of the injection (this continued for several days), and approximately 5-10 minutes after receiving the shot felt faint and the room got very bright for a few seconds, then returned to normal.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1011

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273916-3      **Related reports:** 273916-1; 273916-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	31-Aug-2006	31-Aug-2006	0	16-Mar-2007	19-Mar-2007	ND		27-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Computerised tomogram, Convulsion, Diplopia, Dizziness, Dizziness, Injection site pain, Loss of consciousness, Musculoskeletal stiffness, Nausea, Syncope, Vision blurred

**Symptom Text:** Patient fainted and went into a seizure in the reception area of the clinic 10 minutes after the 1st Gardasil shot was administered. The seizure lasted approximately 2-3 minutes. Several nurses and doctor propped her in a wheelchair at which time she woke up for a few seconds and replaced her shoe that had fallen off. She immediately went into another seizure, losing consciousness, stiffened out like a board raising out of the seat of the wheelchair. The nurses and doctor hurried her back to the exam room and lifted her, still stiff and unconcious, onto the exam table. My best estimate is that this second seizure lasted a minimum of 3-4 minutes. Patient continued to feel weak and slightly nauseated for several hours, also experiencing extreme pain at the sight of the injection and dizziness and double or blurred vision for 2-3 days later. When she told us about her dizziness and blurred vision the day after the 1st shot, we called doctor and he had us come to the emergency room to give her a CT scan. The 2nd Gardasil shot was administered with patient reclining on the exam table. She again complained of the painfulness at the site of the injection (this continued for several days), and approximately 5-10 minutes after receiving the shot felt faint and the room got very bright for a few seconds, then returned to normal.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273919-1      **Related reports:** 273919-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Feb-2007	26-Feb-2007	3	14-Mar-2007	15-Mar-2007	NY		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Myalgia

**Symptom Text:** Two days after injection, complained of joint pains, myalgia not relieved with use if Ibuprofen missed 2 days of school.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273919-2      **Related reports:** 273919-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Feb-2007	01-Mar-2007	6	14-Mar-2007	16-Mar-2007	NY		20-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Myalgia

**Symptom Text:** Generalized myalgia, arthralgia after 2nd injection (HPV). TX with Motrin 200 mg - 400 mg Q 4 hours x 2 days. Pt missed 2 days of school.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273920-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	29-Sep-2006	30-Sep-2006	1	14-Mar-2007	15-Mar-2007	WY		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	P0688F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema, Oedema peripheral

**Symptom Text:** 1st Injection with slight erythema and edema. 2nd Injection noted slight edema and erythema, then next am woke with swollen area over most of deltoid area, continue to increase over next 24 hours - arm swollen from elbow to shoulder and continues for 8 days. Resolved completely.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Allergy to Keflex and Motrin

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273922-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	05-Mar-2007	05-Mar-2007	0	14-Mar-2007	15-Mar-2007	MI		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2720AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1424F		Right arm	Intramuscular	
	MMRV	MERCK & CO. INC.	1397F		Right arm	Subcutaneously	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Fatigue, Pharyngolaryngeal pain, Pyrexia, Rash

**Symptom Text:** Six hours s/p injections developed fever, rash up right arm, right side of neck and face. Also developed sore throat in 24 hours. Temp = 102. Rash responded to Benadryl except for local injection sites. Is having RLQ pain but that started before injections. Generally feels fatigued as well. No rash on left arm.

**Other Meds:** ZYRTEC

**Lab Data:** NONE

**History:** Depression, seasonal allergies

**Prex Illness:** Vague RLQ abd pain

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273925-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	22-Nov-2006	29-Nov-2006	7	14-Mar-2007	15-Mar-2007	NY		15-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oedema peripheral

**Symptom Text:** Patient c/o arm swelling 7 days after 1st injection.

**Other Meds:** Birth Control

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273927-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		14-Mar-2007	15-Mar-2007	NY		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1974AM		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0263U		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Urticaria

**Symptom Text:** Hives come days after vaccine, red on arm.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273929-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	05-Mar-2007	05-Mar-2007	0	14-Mar-2007	15-Mar-2007	SC		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Tinnitus

**Symptom Text:** "Dizziness, ringing in ears" per patient. Treatment: Patient laid down for 15-20 minutes, sx's resolved. Vital signs were stable before, during and after sx's.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273930-1      **Related reports:** 273930-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	06-Mar-2007	07-Mar-2007	1	14-Mar-2007	15-Mar-2007	PA		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Erythema, Nausea, Oedema peripheral, Vomiting

**Symptom Text:** Swelling and redness of arm. Swelling approximately 5 cm, erythema > 26cm also nausea, vomiting, increase temp.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1020

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273930-2      **Related reports:** 273930-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	06-Mar-2007	06-Mar-2007	0	09-Apr-2007	01-May-2007	PA	WAES0703USA01341	01-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fluid replacement, Nausea, Pyrexia, Vomiting

**Symptom Text:** Information has been received from a 24 year old female who on 06, Mar 2007 was vaccinated intramuscularly with a 0.5 mL third dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included drospirenone (+) ethinyl estradiol (YASMIN). The patient mentioned that she did not have any problems with dose 1 or 2 and that these doses were were given in the outer part of her arm. She reported that the third dose was given less in the outer area and more towards the inner arm but still in the muscle. On 06, Mar 2007, the patient started to throw up. and she developed a fever. On 09, Mar 2007, the patient went to the emergency room due to continued vomiting and dizziness. She was treated with intravenous fluid and was released at approximately 04:00 pm. As of 12, Mar 2007, the patient continued to experience dizziness and nausea.

**Other Meds:**

**Lab Data:** unknown

**History:** none

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273935-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	04-Jan-2007	05-Jan-2007	1	14-Mar-2007	15-Mar-2007	NY		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Pt stated she had slight fever after 1st shot.

**Other Meds:** Birth Control

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273937-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	06-Mar-2007	06-Mar-2007	0	14-Mar-2007	15-Mar-2007	MA		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Nausea

**Symptom Text:** Nausea extreme fatigue also fatigue after #1 Gardasil and Menactra on 1/3/07 (not reported).

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273959-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	20-Nov-2006	22-Nov-2006	2	14-Mar-2007	21-Mar-2007	NY	200603463	03-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2159AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	FLU	AVENTIS PASTEUR	U2240AA	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Flushing, Pruritus, Rash macular

**Symptom Text:** Initial report received from a health care professional on 12 December 2006. A 19 year old, female patient (with a medical history of no known allergies) developed a flushed, red and itchy face, 2 days after she received Fluzone (lot number U2240AA) intramuscularly in the left deltoid, Menactra (lot number U2159AA) intramuscularly in the right deltoid and Gardasil (lot number unknown) on 20 November 2006. On 23 November 2006, the patient called to report red spots on hands. The patient did not have any illness at the time of vaccination. She was treated with Benadryl. She was not seen at the doctors office and has moved. It was reported that she recovered.

**Other Meds:** Nevacor, Birth control pills, Celexa, Clonitin

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273969-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	09-Feb-2007	09-Feb-2007	0	14-Mar-2007	16-Mar-2007	CT		16-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0013U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pain, Pain in extremity

**Symptom Text:** C/O pain in extremities and headaches since administration of Gardasil (HPV Vaccine), constant pain, rated 6-7/10 on pain scale. Does not interfere with daily activity.

**Other Meds:** NONE

**Lab Data:** CBC, ESR, Lyme, WB, ANA, DS DNA pending

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 273976-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	14-Feb-2007	27-Feb-2007	13	14-Mar-2007	15-Mar-2007	SD		15-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral, Pain, Pruritus, Skin tightness

**Symptom Text:** erythema, pruritis, edema of palms, soles, fingertips, Pain with flexion of fingers, skin taut & shiny. symptoms started 2/27/07 continued though 3/1/07. Treated with ibuprofen 200 mg two tabs every 4-6 hours and diphenhydramine 25 mg at bedtime.

**Other Meds:** Ortho-tryclen Lo

**Lab Data:**

**History:** allergies to cedar wood products & Demerol

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274024-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	09-Feb-2007	23-Feb-2007	14	15-Mar-2007	16-Mar-2007	AL		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site induration, Muscle atrophy

**Symptom Text:** Area of induration and questionable muscle atrophy appeared 2 weeks after vaccine was administered. Increased to 1 inch diameter over 7-10 day period.

**Other Meds:** Celebrex Minocycline

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274035-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	14-Mar-2007	14-Mar-2007	0	15-Mar-2007	16-Mar-2007	NY		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness, Heart rate normal, Hypoaesthesia, Paraesthesia, Rash macular, Tremor

**Symptom Text:** Approximately 30 secs after vaccine was administered, pt became light headed and dizzy. Nurse had pt lay flat and administered ice pack to back of neck. Pulse normal. Ten minutes later, nurse asked how pt was feeling, she complained of still being dizzy and that both arms felt numb/ tingly. Pulse rechecked, left arm slower than right. Both of patient's arms began to shake. Red blotches noted on patient's chest and neck. The nurse practioner in the office was called and came to eval patient. Nurse practioner ordered Benedryl 25mg to be given.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274044-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	15-Mar-2007	15-Mar-2007	0	15-Mar-2007	16-Mar-2007	WI		16-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1447F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pain, Injection site swelling, Skin tightness

**Symptom Text:** About 2 minutes after vaccine (Gardasil, 2nd dose), patient noticed pain, swelling/tightness of upper arm near vaccine, and streaks of slightly swollen reddened skin out to about 4 cm surrounding injection site. Subsided within 8 minutes. Treatment was MD assessment and Claritin 10mg reinitab.

**Other Meds:** NONE

**Lab Data:** none

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274068-1 (S)    **Related reports:** 274068-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	28-Feb-2007	28-Feb-2007	0	16-Mar-2007	19-Mar-2007	--	WAES0703USA00641	19-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MEN	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Convulsion, Fall, Head injury, Orthostatic intolerance, Syncope, Vomiting

**Symptom Text:** Information has been received from a pharmacist concerning an 18 year old female patient who on 28-FEB-2007 was vaccinated with a first dose of Gardasil, Lot #653735/0688F. Concomitant therapy included Menomune. The patient fainted 10 minutes after injection Gardasil. The patient fell and hit her head when she fainted. The patient then had a seizure for 30 seconds after she fell after fainting. The patient was slow to wake and was Orthostatic (time line was unspecified). The patient also vomited twice (no time line). The patient recovered later in the day. The reporter considered the events to be disabling. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1030

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274068-2 (S) **Related reports:** 274068-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	28-Feb-2007	28-Feb-2007	0	29-Mar-2007	30-Mar-2007	--	200700888	30-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MEN	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Convulsion, Fall, Head injury, Orthostatic hypotension, Syncope, Vomiting

**Symptom Text:** Initial report received on 22 March 2007 from an other manufacturer, reference, reference number WAES 0703USA00641. This manufacturer had received the original report from a pharmacist. Verbatim from report: Information has been received from a pharmacist concerning an 18 year old female patient who on 28-FEB-2007 was vaccinated with a first dose of Gardasil lot # 653735-0688F. Concomitant therapy included Menomune. The patient fainted 10 minutes after injection Gardasil. The patient fell and hit her head when she fainted. The patient then had a seizure for 30 seconds after she fell after fainting. The patient was slow to wake and was orthostatic (time line was unspecified). The patient also vomited twice (no time line). The patient recovered later in the day. The reporter considered the events to be disabling. "Upon internal review, seizure was considered to be an other important medical event." Additional information has been requested."

**Other Meds:**

**Lab Data:**

**History:** It was unknown if the patient had any pre-existing medical conditions at the time of the vaccinations on 28 February 2007.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1031

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274069-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	08-Feb-2007	18-Feb-2007	10	16-Mar-2007	19-Mar-2007	WA	WAES0703USA01160	19-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Crying, Pain in extremity

**Symptom Text:** Information has been received from a medical assistant and a nurse practitioner concerning an 11 year old female with no relevant medical history reported who on 08-FEB-2007 was vaccinated intramuscularly in the right deltoid wit a 0.5 ml dose of Gardasil (lot 654702/0011U). Concomitant therapy included METADATE. On approximately 18-FEB-2007 or 19-FEB-2007, the patient developed upper right arm pain. The patient was seen on 21-FEB-2007 and 02-MAR-2007 for the upper arm pain. The pain occurred on the whole outer portion of the upper arm. The patient has no fever. Office notes indicated that "normal flexion of the elbow without problems with bilateral strength. Normal anterior and posterior rotation of shoulder. Normal internal and external rotation of shoulder. Active abduction of only 90 degrees, stopping due to pain. Able to rotate full 180 degrees with passive range but crying due to tears. Diagnosis was arm pain without reduction of strength, secondary to HPV injection. "The patient was treated with ibuprofen 350mg every 6 hours for 4 to 5 days. The nurse practitioner reported that she assumed the patient recovered from the arm pain because the patient did not return for a follow-up visit scheduled on 08-MAR-2007. The nurse practitioner considered the patient's upper arm pain an other important medical event as the patient's pain lasted longer that the indicated time frame of 48 hours for this experience. Additional information has been requested.

**Other Meds:** METADATE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274070-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	07-Mar-2007	07-Mar-2007	0	16-Mar-2007	19-Mar-2007	IN	WAES0703USA01336	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Throat tightness, Urticaria

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with a history of allergic reaction to antibiotics who on 07-MAR-2007 was vaccinated with first dose of Gardasil (lot # not reported) injection. On 07-MAR-2007, after being vaccinated, the patient broke out in severe hives and her airway began to close. Medical attention was sought. The physician administered an injection of Benadryl. The patient was admitted to the emergency room, it was unknown if the patient was admitted to the hospital. On 08-MAR-2007, the patient recovered. No further information was provided. Upon internal review, airway began to close was considered to be an other important medical event. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Allergic reaction to antibiotics

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274071-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	05-Mar-2007	05-Mar-2007	0	16-Mar-2007	19-Mar-2007	OH	WAES0703USA01473	19-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysphonia, Eye swelling, Nasal congestion, Swelling face, Tenderness, Throat irritation

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 05-MAR-2007 was vaccinated by injection with the first dose of Gardasil. It was reported that the patient experienced an adverse experienced 2 hours after receiving Gardasil. The patient went to the emergency room with a swollen face and eyes, no fever reported. The patient received eye drops and BENADRYL. On 06-MAR-2007 the patient returned to the clinic with tender and a "little puppy eyes". On 07-MAR-2007 the patient had an itchy throat and her eyes were still tender. On 08-MAR-2007, the patient sounded "nasal". The patient sought unspecified medical attention. The physician added an antibiotic and the patient was still taking diphenhydramine hydrochloride. The patient has a "respiratory panel". The physician reported that the patient will not continue the series. At the time of the report, it was unknown if the patient recovered. The physician considered swollen face and eyes, tender eyes, itchy throat, and sounded "nasal" to be other important medical events.

**Other Meds:** UNK

**Lab Data:** diagnostic laboratory - respiratory panel

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274072-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	19-Mar-2007	FR	WAES0703USA02259	19-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Arthralgia, Joint swelling, Urticaria

**Symptom Text:** Information has been received from a dermatologist concerning a female with a sore throat (developed at the time of vaccination) who was vaccinated with primary dose of Gardasil. Concomitant therapy included acetaminophen. Subsequently, four days post vaccination, the patient developed a urticarial rash and joint swelling with arthralgia. The patient was hospitalized for three days, and was treated with erythromycin and CORTISONE. On 07-MAR-2007, the patient contacted the the dermatologist and reported that symptoms had improved notedly. On an unspecified date, the patient had recovered, although, was still receiving CORTISONE therapy. No further information is available. Other business partner number included E2007-01485.

**Other Meds:** acetaminophen Unk - Unk

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274084-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	19-Feb-2007	19-Feb-2007	0	16-Mar-2007	19-Mar-2007	FL		19-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Laceration, Syncope, Tooth repair

**Symptom Text:** 2-19-07 child had well check up, received vaccines of Gardasil, Hep A, Menactra, Varicella. Approx at 3:00pm had syncopal episode on the way out of the office. First aid rendered for lip laceration. B/P and vital signs checked, reverse trendelenburg position. Sent to dental office for tooth repair.

**Other Meds:** NONE

**Lab Data:** PO2 99%

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274087-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	05-Mar-2007	05-Mar-2007	0	16-Mar-2007	19-Mar-2007	OH		19-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Confusional state, Dyspnoea, Erythema, Fall, Loss of consciousness, Neck injury, Syncope

**Symptom Text:** Syncope episode at checkout window 4 min after Gardasil vaccine given. Upon forward fall, pt sustained blow to anterior aspect of neck on our counter top. Unconscious for approx 30-60 sec, then alert but confused as to what happened for about 1 min. Labored breathing and anxiety approx 4-5 min then relaxed. Red raised mark on soft tissue of anterior neck. Remained in supine position with neck neutral at still. EMS here within 10 min. To ER pre EMS with cervical collar and neck immobilizer on.

**Other Meds:** Yaz birth control

**Lab Data:** In emergency room CT head, brain, CT neck soft tissue, BMP, CBC, EKG.

**History:** Abnormal uterine bleeding, irregular menstruation, Menorrhagia, Pelvic pain.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274109-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	08-Nov-2006	08-Nov-2006	0	16-Mar-2007	21-Mar-2007	NY	WAES0611USA02972	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Accidental exposure, Incorrect dose administered, Sensory disturbance, Vaccination complication

**Symptom Text:** Initial and follow up information has been received from a nurse practitioner concerning a 22 year old female student with no acute illness or chronic disease and food allergy to eggplant who on 08 Nov 2006, at 14:00, was vaccinated witha second dose of Gardasil. It was reported that the patient pulled away during administration due to "strange sensation" and a significant amount medication went down the patient's arm. It was estimated that only one third to one half of the dose was administered. It was reported that the patient had to repeat the second. On 08 Nov 2006, the patient recovered from the event. No further information is available.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** food allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1038

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274110-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	25-Jan-2007	25-Jan-2007	0	16-Mar-2007	21-Mar-2007	NH	WAES0702USA00386	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1424F	1	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cold compress therapy, Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling

**Symptom Text:** Informatio has been received from a physician's assistant concerning a 22 year old female who on 25 Jan 2007 was vaccinated IM with a second 0.5 ml dose of Gardasil. On approximately 25 Jan 2007, the patient experienced a 1.3 inch area of swelling, redness, tenderness and itchiness at the injection site. The patient notified the physician's assistant 5 days after vaccination. It was unknown when the events started. The patient was treated with cool compresses and antihistamines with unknown results. No diagnostic laboratory studies were performed. At the time of this report, the patient's outcome was unknown. It was also reported that on 07 Nov 2006, the patient was vaccinated with a first dose of Gardasil. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1039

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274111-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	26-Jan-2007	31-Jan-2007	5	16-Mar-2007	21-Mar-2007	MD	WAES0702USA00395	03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 25 year old female with no medical history or allergies, who on 26 Jan 2007 was vaccinated a first dose of with Gardasil (yeast) (lot#653736/0014U). Concomitant therapy included hormonal contraceptives (unspecified). On 31 Jan 2007 (also reported as four to five days later), the patient developed hives. The patient went to her primary care physician for treatment of the hives. She was prescribed prednisone and Benadryl. Later that day, she went to the emergency room. On 01 Feb 2007 the patient told the nurse her hives were worse. At the time of this report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274112-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	14-Jan-2007	Unknown		16-Mar-2007	21-Mar-2007	UT	WAES0702USA00416	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0688F	1	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site discolouration

**Symptom Text:** Information has been received from a physician concerning a 19 year old female with penicillin allergy who on 02 Nov 2006 was vaccinated intramuscularly in the right arm with Gardasil. Concomitant therapy included Yasmin. On 14 Jan 2007 the patient received her second vaccination of Gardasil intramuscularly in the left arm. On approximately 09 Nov 2006 the patient experienced a lighter coloring of the skin at the injection site. It was reported that the patient did not experience any itching or swelling. On approximately 21 Jan 2007 the patient experienced lighter coloring of the skin at the injection site. At the time of this report the patient's skin discoloration in both arms had not resolved. Additional information has been requested.

**Other Meds:** Yasmin

**Lab Data:**

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1041

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274113-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	01-Feb-2007	01-Feb-2007	0	16-Mar-2007	20-Mar-2007	NY	WAES0702USA00435	20-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure normal, Dizziness, Fall, Heart rate normal, Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 21 year old female with no known allergies who on 01-FEB-2007 was vaccinated intramuscularly in the right deltoid with Gardasil (lot # not provided). The physician reported that after administering the injection she "turned around literally for a second" and when she turned back to the patient she found her "on the floor, with her rear in the air". The physician stated that she called for her assistant for help and the patient was already conscious, "she was only out for a second". The patient reported to the physician that she felt dizzy and felt like she instantly went to sleep. The physician reported that the patients blood pressure and pulse were normal (actual measurements not provided). The physician reported that the patient was observed in the office, had no additional episodes and considered to have recovered from the event and sent home. The physician stated that she did not feel the event was disabling and would continue the series of vaccination of Gardasil with the patient, but would have her reclined when administering future vaccinations. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274114-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	11-Jan-2007	11-Jan-2007	0	16-Mar-2007	20-Mar-2007	NJ	WAES0702USA00437	20-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a 26 year old female with a history of syncope when giving blood, who on 11-Jan-2007 was vaccinated with Gardasil (lot #653978/0955F). It was reported that the patient fainted 15 minutes after vaccination. The patient subsequently recovered. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Syncope

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274115-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	11-Jan-2007	11-Jan-2007	0	16-Mar-2007	20-Mar-2007	WV	WAES0702USA00457	20-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysgeusia

**Symptom Text:** Information has been received from a physician concerning a "23 or 24" year old female with no pertinent medical history or drug reactions/allergies, who on approximately 11-Jan-2007 was vaccinated with Gardasil (0.5 ml). The physician reported that 30 seconds following vaccination, the patient experienced an intense metal taste in her mouth, however immediately recovered. No further details were provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1044

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274116-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	02-Dec-2006	02-Dec-2006	0	16-Mar-2007	20-Mar-2007	IN	WAES0702USA00487	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Injection site erythema, Injection site rash, Presyncope

**Symptom Text:** Information has been received from a physician via a company representative, concerning a 16 year old female who on approximately 02-Dec-2006 was vaccinated IM in the left arm with Gardasil. After receiving the injection, the patient went to school and later during the day, she got very dizzy "that she almost passed out.". She also developed a red rash and bumps all over the site of the left arm where the dose was administered and had to go home. Subsequently, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274117-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA00560	20-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Scleroderma

**Symptom Text:** Information has been received from an office staff member concerning a 14 year old female relative who, on an unspecified date, was vaccinated with a first dose of Gardasil. A couple of days after vaccination, the patient was diagnosed with scleroderma, an autoimmune disease. The patient was referred to a specialist and was currently being treated. At the time of this report, the patient's scleroderma persisted. No product quality complaint was involved. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274118-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA00572	20-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Gait disturbance

**Symptom Text:** Information has been received from a nurse practitioner, via a company representative, concerning an approximately 22 year old female who was 6 weeks post partum and had completed a pelvic exam followed by the vaccination of the first dose (dose unspecified) of Gardasil. The nurse reported that 45 minutes after the appointment, the patient began to experience dizziness. The sensation of movement/dizziness" made it difficult for the patient to walk and persisted for about four hours, then abruptly resolved with no lingering effects. The patient sought unspecified medical treatment. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274119-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	08-Dec-2006	01-Jan-2007	24	16-Mar-2007	20-Mar-2007	TX	WAES0702USA00582	20-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vaginal swelling

**Symptom Text:** Information has been received from a physician concerning a 22 year old female with a history of human papilloma virus infection who on 08-DEC-2006 was vaccinated with Gardasil. In January 2007, the patient experienced swelling of her vaginal walls. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Human papilloma virus infection.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1048

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274120-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	21-Nov-2006	21-Nov-2006	0	16-Mar-2007	20-Mar-2007	IL	WAES0702USA00593	03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza, Insomnia

**Symptom Text:** Information has been received from a Certified Medical Assistant concerning a 24 year old female patient with neurocardiogenic syncope who on 21-NOV-2006 was vaccinated IM with her first dose of Gardasil, lot #653938/0954F. Concomitant therapy included INDERAL. On 21-NOV-2006 the patient experienced insomnia for one month following the administration of Gardasil. She later had the flu from being run down and lack of sleep. Unspecified medical attention was sought. The patient was reported as recovered. Additional information has been requested.

**Other Meds:** Inderal

**Lab Data:** UNK

**History:**

**Prex Illness:** Syncope

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274121-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	FL	WAES0702USA00609	20-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Vomiting

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date, was vaccinated with a second dose of Gardasil. Subsequently the patient became dizzy and had some vomiting. The patient sought unspecified medical attention. At the time of this report, the outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:** UNK

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274122-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Feb-2007	01-Feb-2007	0	16-Mar-2007	21-Mar-2007	PA	WAES0702USA00724	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0013U	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Body temperature increased, Dizziness, Myalgia, Rash

**Symptom Text:** Initial and follow up information has been received from an LPN and the mother of a 12 year old female patient with aortic insufficiency and migraine headaches who on 01-FEB-2007 was vaccinated IM with her first dose of Gardasil, lot #654741/0013U. There was no concomitant medication. Subsequently, the patient experienced dizziness and developed an elevated temperature. It was also reported that the patient felt weak and had muscle aches for several days. The side effects eventually disappeared. However on 21-FEB-2007, the patient woke up with breast rashes. As of 21-FEB-2007 breast rashes persisted. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:**

**Prex Illness:** Aortic incompetence, Migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274123-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	01-Feb-2007	01-Feb-2007	0	16-Mar-2007	20-Mar-2007	NJ	WAES0702USA00727	21-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash, Rash

**Symptom Text:** Information has been received from a registered nurse concerning a 19 year old female with a penicillin allergy. On 01-FEB-2007, at 11:00 AM, the patient was vaccinated in the left arm with the first 0.5 mL dose of HPV (lot# 655619/1427F). Concomitant therapy included Yasmin. On that same day, at 4:00 PM, the patient developed a rash on her left arm from the injection site to the elbow and a rash also on her right arm (unspecified where on her right arm). The patient sought unspecified medical attention. The physician prescribed over-the-counter Benadryl and contacted the patient the next day for follow up. The patient reported that she was fine. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** Yasmin

**Lab Data:** NONE

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274124-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	05-Feb-2007	05-Feb-2007	0	16-Mar-2007	20-Mar-2007	NY	WAES0702USA00744	20-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1162F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Eye movement disorder, Incorrect dose administered, Medical device complication, Tremor

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 15 year old female who on 05-FEB-2007 was vaccinated with a dose of HPV (lot# 654540/1162F). On 05-FEB-2007 the nurse reported that the vaccine prefilled syringe malfunctioned. The nurse pushed the plunger down, the spring never activated and when she pulled the syringe out of the patient's arm some of the liquid sprayed on the table and on the wall. The patient was not re-activated because of her reactions which were she "felt woozy" and her eyes were fluttering, and her whole body was shaking. It was noted that the patient did not lose consciousness. The patient will come back in two months to get re-vaccinated. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274125-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	NY	WAES0702USA00772	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Flushing, Hot flush

**Symptom Text:** Information has been received from medical assistant via a company representative concerning the 26 year old female medical assistant who, on an unspecified date, was vaccinated with a dose of HPV. The medical assistant reported that after her vaccination with HPV, "her face turned very red and hot". The medical assistant recovered on an unspecified date. The patient (medical assistant) sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1054

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274126-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Jan-2007	31-Jan-2007	2	16-Mar-2007	20-Mar-2007	CA	WAES0702USA00785	21-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Contusion

**Symptom Text:** Information has been received from a medical assistant concerning a 16 year old female who on 29-JAN-2007 was vaccinated IM in the right arm with a first 0.5mL dose of HPV. There was no concomitant medication. On approximately 31-JAN-2007 the developed bruises located on her right forearm and right upper arm. The reporter stated that "the patient noticed the bruises 2 days after the day of vaccination." At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274127-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	06-Jan-2007	06-Jan-2007	0	16-Mar-2007	20-Mar-2007	TX	WAES0702USA00858	05-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site mass

**Symptom Text:** Information has been received from a registered nurse concerning a female who on 06-JAN-2007 was vaccinated with a first dose of Gardasil (yeast) (0.5 ml), intramuscularly. On 06-JAN-2007 the patient had a lump at injection site. It was reported that one month later the patient still had lump at injection site. Unspecified medical assistant was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1056

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274128-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA00866	02-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Arthralgia, Decreased activity, Diarrhoea, Dyspnoea, Dysuria, Epigastric discomfort, Headache, Nausea, Neck pain, Pain in extremity, Paraesthesia, Sinusitis, Vision blurred, Vomiting

**Symptom Text:** Information has been received from a pharmacy student concerning a 16 year old female who on December 2006, was vaccinated IM with a first 0.5 ml dose of HPV. Concomitant therapy included given the same day included a dose of influenza and a dose of Menactra. Seven days after vaccination, the patient experienced headache, nausea, vomiting and diarrhea. The patient was treated with Nexium and Phenergan tablets/suppositories. On 13-DEC-2006 the patient experienced a sinus infection and was placed on a Z-pack. All symptoms resolved except the headache. On 19-JAN-2007, the patient was seen by a neurologist and was placed on Prednisone for 10 days. He also ordered Tazepam to help her sleep since the headaches were keeping her awake and Endocet for the headache pain. The patient has missed a lot of school and is sedentary. She was also complaining of tingling in the hands and legs. The following tests have come back negative: CAT scan, MRI, Lyme and "mono" workup. At the time of this report, the patient had not recovered from tingling in the hands and legs and headache. No product quality complaint as involved. Additional information has been requested. 04/10/07-records received from neurologists for DOS 2/6/07-DX: muscular headaches with some functional overlay. Doubt side effect of Gardasil. C/O headaches, back pain, GI problems recent urinary symptoms, difficulty urinating and dysuria. C/O visual symptoms including blurry vision and spots before her eyes. PE: pain in neck, pain with deep palpation of right popliteal fossa. Walks normally. 05/01/07-records received from facility for DOS 02/09-02/12/07-DC DX: Vomiting and Abdominal Pain. HX 2month of chronic somatic complaints including nausea, epigastric discomfort, diffuse soft tissue and joint pain, vomiting, periodic shortness of breath and recent urinary symptoms. Labs, liver enzymes elevated in context of multiple Tylenol usage as an outpatient due to her pain.Hospital course included discontinuance of Tylenol and Percocet. LFTs steadily trended downward and sh

**Other Meds:**

**Lab Data:** computed axial, 12/06; magnetic resonance, 12/06 records received 5/1/07-MRI negative, lab work normal. CT head and MRI of head negative. Normal abdominal ultrasound. Doppler normal of kidneys, normal upper GI series. negative lyme, negati

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1057

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274129-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	20-Mar-2007	IL	WAES0702USA00905	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Paraesthesia oral

**Symptom Text:** Information has been received from a physician concerning a 20 year old female with allergy to unspecified medications who in approximately December 2006, around 2 months ago, was vaccinated with the first dose of HPV (lot #not reported). Concomitant medications were unspecified. In approximately December 2006, five minutes after receiving the first dose of the vaccine, the patient experienced tingling around her mouth and numbness that lasted for 20 minutes. The patient sought medical attention. The patient was then sent home and had no further problems. The patient did not continue the vaccination series because of the reaction. At the time of reporting, the patient had recovered. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274130-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	05-Feb-2007	06-Feb-2007	1	16-Mar-2007	20-Mar-2007	--	WAES0702USA00914	21-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Nausea, Vomiting

**Symptom Text:** Information has been received from a certified medical assistant concerning a 24 year old female that works in the same office On 05-FEB-2007, the patient was vaccinated with a first dose of HPV. There were no concomitant medications. On 06-FEB-2007 the patient developed severe nausea, vomiting and chills. Unspecified medical attention was sought. At the time of the reporter, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274131-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA00920	05-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Presyncope

**Symptom Text:** Information has been received from a certified medical assistant (C.M.A) concerning approximately 19 female patients who were vaccinated with 0.5 mL dose of Gardasil (yeast). (Lot # not reported). Subsequently the patient experienced pain at the injection site lasting for about a week. The C.M.A also reported that another patient experienced pain at the injection site lasting for about a week and reported that she almost passed out from the pain (WAES0702USA04000). Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274132-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	01-Feb-2007	01-Feb-2007	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA00923	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Swelling

**Symptom Text:** Information has been received from an office manager who was the mother of an 18 year old female patient with an unspecified auto immune disorder who in approximately February 2007 was vaccinated with a dose of HPV. The patient developed a "huge" red circle a few inches in diameter on her arm where she was vaccinated. There was a "lot" of swelling and the patient put ice on it all week. Medical attention was sought. The patient was recovering as of the report date. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Autoimmune disorder

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274133-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	26-Jan-2007	05-Feb-2007	10	16-Mar-2007	20-Mar-2007	NC	WAES0702USA00992	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician, via a company representative concerning a 25 year old female with a history of allergies to "many products," who on 26-JAN-2007 was vaccinated with the first dose of Gardasil (yeast). On 05-FEB-2007 the patient called the physician after she developed hives. The patient believed the hives were "caused by the vaccination," though the development and timing of the onset of the hives was unclear. The patient was instructed to take BENADRYL as treatment. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:**

**Prex Illness:** Multiple allergies

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274134-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	05-Feb-2007	05-Feb-2007	0	16-Mar-2007	20-Mar-2007	CT	WAES0702USA00994	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNC	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Deafness, Dizziness, Injection site pain, Sudden hearing loss

**Symptom Text:** Information has been received from a registered nurse, via a company representative, concerning a female who on 05-FEB-2007 was vaccinated with a dose of Gardasil (yeast) in one arm and possibly a meningococcal vaccine (unspecified) in the other arm. Subsequently the patient felt faint, experienced a temporary loss of hearing, and also experienced pain from the injection. The nurse indicated that the patient's "fair hair (red or blonde) made them more susceptible to the adverse events." The patient was observed in the office and after a short time recovered and left. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1063

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274136-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	13-Mar-2007	14-Mar-2007	1	16-Mar-2007	19-Mar-2007	FL		19-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	02434	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blister, Pain

**Symptom Text:** Blister, area looks burned. Pain at blistered site. Appears to be lower than site of injection. Patient denies other injury. Treated with tylenol #3 and omnicef. Will follow up with doctor next week.

**Other Meds:** None

**Lab Data:** N/A

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274146-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	08-Mar-2007	08-Mar-2007	0	16-Mar-2007	19-Mar-2007	MD		19-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1447F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site swelling

**Symptom Text:** Patient Seen on 3/14/07 for complaints of pain and swelling at the site of the Gardasil vaccine given on the left upper arm. Injection administered on 3/8/07

**Other Meds:** Psych meds not prescribed by this MD

**Lab Data:**

**History:** None

**Prex Illness:** None - Was here for a physical/Well check

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274169-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	14-Mar-2007	14-Mar-2007	0	16-Mar-2007	19-Mar-2007	CA		05-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0181U	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site swelling, Rash generalised, Similar reaction on previous exposure to drug, Swelling face, Urticaria

**Symptom Text:** Received Gardasil #2, developed swelling around injection site after 2-5 minutes. That evening she developed hives on body and extremities-Mom gave Benadryl. Rash subsided but left side of face swollen but improved later in the day. 2 months ago 1st Gardasil given; she developed hives. Mom thought it was due to other allergies. Has been getting all over rash and swollen face since then.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274180-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	23-Jan-2007	23-Jan-2007	0	16-Mar-2007	20-Mar-2007	FL	WAES0702USA00996	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	1425F	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash, Rash generalised

**Symptom Text:** Information has been received from a registered nurse, concerning a 13 year old female with multiple allergies, who on 23-JAN-2007 was vaccinated IM in the right arm, with the first dose of Gardasil (yeast) (Lot # 655165/1425F). There was no concomitant medication. Approximately five to ten minutes later, the patient developed a rash that "started at the injection site and then spread to the arm and the whole body." Treatment with ZYRTEC was immediately given in the office, and the patient was instructed to take BENADRYL at home, if needed. The nurse reported that "rash was mild and self-limiting," and remarked "it was easily treated with antihistamine and resolved soon after treatment was given." He clarified that "this was a mild reaction," and he did not feel the patients condition would have required hospitalization or threatened her safety. The mother of the patient wanted her daughter to receive the subsequent doses of the vaccine, however the nurse stated he felt the patient's system was "sensitized" and believed a second dose would be "too risky." Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:**

**Prex Illness:** Multiple allergies

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1067

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274181-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Feb-2007	02-Feb-2007	1	16-Mar-2007	20-Mar-2007	PA	WAES0702USA00999	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Muscular weakness, Myalgia, Nausea, Pyrexia, Rash

**Symptom Text:** Initial and follow up information has been received from a physician via a company representative, and the mother of the patient, concerning a 12 year old female who on 01-FEB-2007 was vaccinated with the first dose of Gardasil (yeast). On approximately 02-FEB-2007 (within 24 hours), the patient developed nausea, a low grade fever, and experienced "muscle weakness that hurt." On approximately 06-FEB-2007 ("lasted for 4-5 days"), the patient recovered. Follow up information received from the mother of the patient, reported that on the morning of 21-FEB-2007, her daughter woke up with " a rash on her breasts, looks like pimples." The mother reported her daughter did not experience fever or itching with the rash, and the rash was "not on any other part of her body." The mother added that her daughter went to school, but "has not recovered from the rash." The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274182-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	29-Jan-2007		16-Mar-2007	20-Mar-2007	NY	WAES0702USA01031	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Information has been received from a nurse concerning a female who was vaccinated with Gardasil. Subsequently, "within last week or week and a half," the patient developed a fever and was admitted to the hospital for 24 hours. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274183-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	06-Feb-2007	06-Feb-2007	0	16-Mar-2007	20-Mar-2007	IL	WAES0702USA01062	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female, with no pertinent medical history with allergies to erythromycin and sulfamethoxazole (+) SEPTRA who on 06-FEB-2007 was vaccinated with Gardasil (yeast), (Lot # 654885/1424F). There was no concomitant medication. On 06-FEB-2007 the patient developed chest pain when taking deep breaths. No other symptoms. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:**

**Prex Illness:** Allergic reaction to antibiotics

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1070

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274184-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	20-Mar-2007	MT	WAES0702USA01074	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Subcutaneously		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Incorrect route of drug administration, Injection site pain

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female (age not reported) who in December 2006, was vaccinated with Gardasil (yeast) which may have been given by the SQ route or a partial SQ route. Subsequently, the patient developed slight injection site soreness (date unknown). The nurse reported that the nurse who administered this vaccination was left handed and his technique appeared "odd" and it may have looked like a SQ injection when it was really intramuscular. The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274185-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	CA	WAES0702USA01078	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Information has been received from a female medical assistant who was vaccinated IM, into the arm, with a first dose of Gardasil (yeast). Subsequently the patient experienced had pain in the arm that lasted a few minutes after vaccination. Unspecified medical attention was sought. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274186-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA01091	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Dizziness, Hyperhidrosis

**Symptom Text:** Information has been received from a nurse practitioner concerning a 15 year old female who was vaccinated IM with a first dose of Gardasil (yeast) (lot# 653938/0954F). Subsequently, the patient experienced diaphoresis, and felt faint moments after the injection. The patient;s lungs were clear and her pulse was 82. The patient went to the emergency room and was evaluated as being normal. The patient was released from the emergency room; however, the patient went to her primary care physician for evaluation. The physician determined that the patient was fine. The patient's mother called the nurse practitioner and said that her daughter gets extremely anxious with injections which may have contributed to the symptoms. In addition, the patient also had an empty stomach at the time of vaccination. The patient's mother and the felt that the patient is eligible to receive the subsequent doses of the vaccine. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** respiratory rate - clear, total heartbeat count - 82

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274187-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	06-Feb-2007	06-Feb-2007	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA01096	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Erythema, Hypoaesthesia, Injection site pain, Local reaction

**Symptom Text:** Information has been received from a health professional concerning a 16 year old female with no medical history who on 06-FEB-2007 was vaccinated IM in to the right deltoid with a 0.5 ml dose of Gardasil (yeast) (lot # 654535/0960F). There was no concomitant medication. On 06-FEB-2007 after vaccination the patient developed a local reaction. She experienced 30 seconds of dizziness. The local reaction started with pain at the injection site that radiated down her arm and her entire arm was red. After the patient subsided the arm went numb and then the patient was fine. The entire episode lasted only 5 minutes and the patient seemed fully recovered. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274188-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	PA	WAES0702USA01154	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a physician via a company representative, concerning a female patient who was vaccinated with either a first dose or second of Gardasil (yeast). Subsequently the patient experienced nausea after vaccination. The patient recovered within a day. The patient sought unspecified medical attention.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1075

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274189-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	06-Nov-2006	06-Nov-2006	0	16-Mar-2007	21-Mar-2007	VA	WAES0702USA01175	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0013U	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Head injury, Inappropriate schedule of drug administration, Loss of consciousness

**Symptom Text:** Initial and follow up information has been received from a licensed practical nurse via a company representative, concerning a 12 year old white female student, who on 06 Nov 2006 was vaccinated in the right deltoid with 0.5 ml of the first dose of Gardasil. There was no concomitant medication. There was no illness at the time of vaccination. The patient passed out in the physician's waiting room after receiving the vaccination. The patient stated she did not eat breakfast. Upon awakening, the patient was given crackers and soda, and stated she felt better. On 05 Feb 2007, three months after the first dose, the patient was vaccinated in the left deltoid with the second dose of Gardasil. After the second vaccination, the mother called and reported her daughter had passed out at home and hit her head. The patient did not receive medical attention, but her physician was informed. The patient recovered the same day, 05 Feb 2007. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274190-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	07-Feb-2007	07-Feb-2007	0	16-Mar-2007	21-Mar-2007	NY	WAES0702USA01180	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash generalised

**Symptom Text:** Information has been received from a physician via a company representative, concerning a 19 year old female who on 07 Feb 2007 was vaccinated with an 0.5 ml dose of Gardasil. By the evening of the same day, the patient developed a "rash from head to toe and itching." The patient has not recovered at the time of this report. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274191-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	25-Jan-2006	25-Jan-2007	365	16-Mar-2007	21-Mar-2007	MD	WAES0702USA01217	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fungal infection

**Symptom Text:** Information has been received from a 22 year old female health professional who on 25 Jan 2006 was vaccinated with a first dose of Gardasil. The patient reported that within 24 hours of vaccination she experienced a yeast infection. It was reported that the patient sought medical attention for this event. The patient recovered after approximately 2 days. Patient would complete her vaccination series. Additional informatio has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274192-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Nov-2006	01-Nov-2006	0	16-Mar-2007	21-Mar-2007	MD	WAES0702USA01225	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syphilis test positive

**Symptom Text:** Information had been received from a physician and a Registered Nurse concerning a 16 year old female who was sexually active. In August 2006, the patient was vaccinated with the first dose of Gardasil, at the end of November 2006 with the second dose. She received the vaccination at the pediatrician's office. The patient was tested for syphilis " a couple of days" later. The patient's Rapid Plasma Reagin (RPR) test titers were 1-256 (high), with a negative Fluorescent Antibody Absorption (FTA) test. The patient was tested again approximately one week later and the RPR titers were still high but lower. The physician mentioned that the patient underwent other antibody tests such as serum antinuclear antibodies (ANA) test, and Lyme disease test. The results were normal for those tests. The physician stated that the patient had not been sick with the flu nor mononucleosis, and that the patient had tested negative for other sexually transmitted diseases. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Diagnostic laboratory, 11/06, negative, sexually transmitted disease; lyme disease assay, 11/06, Normal; rapid plasma reagin, 11/06, 1-256, High; serum ANA, 11/06, Normal; rapid plasma reagin, 11/06, positive but lower; FTA-ABS, 11/06, Nega

**History:** sexually active

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1079

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274193-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	13-Nov-2006	13-Nov-2006	0	16-Mar-2007	21-Mar-2007	CA	WAES0702USA01274	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Lethargy, Nausea, Pseudomononucleosis

**Symptom Text:** Information has been received from a health professional concerning a 15 year old female on 13 Nov 2006 was vaccinated with a first dose of Gardasil. There were no concomitant medications. On approximately 13 Nov 2006 the patient experienced nausea, lethargy and "mono like symptoms." Subsequently, the patient recovered. On 03 Feb 2007, the patient was vaccinated with a second dose of Gardasil. On 03 Feb 2007 the patient experienced nausea, marked lethargy, "mono like symptoms" and diarrhea for 2 days after the vaccination. On 05 Feb 2007, the patient returned to the doctors office and underwent a complete blood cell count and an Epstein-Barr virus antibodies screen. It was reported that "mono" was ruled out. At the time of the report, the patient was recovering. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** Epstein-Barr virus, 2/5/07; complete blood cell, 2/5/07

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274194-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	31-Jan-2007	31-Jan-2007	0	16-Mar-2007	21-Mar-2007	CT	WAES0702USA01291	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Injection site pain, Sudden hearing loss

**Symptom Text:** Information has been received from a registered nurse, via a company representative, concerning a female who on approximately 31 Jan 2007 was vaccinated with a dose of Gardasil in one arm and possibly a meningococcal vaccine (unspecified) in the other arm. Subsequently the patient felt faint, experienced a temporary loss of hearing, and also experienced pain from the injection. The nurse indicated that the patient's "fair hair (red or blonde) made them more susceptible to the adverse events." The patient was observed in the office and after a short time recovered and left. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274195-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	04-Jan-2007	04-Jan-2007	0	16-Mar-2007	21-Mar-2007	PA	WAES0702USA01321	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old white female with no known drug allergies or illness at the time of vaccination who on 01 Jan 2007 was vaccinated in the right deltoid with a 0.5 mL first dose of Gardasil. Concomitant therapy included Yaz, Zelnorm and Miralax. On 04 Jan 2007, the patient became lightheaded and had to lie down after receiving Gardasil vaccination. The patient stated that she had gotten lightheaded after injections in the past. She also did not have much to eat that morning. The patient did not lose consciousness and remained alert and responsive. The patient was given some peanut butter crackers and coke and subsequently felt better and recovered. Additional information is not expected.

**Other Meds:** Yaz, Miralax, Zelnorm

**Lab Data:** UNK

**History:** dizziness

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274196-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	26-Jan-2007	26-Jan-2007	0	16-Mar-2007	21-Mar-2007	WI	WAES0702USA01324	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 26 Jan 2007 was vaccinated intramuscularly with a first 0.5 mL dose of Gardasil. On 26 Jan 2007 the patient developed a rash at her injection site. The patient sought unspecified medical attention. On 27 Jan 2007 the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274197-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	08-Feb-2007	08-Feb-2007	0	16-Mar-2007	21-Mar-2007	TX	WAES0702USA01341	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0013U		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, Injection site reaction, Medical device complication, Pain in extremity, Skin irritation

**Symptom Text:** Information has been received from a licensed visiting nurse concerning a 14 year old female with no medical history and no known drug allergies, who on 08 Feb 2007 was vaccinated IM with a dose of Gardasil. Concomitant therapy included Ortho Tri Cyclen Lo and Synthroid. The patient inadvertently received less than the recommended dose and experienced an injection site reaction. The nurse withdrew the vaccine from a vial and the medication leaked near the hub of the syringe while administering it to the patient. The patient complained of irritation on the left deltoid about a two inch radius from the injection site. She also reported that the pain "ran down" her left arm. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Ortho Tri Cyclen Lo, Synthroid

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1084

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274198-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	21-Mar-2007	IA	WAES0702USA01347	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness, Injection site erythema, Injection site mass, Injection site pruritus, Injection site swelling

**Symptom Text:** Information has been received from a licensed practical nurse concerning a female with pertinent medical history unspecified and drug reaction/allergies unspecified who in December 2006, two months ago, was vaccinated with first dose of Gardasil 0.5 ml IM. Concomitant therapy was unspecified. In December 2006, one day after receiving the injection, the patient experienced redness, swelling, itching, and bumps on her arm at the injection site. The patient also experienced light-headedness, and dizziness. The patient sought medical attention. Subsequently, the patient recovered. No other information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK  
**Lab Data:** NONE  
**History:** UNK

**Prex Illness:**  
**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274199-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	PA	WAES0702USA01353	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from an office manager concerning a female (age not reported) with a history of passing out when receiving shots who on an unspecified date was vaccinated with Gardasil (lot # not reported) 0.5 ml injection. On an unspecified date, the patient passed out after the shot of Gardasil, unknown which dose. Unspecified medical attention was sought. The patient recovered later in the day. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** passed out

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274200-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	CA	WAES0702USA01367	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site swelling

**Symptom Text:** Information has been received from a female receptionist who was vaccinated with a dose of Gardasil. Subsequently the injection site became swollen after a week, "about the size of a half dollar." It was reported that there were "rings around the swelling an it was painful." Unspecified medical attention was sought. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274201-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA01375	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus

**Symptom Text:** Information has been received from a physician concerning a 16 year old female with asthma who in December 2006, was vaccinated with the first dose of Gardasil. Concomitant therapy included FLOVENT, albuterol and ZYRTEC. In December 2006, a few hours following vaccination with Gardasil, the patient experienced itchiness and redness of her face. The patient sought unspecified medical attention. Subsequently on an unspecified date, the patient recovered from itchiness and redness of her face. Additional information has been requested.

**Other Meds:** albuterol, Zyrtec, Flovent

**Lab Data:**

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274202-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	26-Nov-2006	26-Nov-2006	0	16-Mar-2007	21-Mar-2007	--	WAES0702USA01383	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Injection site erythema, Injection site mass, Injection site pain, Injection site pain, Injection site reaction

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on 26-NOV-2006 was vaccinated with the first dose of Gardasil and on 31-JAN-2007 was vaccinated with the second dose of Gardasil. Concomitant medication was not reported. On approximately 26-NOV-2006 the patient experienced headache after the first dose of Gardasil, which lasted about one month. The outcome and causality of the headache was not reported. On 07-FEB-2007, about 7 days after the second dose of Gardasil, the patient developed a "lump," redness and pain in her arm, at the injection site. The physician reported that the injection site reaction was approximately one half centimeter which was extremely tender and painful. On an unspecified date, the patient sought unspecified medical attention. The patient's events persisted. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1089

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274203-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	01-Aug-2006	01-Aug-2006	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA01391	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Burning sensation, Rash pruritic

**Symptom Text:** Information has been received from a physician concerning a 26 female who in August 2006, "in the morning" was vaccinated with Gardasil. By nighttime, the patient experienced burning sensation in cheeks. The next morning she developed an itchy rash on her cheeks. The patient sought unspecified medical attention. Subsequently, the patient recovered from burning sensation in cheeks and itchy rash on her cheeks. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274204-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	02-Feb-2007		16-Mar-2007	21-Mar-2007	--	WAES0702USA01396	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a nurse practitioner concerning a female (age unknown) who, on an unspecified date, was vaccinated intramuscularly with a 0.5 ml dose of Gardasil. The patient was administered Gardasil in one arm ant Tetanus vaccine in the other arm on the same day. On approximately 02-FEB-2007 the patient developed a rash on her whole body. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274205-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	MI	WAES0702USA01403	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a dose of Gardasil. Subsequently the patient experienced dizziness and sought unspecified medical attention. No further information was provided. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1092

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274206-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	22-Jan-2007	10-Feb-2007	19	16-Mar-2007	21-Mar-2007	CA	WAES0702USA01736	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site bruising, Injection site rash, Nausea

**Symptom Text:** Information has been received from a registered nurse via a company representative, concerning a 25 year old female who on approximately 22-JAN-2007 (about three weeks ago), was vaccinated with the second dose of Gardasil, 0.5 ml. Concomitant therapy included ZELNORM. On approximately 10-FEB-2007 ("within the past day or two"), the patient developed "a bump and bruise at injection site, and nausea. It was reported that the patient had "no ill effects after the first dose" (date not provided). At the time of this report, the patient had not yet recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Zelnorm

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274207-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	CA	WAES0702USA01781	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Sensory disturbance

**Symptom Text:** Information has been received from a nursing supervisor concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil. Subsequently, the patient reported that her arm felt dead. At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274208-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	08-Feb-2007	Unknown		16-Mar-2007	21-Mar-2007	FL	WAES0702USA01826	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness

**Symptom Text:** Information has been received from a physician concerning an 11 year old female who on 08-FEB-2007 was vaccinated with her first dose of Gardasil and experienced flu-like symptoms after the vaccination. Concomitant therapy included Menactra. Unspecified medical attention was sought by the patient. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1095

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274209-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	M	07-Feb-2007	12-Feb-2007	5	16-Mar-2007	21-Mar-2007	NJ	WAES0702USA01859	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Fatigue, Nausea, Pain, Wrong drug administered

**Symptom Text:** Information has been received from the mother of an 11 year old male with severe acid reflux and possibly a hiatal hernia, severe allergies to many different things such as pollen, dust, and various foods, mild asthma, anxiety problems and a history of seizure as an infant after DPT vaccination, who on 07-FEB-2007 was vaccinated with a dose of Gardasil by mistake. Concomitant therapy included ZYRTEC, PAXIL, PRILOSEC and different allergy shots. The report stated that her son was supposed to have received an unspecified hepatitis vaccine. On 12-FEB-2007 the patient was feeling achy, weak, tired and nauseous. She also stated that she was not sure that these symptoms were related to the vaccine. Medical attention was sought. The patient was reported as not recovered at the time of this report. Additional information has been requested.

**Other Meds:** Allergenic extract, Zyrtec, Prilosec, Paxil

**Lab Data:** UNK

**History:** Convulsion

**Prex Illness:** Pollen allergy, House dust allergy, Food allergy, Acid reflux (Oesophageal), hypersensitivity, asthma, anxiety disorder.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274210-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	03-Jan-2007	04-Jan-2007	1	16-Mar-2007	20-Mar-2007	FL	WAES0702USA01925	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0954F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 14 year old female patient with possible allergy to penicillin and erythromycin who on 03-JAN-2007 was vaccinated with a first dose of Gardasil (yeast), lot # 653938/0954F. The patient was not on any medication. On 04-JAN-2007 the patient developed hives. The patient was examined by the physician on 05-JAN-2007. The patient was reported as completely recovered by 06-JAN-2007. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:**

**Prex Illness:** Penicillin allergy; Allergic reaction to antibiotics

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274211-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	09-Feb-2007	09-Feb-2007	0	16-Mar-2007	20-Mar-2007	CA	WAES0702USA01931	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Muscular weakness, Tremor

**Symptom Text:** Information has been received from a physician concerning an 18 year old female with pertinent medical history and drug reactions/allergies unspecified who on approximately 09-FEB-2007 was vaccinated with first dose of Gardasil (yeast) (lot # not reported) 0.5 ml IM. On approximately 09-FEB-2007, the patient experienced dizziness, weakness and shaky legs after receiving Gardasil (yeast). Medical attention was sought. As a result of the symptoms, the patient was home from school for 3 days. At the time of reporting, the patient was recovering. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274212-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA01971	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Information has been received from a nurse concerning a 26 year old female who was vaccinated with a first dose of Gardasil (yeast). Subsequently the patient experienced "vomited eight hours with no fever". Subsequently, the patient recovered (date unspecified). No further information is available.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274213-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	20-Mar-2007	WI	WAES0702USA01991	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Dyspnoea

**Symptom Text:** Information has been received from a physician concerning a 23 year old female who in December 2006, was vaccinated with a second dose of Gardasil (yeast). In December 2006, the patient's blood pressure went up and she developed shortness of breath. After 30 minutes, the patient's blood pressure returned to normal. The patient was not pregnant. At the time of this report, the outcome of the shortness of breath was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1100

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274214-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA02049	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site, Malaise, Muscle tightness

**Symptom Text:** Information has been received from a "healthcare worker" concerning a female (patient 2 of 4), either 14 years or 17 years old, who was vaccinated with the first dose of Gardasil (yeast) 0.5 ml IM in the gluteal region. The patient experienced "knots in her neck and ill feeling" one to two weeks after receiving the vaccination. The healthcare worker noted that the patient was being treated for "something else that had absolutely nothing to do with the vaccination". This patient "had no problems". Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274215-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	08-Feb-2007	11-Feb-2007	3	16-Mar-2007	20-Mar-2007	NC	WAES0702USA02321	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Injection site discolouration, Melanocytic naevus, Pain, Rash, Skin hyperpigmentation

**Symptom Text:** Information has been received from a physician concerning a 22 year old female with mild asthma and a history of CIN grade I (2003, 2005 and 2006) and a benign pigmented lesion removed from her inner thigh (2006) who on 08-FEB-2007 was vaccinated IM into the right arm with a 0.5 ml dose of Gardasil (yeast) (lot # 654535/0960F). Concomitant therapy included oral hormonal contraceptives (unspecified). Three on 11-FEB-2007 the patient developed two raised areas of hyperpigmented skin in the area of the injection site. The areas are 4 x 4 mm and 3 x 3 mm. The areas are described as are nevus like in appearance, linear, surrounded by erythema and painful. The patient is being evaluated for a "possible skin rash." The patient had not yet recovered from her experiences. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** UNK

**History:** Cervical intraepithelial neoplasia; Benign pigmented naevus excision

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274216-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	PA	WAES0702USA02391	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1427F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness

**Symptom Text:** Information has been received from a health professional concerning a female who was vaccinated with IM with a 0.5 ml dose of Gardasil (yeast) (lot 654885/1424F # or lot # 655619/1427F). Subsequently within a few minutes the patient experienced dizziness and felt as if she was going to faint. The patient did not faint and was not sent to the hospital. The patient laid down for a few minutes and had something to drink. The patient recovered on an unspecified date. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274217-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	15-Dec-2006	11-Jan-2007	27	16-Mar-2007	20-Mar-2007	MT	WAES0702USA02397	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthma exercise induced

**Symptom Text:** Information has been received from a certified medical assistant concerning her 11 year old daughter with no past medical history and no allergies who on 15-DEC-2006 was vaccinated with a first dose of Gardasil (yeast), IM. There was no concomitant medication. On 11-JAN-2007 the patient experienced exercise induced asthma. The patient noticed that she was short of breath during exercise during sports. The patient had recovered without treatment on 30-JAN-2007. There were no relevant diagnostic tests or laboratory data. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274218-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA02437	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician's assistant concerning a 22 year old female who on an unspecified date was vaccinated with Gardasil (yeast) (lot # not reported) IM injection. Concomitant therapy was unspecified. The patient sought unspecified medical attention. Subsequently, the patient experienced an extreme rash across her chest and up to her neck. At the time of reporting, the patient was "fine". Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1105

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274219-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	17-Oct-2006	17-Oct-2006	0	16-Mar-2007	20-Mar-2007	CA	WAES0702USA02440	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0800F		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Alpha 1 foetoprotein abnormal, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a licensed practical nurse (LVN) as part of the pregnancy registry concerning a 17 year old female with penicillin allergy and drug reaction/allergy to DARVOCET, and VICODIN. She had no other concurrent medical conditions, or significant past medical history including no history or pregnancies. On 17-OCT-2006, the patient was vaccinated with first dose of Gardasil (yeast) (lot # 654540/0800F also reported as 653937/0637F) 0.5 ml IM. There was no concomitant medication. The patient's last menstrual period was 18-OCT-2006. Medical attention was sought. On 11-DEC-2006, an ultrasound was performed that revealed pregnancy of 8 weeks and 2 days (estimated date of delivery 25-JUL-2007). On approximately 11-DEC-2006, maternal serum alpha-fetoprotein (MSAFP) test was performed that indicated the baby was at increased risk (positive) for neural tube defect (NTD). Medication taken during the pregnancy included prenatal vitamins. The patient was scheduled for follow-up testing with a perinatologist. No other information was available at the time of reporting. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** ultrasound 12/11/06 - prenatal testing: 8 weeks and 2 days, serum alpha-fetoprotein 12/11/06 - positive screen for neural tube defect

**History:**

**Prex Illness:** Pregnancy NOS (LMP = 10/18/06), Penicillin allergy; Drug Hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274220-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Jan-2007	26-Jan-2007	0	16-Mar-2007	20-Mar-2007	PA	WAES0702USA02449	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pruritus, Pruritus generalised

**Symptom Text:** Information has been received from a consumer concerning her 18 year old old daughter with no pertinent medical history who on 26-JAN-2007 was vaccinated with her first dose of HPV. Concomitant therapy included hormonal contraceptives (unspecified). On 26-JAN-2007 the patient experienced itching at the injection site that developed into full body itching. Medical attention was sought. The patient was treated with Benadryl. There were no laboratory or diagnostic tests performed. At the time of the report, the patient had not recovered. Her second dose was scheduled for 23-MAR-2007. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1107

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274221-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
35.0	F	22-Jan-2007	22-Jan-2007	0	16-Mar-2007	20-Mar-2007	ME	WAES0702USA02476	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Injection site calcification, Injection site pain, Injection site pruritus

**Symptom Text:** Information has been received from a 35 year old female with no pertinent medical history who on 22-JAN-2007 was vaccinated intramuscularly with a 0.5 ml first dose of HPV. There was no concomitant medication. On 31-JAN-2007 the patient developed a painful itch at the injection site. The patient reported that after careful study of the site, she noted and then felt a bump at the injection site. The patient consulted with her physician who stated it was a calcification. There were no laboratory or diagnostic tests performed. At the time of the report, the patient had not recovered.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274222-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	31-Jan-2007	11-Feb-2007	11	16-Mar-2007	20-Mar-2007	WV	WAES0702USA02541	05-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0011U	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash maculo-papular

**Symptom Text:** Information has been received from a nurse practitioner concerning a 24 year old female patient with Hyperlipidemia, polycystitis ovarian syndrome and penicillin allergy who on 31-JAN-2007 was vaccinated with a first dose of Gardasil (yeast) (lot# 654702/0011U), intramuscularly. Concomitant therapy included cholestyramine resin, atorvastatin calcium (Lipitor) and drospirenone + ethinyl estradiol (Yasmin). On 11-FEB-2007, the patient developed a maculopapular rash on her torso and bilateral upper extremities. The patient was evaluated at an urgent care facility and was prescribed a Prednisone pack. At the time of the report the patient was considered to be not recovered. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Lipitor, Cholestyramine Resin, Yasmin

**Lab Data:** NONE

**History:** Hyperlipidaemia; Ovarian cyst; Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274223-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA02542	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Information has been received from a physician's assistant concerning a 23 year old female with genital warts who in December 2006, was vaccinated with first dose of HPV (lot # not reported) 0.5 ml injection. Concomitant therapy was unspecified. The patient sought medical attention. In December 2006, after taking the first dose of vaccine, the genital warts seemed to worsen. The patient was treated with thioguanine and cytarabine (TCA). On approximately 07-FEB-2007, the patient was given the second dose of HPV (lot # not reported) 0.5 ml injection. The outcome of the worsening genital warts was not specified. No further information was provided at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1110

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274224-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Nov-2006	01-Nov-2006	0	16-Mar-2007	20-Mar-2007	--	WAES0702USA02660	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Rash generalised

**Symptom Text:** Information has been received from a nurse practitioner concerning her 17 year old daughter with attention deficit/hyperactivity disorder and a history of shellfish allergy (as a child: outgrew) who in November 2006, was vaccinated in the right deltoid, IM with a first dose of HPV (Lot # not reported). Her second dose of HPV (Lot # 653650-0640F) was administered IM into the right deltoid in January 2007. Concomitant therapy included Adderall. The nurse practitioner reported that 3 days after each dose of HPV, her daughter developed diarrhea (unspecified dates in November 2006 and January 2007). The diarrhea was reported to be "relatively severe and spontaneously resolved". On an unspecified date in January 2007, on the fourth day after the second dose, the patient "developed a rash on her knees and thigh that spread during the day until she was covered in a rash from her neck to her feet." She was treated with Benadryl and it resolved. The reporter noted that the decision was made to discontinue the series so a third dose would not be given. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Adderall Tablets

**Lab Data:** NONE

**History:** Shellfish allergy; Attention deficit/hyperactivity disorder

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274225-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	--	WAES0702USA02761	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Information has been received from a registered nurse concerning a female who was vaccinated with a first dose of HPV. Subsequently the patient experienced nausea and vomiting. At the time of the report the patient was recovering. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274226-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	NY	WAES0702USA02815	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Crying, Pain

**Symptom Text:** Information has been received from a nurse practitioner and a licensed practical nurse concerning a teenage female (age not reported) who on an unspecified date was vaccinated with 0.5 mL of HPV. Subsequently, the patient ended up crying and reported she had pain, when the vaccine was being administered, either left or right arm and had some pain afterwards. The licensed practical nurse further reported that the patient developed pain one hour after the injection. The patient reported that the pain had subsided, however, when the patient went to bed that evening, the pain had returned. Unspecified medical attention was sought. At the time of this report, the patient had fully recovered from the events (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274227-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	04-Dec-2006	04-Dec-2006	0	16-Mar-2007	20-Mar-2007	MN	WAES0702USA02816	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0962F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Hyperhidrosis, Nausea, Pyrexia

**Symptom Text:** Information has been received from a nurse concerning a 21 year old female with no past medical history who on 04-DEC-2006 was vaccinated with HPV (lot # 654510/0962F), intramuscularly. There was no concomitant medication. On 04-DEC-2006, "five hours after vaccination", the patient felt feverish plus experienced dizziness and nausea and diaphoretic. The patient went to bed that evening and the next morning symptoms had resolved. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274228-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	20-Mar-2007	OR	WAES0702USA02826	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with established papilloma viral infection and a colposcopy was performed who on an unspecified date was vaccinated with HPV (lot# not reported). Subsequently, the patient experienced an outbreak of genital warts. Medical attention was sought. The outcome of the genital warts was not reported. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274229-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	26-Jan-2007	Unknown		16-Mar-2007	21-Mar-2007	NC	WAES0702USA02906	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0011U	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a LPN concerning a 25 year old female patient with sulfonamide allergy and allergic reaction to Biaxin who on 26-JAN-2007 was vaccinated IM in right deltoid with her first dose of Gardasil, lot #654702/0011U. She developed generalized hives after the vaccination. The nurse did not know when the hives started. Benadryl was recommended as treatment. The outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Sulfonamide allergy and allergic reaction to antibiotics.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1116

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274230-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	U	13-Feb-2007	13-Feb-2007	0	16-Mar-2007	21-Mar-2007	--	WAES0702USA02913	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Nausea, Urticaria, Wheezing

**Symptom Text:** Information has been received from registered nurse supervisor, via a company representative, concerning a 12 year old patient who on 13-FEB-2007 was vaccinated IM in the left deltoid a 5:00 pm with the first dose of Gardasil. Three hours later (8:00pm), the patient had developed hives on the face, back and bottom. By 8:30pm, the patient began to experience wheezing, but then "slept fine through the night". Treatment was not specified. The next morning (14-FEB-2007), hives "had subsided," but the patient "felt nauseous and tired." At the time of this report, the patient had not recovered. The nurse also reported that the patient will not be given the second and third dose of the vaccine. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1117

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274234-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	15-Feb-2007	15-Feb-2007	0	19-Mar-2007	20-Mar-2007	FR	WAES0703CAN00131	21-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0444F		Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Confusional state, Fall, Head injury, Subarachnoid haemorrhage, Syncope

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 15-FEB-2007 was vaccinated with Gardasil (lot # 654672/0444F). There was no concomitant therapy. On 15-FEB-2007, 2-3 minutes after Gardasil injection the patient experienced syncopal episode, fell and hit her head. The patient had a head injury and central lateral subarachnoid bleeding and was hospitalized. The patient's syncopal episode and head injury and central lateral subarachnoid bleeding persisted. It was reported that the patient had a gradual clearing of confusion. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1118

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274235-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	05-Feb-2007	05-Feb-2007	0	19-Mar-2007	20-Mar-2007	TX	WAES0703USA01354	21-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0702F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Hypersensitivity, Injection site erythema, Injection site pruritus, Injection site rash, Rash, Rash

**Symptom Text:** Information has been received from a health professional concerning a 20 year old female with no pertinent medical history who on 05-FEB-2007 was vaccinated intramuscularly with a 0.5 ml dose of Gardasil (lot #653650/0702F). There was no concomitant medication. In February 2007, after the vaccination, the patient experienced an "allergic type reaction." The patient developed red raised bumps and itching at the injection site. It was reported that a rash spread to her arms, trunk and legs and the patient experienced a tight chest (she was able to breathe). Medical attention was sought and the patient was treated with a MEDROL DOSEPAK. There were no laboratory or diagnostic tests performed. On 14-FEB-2007, the patient fully recovered. The registered nurse considered red raised bumps and itching at the injection site, rash spread to her arms, trunk and legs and tight chest to be other important medical events. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1119

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274236-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	01-Feb-2007	01-Feb-2007	0	19-Mar-2007	20-Mar-2007	NY	WAES0703USA02171	21-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Paraesthesia, Paraesthesia

**Symptom Text:** Information has been received from a physician concerning a 22 year old female with no pertinent medical history who in February 2007, was vaccinated with a first dose of Gardasil. There was no concomitant medication. Approximately two weeks post vaccination, the patient experienced paresthesia of hands and feet and was hospitalized. The patient was in the hospital for approximately 5 days and was treated with immune globulin. The physician reported that "blood studies" and "agency reported" had normal results. The patient was discharged from the hospital and had subsequently fully recovered. The reporting physician considered paresthesia of hands and feet to be disabling and an other important medical event. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** complete blood cell - normal results, hematology - normal results

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274243-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	05-Mar-2007	Unknown		19-Mar-2007	19-Mar-2007	CA		19-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1161F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injected limb mobility decreased, Musculoskeletal pain

**Symptom Text:** Left should still in pain one week after injection. No swelling, no redness. Seen by doctor today for follow up. Unable to lift arm completely.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274245-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	07-Mar-2007	07-Mar-2007	0	19-Mar-2007	19-Mar-2007	NY		19-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188UU	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling jittery, Pallor, Paraesthesia, Throat irritation

**Symptom Text:** Pt called on-call doctor, complaining of tingling in her fingers, pressure in her throat, pale and jittery. He instructed her to go to Emergency room. Pt did not go. When we reached her she said she felt fine by the next morning.

**Other Meds:**

**Lab Data:**

**History:** Allergy to Sulfa and Amoxicillin

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274256-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	07-Mar-2007	11-Mar-2007	4	19-Mar-2007	21-Mar-2007	MA		21-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Feeling abnormal, Hypoaesthesia, Loss of consciousness, Paraesthesia

**Symptom Text:** About 3rd day after receiving HPV #2 got up at night (early AM) and was looking in mirror trying to adjust nose ring-became frustrated at fit and put swollen ring back in. On way back to bed, felt numbness and tingling in legs, then "blacked out" few minutes as friend woke her up-felt tired all day. Later afternoon, took shower and went up to room didn't "feel right" and had tingling and numbness of legs and arms for 5-10 minutes-resolved.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274273-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	16-Mar-2007	16-Mar-2007	0	19-Mar-2007	20-Mar-2007	ND		21-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1161F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Feeling cold, Feeling hot, Loss of consciousness

**Symptom Text:** Approx 20 min after vaccine pt felt dizzy, weak and blacked out. Caught by mother before falling to ground. Also felt hot. Taken home (was at grocery store). Felt slightly weak and then at 9 pm that night felt very cold and weak at 9pm. No rxn at injection site.

**Other Meds:** Ortho Lo birth control

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1124

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274276-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	15-Jan-2007	19-Jan-2007	4	16-Mar-2007	21-Mar-2007	CA	WAES0702USA02914	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fatigue, Injection site erythema, Injection site swelling, Pain in extremity, Tonsillar hypertrophy

**Symptom Text:** Information has been received from a physician concerning a 16 year old female patient who on 15-JAN-2007 was vaccinated with her first dose of Gardasil. On 19-JAN-2007 the patient developed red and swollen arm in the injection area. The physician advised patient to take Tylenol. On 22-JAN-2007 the patient reported that her tonsils were swollen. She felt really tired and that her leg was hurting and she could not put weight on it. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1125

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274277-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	02-Feb-2007	02-Feb-2007	0	16-Mar-2007	21-Mar-2007	FL	WAES0702USA02941	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0012U	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Eating disorder, Loss of consciousness, Syncope

**Symptom Text:** Information has been received from a nurse concerning a 25 year old female who on 02-FEB-2007 was vaccinated IM with a first 0.5 ml dose of Gardasil (lot #655503/012U). Concomitant therapy included Depo-Provera. Illness at the time of vaccination included flu-like symptoms. Immediately after vaccination, the patient had syncope and passed out for approximately one minute. It was also noted that her eating was sporadic. The patient has not passed out with previous injections in the past. The physician did not believe the injection cause the syncope. Unspecified medical attention was sought. On 02-FEB-2007, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Depo-Provera

**Lab Data:** UNK

**History:** Immunisation

**Prex Illness:** Flu Symptoms

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1126

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274278-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	12-Feb-2007	12-Feb-2007	0	16-Mar-2007	21-Mar-2007	MO	WAES0702USA02968	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0955F	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure fluctuation, Drug administered at inappropriate site, Headache, Hyperventilation, Malaise, Migraine

**Symptom Text:** Information has been received from a health professional concerning a 15 year old female with no medical history, who on 12-FEB-2007 at 15:30 was vaccinated IM with a second dose of Gardasil (lot# 653978/0955F). Concomitant therapy included ORTHO TRI-CYCLEN LO, BENADRYL and TYLENOL EXTRA STRENGTH. Illness at the time of vaccination included bronchitis. It was noted that the patient may have not eaten all day. "At the patient's request she received the vaccination in her gut." After 2 to 3 minutes, the patient felt sick and began to hyperventilate. The patient's blood pressure went up and down and she complained of a left-sided headache. The patient was diagnosed with a migraine. It was noted that the patient was sent to the emergency room. A "CT of her head" was performed. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** ORTHO TRI-CYCLEN LO, BENADRYL, TYLENOL EXTRA STRENGTH

**Lab Data:** head computed axial -

**History:** NONE

**Prex Illness:** Bronchitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274279-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	CA	WAES0702USA02972	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female (age unknown) who on an unspecified date was vaccinated with a 0.5 ml dose of Gardasil. Subsequently, on an unspecified date, the patient passed out. The patient sought unspecified medical attention. subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274280-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Mar-2007	21-Mar-2007	SC	WAES0702USA03073	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with Gardasil (conflictingly reported oral route). Reportedly. the patient passed out. At the time of the report, it was unknown if the patient recovered.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274281-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	15-Feb-2007	Unknown		16-Mar-2007	21-Mar-2007	DC	WAES0702USA03090	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, Injection site extravasation, No adverse effect, Underdose

**Symptom Text:** Information has been received from a physician concerning a patient who on 15-FEB-2007 was vaccinated, intramuscularly, into the deltoid muscle with the first 0.5 ml dose of Gardasil (lot not reported). It was reported that during the administration of the first dose there was some leaking of the vaccine at the injection site. The patient was not able to receive the complete dose. No adverse experience related to this event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274282-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03112	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a physician's assistant concerning a female (age not reported) who on an unspecified date was vaccinated with first dose of Gardasil (lot # not reported) IM. The patient reported feeling nauseous in between the first and second dose of vaccine. Medical attention was not sought. The outcome of the nausea was not reported. No additional information was provided at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274283-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
35.0	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03117	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Pain in extremity

**Symptom Text:** Information has been received from a family nurse practitioner (FNP), the consumer, a mid thirties year old female who on an unspecified date was vaccinated with first dose of Gardasil (lot # not reported). Subsequently, the patient experienced stinging after the vaccination. The patient also reported that her arm was sore and stung more after the second and third vaccination with Gardasil. The patient sought medical attention. At the time of reporting, the patient had recovered. No other information was available at the time of reporting. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274284-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Jan-2007	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03124	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pharyngolaryngeal pain, Pyrexia

**Symptom Text:** Information has been received from a nurse concerning a 17 year old female patient with pertinent medical history and drug reactions/allergies reported as unspecified on 23-JAN-2007 was vaccinated with Gardasil (lot # not reported) injection. On an unspecified date, the patient went to the hospital with a sore throat and a fever of 100 degrees. After receiving the Gardasil injection, her temperature went to 104.8 degrees on 23-JAN-2007. The physician administered antibiotics for her sore throat. The outcome of the events was unspecified. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** temperature measurement 01/23/07 100, temperature measurement 01/23/07 104.8

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274285-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	01-Jan-2007	01-Jan-2007	0	16-Mar-2007	21-Mar-2007	MA	WAES0702USA03141	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Arthralgia

**Symptom Text:** Information has been received from a nurse practitioner concerning a 13 year old female who in January 2007, was vaccinated with Gardasil. In January 2007, the patient developed arthritic symptoms. The patient had developed achy knees and wrists. There was no redness on the knees and the wrists but were sore. It was reported that ibuprofen was little help in relieving the pain. The nurse practitioner reported that she would ask for lab work to be done for rheumatoid arthritis and a sedimentation rate. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered from the events. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274286-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	PA	WAES0702USA03145	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Varicella

**Symptom Text:** Information has been received from a physician concerning a female "between 12-14 years" old who on an unspecified date was vaccinated with Gardasil. That same day, concomitant suspect therapy included Varivax. On an unspecified date, eight days after administration, the patient developed a chicken pox rash. The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274287-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	25-Jan-2007	25-Jan-2007	0	16-Mar-2007	21-Mar-2007	NY	WAES0702USA03151	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation delayed

**Symptom Text:** Information has been received from a physician concerning a female who on approximately 25-JAN-2007 was vaccinated with a 0.5 ml dose of Gardasil. On approximately 25-JAN-2007 the patient experienced "delayed mensis." Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274288-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	15-Dec-2006	15-Dec-2006	0	16-Mar-2007	21-Mar-2007	MN	WAES0702USA03157	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Adverse event, Dizziness, Pyrexia

**Symptom Text:** Information has been received from a registered nurse concerning a female who on approximately 15-DEC-2006 was vaccinated with a 0.5 ml dose of Gardasil. On approximately 15-DEC-2006 the patient developed high fever, dizziness and "several adverse events." Unspecified medical attention was sought. At the time of the report, the patient was recovering and the physician discontinued further series of Gardasil. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1137

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274289-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03177	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Information has been received from a female patient who was vaccinated with her first Gardasil and developed a rash on her thigh, hip and stomach. After receiving second dose of Gardasil the patient developed hives and a rash. The patient's outcome was unknown. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1138

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274290-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	16-Jan-2007	16-Jan-2007	0	13-Mar-2007	21-Mar-2007	NJ	WAES0702USA03295	26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1968AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB143BA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyskinesia, Fall, Hyperhidrosis, Pain in extremity, Staring

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 16 year old female student with no pertinent medical history who on 16-Jan-2007, at 14:45, was vaccinated, into the left deltoid, with a first dose of Gardasil (lot #655619/1427F) concomitantly with a first dose of Havrix (lot AHAVB143BA) in the left arm and a first dose of Menactra (lot U1968AA) into the right deltoid. On 16-Jan-2007, at 14:45, while sittings on table, the patient complained of severe pain in the left arm. As the patient was complaining, she fell forward, and the licensed practical nurse laid her down. The patient's eyes were fixed staring at the ceiling and her body started jerking wildly and thrashing. The patient went from jerking and trashing to "jumping up and asking what happened." The patient was guided back to the table and her body started jerking and thrashing with her eyes fixed on the ceiling and non-reactive. Subsequently, the patient came to diaphoretic. In January 2007, the patient recovered. No further information is available.

**Other Meds:**

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274291-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	OK	WAES0702USA03416	21-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstrual disorder

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a first dose of Gardasil. Subsequently, the patient experienced her first menstrual cycle which was extremely heavy. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1140

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274292-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	CA	WAES0702USA03417	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information had been received from a physician concerning a female (age unknown) who on an unspecified date was vaccinated with a 0.5 ml dose of Gardasil. Subsequently, on an unspecified date, the patient passed out. The patient sought unspecified medical attention. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274293-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	10-Feb-2007	10-Feb-2007	0	16-Mar-2007	21-Mar-2007	MI	WAES0702USA03422	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Diarrhoea, Dizziness, Headache, Muscle spasms, Nausea, Pyrexia, Tachycardia, Vomiting

**Symptom Text:** Information has been received from a consumer's mother and physician concerning a 16 year old female with a MOTRIN allergy, and no medical history who on 10-FEB-2007 was vaccinated IM with a first 0.5 ml dose of Gardasil. There was no concomitant medication. On 10-FEB-2007 (consumer's mother reports as 12-FEB-2007), the patient experienced "heart racing, nausea, dizziness, temp of 99.7 (consumer's mother reported as 101 deg F), cramps, vomiting, bad headache and diarrhea." The patient's mother reported that the patient "had been out of school all week and was not feeling well." She also stated that "there was a follow up visit with the physician who associated the experience with the vaccine and she was given a medicine for the nausea and cramps." At the time of this report, the patient had not recovered according to the consumer's mother. The physician reported that on 17-FEB-2007 the patient recovered from diarrhea, nausea, vomiting, cramping and low grade fever. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** body temp 02/10/07 99.7 degF - fever

**History:**

**Prex Illness:** Drug Hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1142

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274294-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	12-Feb-2007	12-Feb-2007	0	16-Mar-2007	21-Mar-2007	CA	WAES0702USA03444	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning a 12 year female who on approximately 12-FEB-2007 was vaccinated intramuscularly with a dose of Gardasil. On approximately 12-FEB-2006 the patient fainted after the administration of Gardasil. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1143

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274295-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	20-Oct-2006	22-Oct-2006	2	16-Mar-2007	21-Mar-2007	CO	WAES0702USA03446	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Information has been received from a physician concerning a 23 year old female with sulfonamide allergy and no pertinent medical history who on 20-OCT-2006 was vaccinated with Gardasil. Concomitant therapy included YASMIN. On 22-OCT-2006, 48 hours after receiving the immunization, the patient developed itching without a visible rash. The patient sought unspecified medical attention. No laboratory tests were performed. The itching persisted for 3 weeks. At the time of reporting, the patient had recovered from the itching on approximately 10-NOV-2006. No other information was available at the time of reporting. Additional information has been requested.

**Other Meds:** YASMIN

**Lab Data:** NONE

**History:**

**Prex Illness:** Sulfonamide allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1144

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274296-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	09-Feb-2007	09-Feb-2007	0	16-Mar-2007	21-Mar-2007	--	WAES0702USA03462	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1447F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pain, Injection site swelling

**Symptom Text:** Information has been received from a nurse practitioner concerning a 15 year old female with no pertinent medical history and no history of drug reactions/allergies who on 09-FEB-2007 was vaccinated with first dose of Gardasil (lot # 655617/1447F) 0.5 ml injection. There was no concomitant medication. On 09-FEB-2007, the patient experienced swelling, tenderness, and redness in the injection site after receiving her first Gardasil dose. The patient sought medical attention. The next morning, the clinic administered 50 mg of BENADRYL and "it went back to normal". The nurse practitioner did not mention if it was because of the diphenhydramine. Subsequently, the patient recovered. They plan to give the second shot. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274297-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03468	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a female patient between the ages of 11 to 13 who within the last 3 months was vaccinated IM with a 0.5 mL dose of Gardasil. Subsequently the patient experienced dizziness to the point of losing consciousness. The event lasted for a matter of seconds. The patient was well enough to leave in a few minutes. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274298-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	02-Feb-2007	06-Feb-2007	4	16-Mar-2007	21-Mar-2007	CA	WAES0702USA03493	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Skin papilloma

**Symptom Text:** Information has been received from a nurse via a company representative concerning a 26 year old female with a history of warts from childhood who on 02-FEB-2007 was vaccinated with a first 0.5 mL dose of Gardasil. Concomitant therapy included hormonal contraceptives (unspecified). It was reported by the nurse that the patient informed the clinic that she had a breakout of warts in her forearm 4 days after vaccination, on 06-FEB-2007. At the time of the report, it was unknown if the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** NONE

**History:** Wart

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1147

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274299-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03496	05-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with Gardasil (yeast). Subsequently the patient experience rash on back. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1148

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274300-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	31-Jan-2007	31-Jan-2007	0	19-Mar-2007	21-Mar-2007	TX	WAES0702USA03500	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Condition aggravated, Schizophrenia

**Symptom Text:** Information has been received from a physician concerning a 16 year old female with schizophrenia. On 31-JAN-2007, the patient was vaccinated with the first dose of Gardasil. Concomitant therapy included LEXAPRO and ABILIFY. On 31-JAN-2007, the patient's schizophrenia symptoms became worse. The patient sought unspecified medical attention. At the time of this report, the patient had recovered from the event (date unknown). Additional information has been requested.

**Other Meds:** Abilify, Lexapro

**Lab Data:** UNK

**History:**

**Prex Illness:** Schizophrenia

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1149

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274301-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	19-Feb-2007	19-Feb-2007	0	16-Mar-2007	21-Mar-2007	MI	WAES0702USA03530	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0013U		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse concerning a 20 year old female who on 19-FEB-2007 was vaccinated IM with a dose of Gardasil (Lot # 654741/0013U). On 19-FEB-2007, the patient fainted after receiving the Gardasil injection. The patient was known by the provider to be squeamish with injections. After the fainting episode, the patient was observed for a brief period of the time and then was discharged from the physician's office. On 19-FEB-2007, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274302-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	18-Jan-2007	18-Jan-2007	0	16-Mar-2007	21-Mar-2007	WI	WAES0702USA03560	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Fatigue, Injection site pain, Musculoskeletal pain

**Symptom Text:** Information has been received from a registered nurse concerning a 12 year old female who on 18-JAN-2007 was vaccinated IM with a first dose of Gardasil. No other vaccinations were administered. On approximately 18-JAN--2007, the patient experienced soreness at injection site, fatigue, musculo-skeletal pain, and joint pain. The following laboratory tests were performed on the patient: complete blood cell (CBC) count; erythrocyte sedimentation rate (sed rate); rheumatoid factor (RF); antinuclear antibodies test (ANA); creatine kinase (CPK); "strep test"; influenza A and B; Lyme disease enzyme-linked immunosorbent assay. All lat test results were reported as normal. The patient was not prescribed any treatment. By 20-FEB-2007, the patient was fully recovered. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** diagnostic microbiology 01/18?/07 - normal strep test, Lyme disease assay 01/18?/07 - normal, serum creatine kinase 01/18?/07 - normal, serum influenza B virus 01/18?/07 - normal, serum rheumatoid factor 01/18?/07 - normal, serum influenza

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274303-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	12-Feb-2007	14-Feb-2007	2	16-Mar-2007	21-Mar-2007	--	WAES0702USA03567	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Formication, Limb discomfort, Pain in extremity, Sensory disturbance

**Symptom Text:** Information has been received from a 24 year old female consumer with a history of prednisone reaction unspecified, and a history of papilloma viral infection, knee surgery 6 weeks for unspecified condition who on 12-FEB-2007 was vaccinated with Gardasil (lot # not reported) injection. Concomitant therapy ORTHO TRI-CYCLEN LO. On 14-FEB-2007, the patient experienced legs (from mid thigh to mid calf) felt creepy-crawling, uncomfortable especially when laying down, they don't feel like my legs after receiving the injection. The patient also reported that her arm was very sore for about 3 days after receiving the injection but that went away. At the time of reporting the creepy-crawling feeling, and limb discomfort persisted. No further information was provided at the time of reporting. Additional information has been requested.

**Other Meds:** ORTHO TRI-CYCLEN LO

**Lab Data:** NONE

**History:** Papilloma viral infection; Knee operation; General symptom

**Prex Illness:** Adverse drug reaction

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274304-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	VA	WAES0702USA03585	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a female patient who on an unspecified date was vaccinated IM with Gardasil and experienced a "sore arm" after being vaccinated. Medical attention was sought. The patient was reported as recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274305-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03595	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a nurse via a company representative concerning a female (age not reported) with an allergy to bakers yeast and on a gluten free diet who, on an unspecified date, was vaccinated with a second dose of Gardasil and passed out (dates not reported). It was reported that the patient received the first dose with "no problem". At the time of the report, recovery status of the patient was unspecified. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Gluten free diet; Hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274306-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03602	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nasopharyngitis

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who was vaccinated with a Gardasil. Subsequently the patient developed a cold after the second and third dose. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1155

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274307-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	MO	WAES0702USA03609	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Drug administered at inappropriate site, Nausea

**Symptom Text:** Information has been received from a nurse concerning a female patient who was vaccinated with a second dose of Gardasil. The patient was vaccinated in the "glut" per the patient's request. Subsequently the patient felt dizzy and nauseous. It was noted that the patient may have not eaten all day. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274308-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	PA	WAES0702USA03636	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a physician via a company representative, concerning a female patient who was vaccinated with either a first dose or second dose of Gardasil. Subsequently the patient experienced nausea after vaccination. The patient recovered within a day. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1157

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274309-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	PA	WAES0702USA03637	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a physician via a company representative, concerning a female patient who was vaccinated with either a first dose or second dose of Gardasil. Subsequently the patient experienced nausea after vaccination. The patient recovered within a day. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1158

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274310-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	PA	WAES0702USA03638	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from a physician via a company representative, concerning a female patient who was vaccinated with either a first or second dose of Gardasil. Subsequently the patient experienced nausea after vaccination. The patient recovered within a day. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1159

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274311-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03690	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site bruising, Injection site pain

**Symptom Text:** Information has been received from a health professional concerning a 25 year old female who was vaccinated with Gardasil. Subsequently the patient experienced injection site pain and the site was bruised. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1160

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274312-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03691	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a health professional concerning an 18 year old female who was vaccinated with Gardasil. Subsequently, the patient experienced injection site pain. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274313-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	01-Feb-2007	25-Jan-2007	-7	16-Mar-2007	21-Mar-2007	MO	WAES0702USA03693	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0013U	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Gonorrhoea

**Symptom Text:** Information has been received from a nurse practitioner through the pregnancy registry concerning a 19 year old female with asthma and genital warts and a history of migraines, miscarriage at 4 months of pregnancy and high blood pressure who on 01-FEB-2007 was vaccinated with the first dose of Gardasil (lot # 654741/0013U). Concomitant therapy included ADVAIR and trichloroacetic acid. On 25-JAN-2007 the patient was noted to be pregnant (last menstrual period was on 03-JAN-2007). On 03-FEB-2007 the patient was treated with 500 mg of CIPRO for gonorrhoea. At the time of this report, the outcome of the events was unknown. No further details were provided. Additional information has been requested.

**Other Meds:** albuterol, ADVAIR, trichloroacetic acid 80 %

**Lab Data:** UNK

**History:** Migraines; Miscarriage; Blood pressure high

**Prex Illness:** Pregnancy NOS (LMP = 1/3/2007), Asthma; Genital wart

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274314-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	FL	WAES0702USA03704	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Information has been received from a female consumer (age unknown) who, on an unspecified date, was vaccinated intramuscularly with a second dose of Gardasil. Subsequently, on an unknown date, the patient experienced nausea and dizziness after receiving the second dose of vaccine which was administered with a regular needle. Symptoms subsided after 15-20 minutes. The reporting physician stated that the patient was not affected by the first dose of vaccine which was administered with a safety syringe. The patient sought unspecified medical attention. Subsequently, the patient recovered from nausea and dizziness. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274315-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	19-Feb-2007	19-Feb-2007	0	16-Mar-2007	21-Mar-2007	NY	WAES0702USA03724	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Pyrexia, Syncope, Vomiting

**Symptom Text:** Information has been received from a physician, via a company representative, concerning a 15 year old female patient who on 19-FEB-2007 was vaccinated with the first dose of Gardasil. On 19-FEB-2007 ("last night"), the patient experienced nausea, began vomiting, fainted for couple of seconds, and developed a fever of 100.7 degrees 12 hours after getting Gardasil. Subsequently, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Body temp 02/19/07 100.7 deg.

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1164

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274316-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	01-Feb-2007	01-Feb-2007	0	16-Mar-2007	21-Mar-2007	MD	WAES0702USA03735	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician, via a company representative, concerning a 15 year old female patient who was vaccinated "during the last couple of weeks" (February 2007), with the first dose of Gardasil. Concomitant suspect therapy included other vaccines (therapy unspecified) that were administered at the visit. The physician reported that the patient "fainted after getting Gardasil and several other vaccines were administered at the same visit. Subsequently, the patient recovered. The patient sought unspecified medical attentions. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274317-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	MO	WAES0702USA03740	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Information has been received from a physician concerning a female with papilloma viral infection who was vaccinated intramuscularly with a first dose of Gardasil. The next day, the patient developed a high temperature of 103 degrees F. Unspecified medical attention was sought. Subsequently, the patient recovered. The physician plans to continue the series of Gardasil. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** Body temp 103 deg

**History:**

**Prex Illness:** Papilloma viral infection

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1166

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274318-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Jan-2007	Unknown		16-Mar-2007	21-Mar-2007	OH	WAES0702USA03751	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site induration, Injection site pain

**Symptom Text:** Information has been received from a pharmacist concerning a 12 year old female with no pertinent medical history who in approximately January 2007, was vaccinated with a first dose of Gardasil. There was no concomitant medication. Subsequently the patient developed a lump at the injection site. It was reported that the lump at the injection site "recently" became painful. Unspecified medical attention was sought. There were no laboratory or diagnostic tests performed. At the time of the report, the lump and pain at the injection site persisted. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1167

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274319-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	19-Feb-2007	20-Feb-2007	1	16-Mar-2007	21-Mar-2007	AR	WAES0702USA03754	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Influenza like illness, Malaise, Pain

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with no pertinent medical history and history of drug reactions/allergies unspecified who on 19-FEB-2007 was vaccinated with first dose of Gardasil (lot # not reported) 0.5 IM. There was no concomitant medication. On 20-FEB-2007, the patient developed flu-like symptoms. The patient sought medical attention. The patient reported to the physician that she was experiencing a headache, not feeling well, and all over body pain (but not pain at the injection site). At the time of reporting, the outcome was unspecified. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1168

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274320-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	05-Jan-2007	05-Jan-2007	0	16-Mar-2007	21-Mar-2007	--	WAES0702USA03765	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal discomfort, Drug exposure during pregnancy, Pregnancy test positive

**Symptom Text:** Information has been received from a registered nurse, for the Pregnancy registry for Gardasil, concerning a 19 year old female with no known drug allergies and no pertinent medical history who on 03-NOV-2006 was vaccinated with first dose of Gardasil (lot # not reported) 0.5 ml in the left deltoid. There was no concomitant medication. On 05-JAN-2007, the patient was vaccinated with second dose of Gardasil (lot # not reported). The patient sought medical attention. Her last menstrual period was on 05-DEC-2006. On 29-JAN-2007, the patient's primary physician performed a quantitative beta blood test at the physician's office which was positive for pregnancy. Estimate date of delivery is 11-SEP-2007. On 08-FEB-2007, the patient experienced abdominal discomfort and was sent to the hospital for an ultrasound which was positive for pregnancy. The patient was not hospitalized. At the time of reporting, the patient no longer had abdominal discomfort. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** Ultrasound 02/08/2007 positive for Pregnancy, serum beta-human 01/29/07 positive for pregnancy

**History:** Serum Beta Human 01/29/07 positive for pregnancy.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274321-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	OH	WAES0702USA03771	21-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site rash

**Symptom Text:** Information has been received from a physician concerning a female who on an unspecified date, was vaccinated intramuscularly with a first dose of Gardasil. Subsequently the patient experienced a rash and redness around at the injection site. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274322-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	16-Feb-2007	17-Feb-2007	1	16-Mar-2007	21-Mar-2007	--	WAES0702USA03784	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dysmenorrhoea, Fatigue, Somnolence

**Symptom Text:** Information has been received from a 21 year old female consumer with pertinent medical history reported as unspecified who on 16-FEB-2007 was vaccinated with the second dose of Gardasil. Concomitant therapy included Yasmin and Amitiza. On 17-FEB-2007, the patient experienced dizziness, menstrual cramping and she felt extremely tired and heavily medicated since she was administered Gardasil on 16-FEB-2007. The patient sought unspecified medical attention. The patient advised that her symptoms were becoming worse and have not improved. Additional information has been requested.

**Other Meds:** Yasmin, Amitiza

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274323-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	--	WAES0702USA03792	22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a nurse concerning a female (age not reported) who on an unspecified date was vaccinated with the first dose of Gardasil, 0.5ml, IM. The nurse reported that the patient received four other vaccinations that same day but the names of the vaccines were unknown and the Gardasil was given first. Subsequently on an unspecified date, the patient experienced dizziness shortly after administration of the Gardasil. The patient became dizzy, she was laid down, given a drink of juice and was able to get up and leave a few minutes later. Subsequently, the patient recovered from dizziness. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274324-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	21-Mar-2007	TX	WAES0702USA03799	21-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus generalised, Urticaria

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with her first dose of Gardasil and one day later developed hives and itchiness through out her body. Unspecified medical attention was sought. Her outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1173

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274325-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	09-Feb-2007	09-Feb-2007	0	16-Mar-2007	21-Mar-2007	CA	WAES0702USA03827	22-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1208F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Muscle rigidity, Pallor

**Symptom Text:** Information has been received from an RN concerning a 21 year old white female student who on 09 Feb 2007 at 11:00 a.m. was vaccinated with her first dose of Gardasil. After giving the injection, the nurse reported that the patient "passed out less then 2 seconds. Patient got extremely almost like a seizure less than 1 second." The patient never lost breathing and came back pale. She was left lying down for 20 minutes, and was discharged well. It was reported that no medical attention was required. No further information is available.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274326-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	12-Jan-2007	12-Jan-2007	0	16-Mar-2007	21-Mar-2007	CA	WAES0702USA03834	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hyperhidrosis, Nausea

**Symptom Text:** Information has been received from a health professional concerning a 19 year old white female waitress who on 12 Jan 2007 was vaccinated IM in left deltoid with her second dose of Gardasil and got dizzy, was sweating and nauseated. Her outcome was unknown. There were no concomitant medications; and no adverse events following prior vaccination. No further information is available.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1175

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274327-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	Unknown	26-Oct-2006		16-Mar-2007	21-Mar-2007	CA	WAES0702USA03840	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site, Flushing, Nausea, Vomiting

**Symptom Text:** Information has been received from a health professional concerning a 25 year old Hispanic female engineer with no known drug allergies who, on an unspecified date, was vaccinated in the left gluteal muscle with a first dose of Gardasil. There was no concomitant medication. On 26 Oct 2006 the patient became flush, experienced vomiting and nausea. There was no illness at the time of vaccination. It was reported that the patient recovered the same day, 26 Oct 2006. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274328-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	04-Dec-2006	04-Dec-2006	0	16-Mar-2007	20-Mar-2007	CA	WAES0702USA03841	23-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling hot, Hyperhidrosis, Nausea, Pain

**Symptom Text:** Information has been received from a health professional concerning a 17 year old female who on 04-DEC-2006 in the PM was vaccinated with a second dose of Gardasil (lot # 653735/0688F), in the left deltoid. There was no concomitant therapy. On 04-DEC-2006 the patient experienced "pain, hot, sweating, dizzy, nauseated." On 14-SEP-2006 the patient was vaccinated with a first dose of Gardasil (yeast). Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274329-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	06-Dec-2006	01-Jan-2007	26	16-Mar-2007	21-Mar-2007	CA	WAES0702USA03842	22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Flushing, Hyperhidrosis, Injection site pain, Nausea, Syncope

**Symptom Text:** Information has been received from a health professional concerning a 22 year old female with allergy to CECLOR who on 06-DEC-2006 was vaccinated with a second dose of Gardasil (lot #655619/1427F), in the left deltoid. There was no concomitant medication. on 01-JAN-2007 the patient experienced "faint, sweaty, flushed, nauseated and pain (site). Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** UNK

**History:**

**Prex Illness:** Allergic reaction to antibiotics.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1178

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274336-1 (S) **Related reports:** 274336-2; 274336-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	28-Feb-2007	01-Mar-2007	1	19-Mar-2007	20-Mar-2007	LA		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2136AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Chest pain, Cough, Extensor plantar response, Gait disturbance, Guillain-Barre syndrome, Headache, Hypoaesthesia, Hypokinesia, Hyporeflexia, Malaise, Pyrexia, Tremor, Vomiting

**Symptom Text:** The next day after receiving Gardasil and Menactra vaccines pt began to have fever and vomiting as well as headache. On the second day after vaccination she began to experience right hand tremor and left foot numbness. 03/20/07-records received from facility for DOS 3/6-3/9/07. DC DX: Mild Guillain Barre Syndrome status post intravenous immune globulin. Developed subjective fever and feeling ill as well as vomiting. Started having numbness of left foot shaking of right hand and headache. C/O initial chest pain with cough. Suspected Guillain Barre and treatment included immune globulin. Neuro consult plan included IVIG. PE:WNL except for not able to dorsiflex or plantar flex at all as well as limitation although some movement of toes with active motion. Did not elicit ankle jerk at the left. Toes were downgoing on Babinski. Gait slightly unsteady

**Other Meds:** Icar, Advair

**Lab Data:** CBC-wnl, Chest x-ray-wnl, glucose-wnl, urine-wnl, spinal fluid- wnl, MS eval-wnl records received 3/20/07-CSF did not show elevated protein level. CXR:normal EKG normal.

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1179

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274336-2      **Related reports:** 274336-1; 274336-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	28-Feb-2007	05-Mar-2007	5	27-Mar-2007	28-Mar-2007	LA	200700967	06-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0960F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Guillain-Barre syndrome

**Symptom Text:** Initial report received on 28 March 2007 from an other manufacturer, reference number WAES 0703USA03222. The initial reporter to the other manufacturer was a health care professional. This is a verbatim copy of the report from the other manufacturer. "Information has been received from a Nurse Practitioner concerning a 15 year old female patient with asthma who on 28-FEB-2007 was vaccinated with a dose of Gardasil, lot # 654535/0960F. Concomitant suspect therapy included MENACTRA, administered on the same day. Other concomitant therapy included ADVAIR. ON 05-Mar-2007 the patient was diagnosed with Guillain-Barre syndrome. Her outcome was not reported. The reporter felt that Guillain-Barre syndrome was a result of MENACTRA, and not Gardasil. Upon internal review, Guillain-Barre syndrome was considered to be an other important medical event. Additional information has been requested." The information received included a VAERS ID #. This case is being evaluated by CISA (Clinical immunization Safety Assessment network) and has not yet been confirmed.

**Other Meds:** ADVAIR

**Lab Data:**

**History:** Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1180

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274336-3      **Related reports:** 274336-1; 274336-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	28-Feb-2007	05-Mar-2007	5	27-Mar-2007	28-Mar-2007	LA	WAES0703USA03222	05-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0960F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Guillain-Barre syndrome

**Symptom Text:** Information has been received from a Nurse Practitioner concerning a 15 year old female patient with asthma who on 28-FEB-2007 was vaccinated with a dose of Gardasil, lot #654535/0960F. Concomitant suspect therapy included Menactra, administered on the same day. Other concomitant therapy included Advair. On 05-MAR-2007 the patient was diagnosed with Guillain-Barre syndrome. Her outcome was not reported. The reporter felt that Guillain Barre syndrome was a result of Menactra, and not Gardasil. Upon internal review, Guillain-Barre syndrome was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Advair

**Lab Data:** UNK

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274341-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	15-Mar-2007	16-Mar-2007	1	19-Mar-2007	20-Mar-2007	MO		20-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0244U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Patient experienced nausea and vomiting hours after receiving vaccine. Patient also went out to eat after vaccine so it is difficult to determine cause of nausea and vomiting.

**Other Meds:** Nuvaring

**Lab Data:**

**History:** NKDA. Scoliosis

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274343-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Feb-2007	01-Mar-2007	1	20-Mar-2007	21-Mar-2007	MA		22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	1	Right arm	Unknown	HPV4

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Three week pain in right deltoid after vaccine with Gardasil.

**Other Meds:** NONE

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274356-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	23-Jan-2007	23-Jan-2007	0	19-Mar-2007	20-Mar-2007	CA		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	
	FLU	AVENTIS PASTEUR	U2176FA	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Broke out in hives within 24 hours of receiving HPV and Flu vaccine.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274360-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		20-Mar-2007	21-Mar-2007	FL	WAES0703USA01318	21-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Initial and follow up information has been received from a Licensed Practical nurse and a physician concerning a female patient who was vaccinated with a first dose of Gardasil. She developed hives within 2-3 hours of receiving the injection. Unspecified medical attention was sought. The patient was not recovered. The nurse considered hives to be disabling she was not available for follow up, and when the physician was contacted, he could not provide any information regarding why the nurse considered the event disabling. He had not been able to contact the patient. He had no further information regarding her outcome. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1185

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274361-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		20-Mar-2007	21-Mar-2007	NY	WAES0703USA01477	06-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Vaccine positive rechallenge

**Symptom Text:** Information has been received from a physician concerning an adolescent female (demographics not provided) who on an unspecified date was vaccinated with the first dose of Gardasil (lot # not provided). Concomitant therapy included an unspecified anti malaria medication. Subsequently, on an unspecified date "a few days later" the patient had a seizure. It was reported by the physician that at the time "the patient has a series of tests (NOS) but no diagnosis was found. On another unspecified date the patient received the second dose of Gardasil (lot # not provided) and sixteen days post vaccination, on an unspecified date the patient had seizure. The patient sought unspecified medical attention. The physician reported that it was not known if additional test were completed. The physician reported that the patient had recovered from the seizures. Upon internal medical review, the seizures were felt to be other medical events. Additional information has been requested.

**Other Meds:** Therapy unspecified

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274362-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Mar-2007	01-Mar-2007	0	20-Mar-2007	21-Mar-2007	FR	WAES0703USA02432	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Loss of consciousness, Meningism, Muscle spasms, Syncope

**Symptom Text:** Information has been received from a gynecologist concerning a 17 year old female with a history of emotional lability and probably "stress-related" amenorrhoea who on 01-MAR-2007 was vaccinated with the first dose of Gardasil, IM into the left arm. Concomitant medication was not reported. On 01-MAR-2007, about 2 minutes post vaccination, the patient experienced a convulsion syncope with meningism, muscular spasm and unconsciousness. Subsequently after about 3 minutes, the patient recovered from convulsion syncope. The patient was admitted to the hospital. Other business partner numbers included E2007-01514. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Amenorrhoea; Affect lability

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274374-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	Unknown	Unknown		20-Mar-2007	21-Mar-2007	CT		22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Pt received vaccine/Gardasil 1/15/07. One week later, developed hives which lasted one week. Pt treated with Benadryl for symptoms relief.

**Other Meds:** Ortho Tricyclen

**Lab Data:**

**History:** Neurofibromytosis

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1188

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274378-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	09-Feb-2007	16-Feb-2007	7	20-Mar-2007	22-Mar-2007	SC		12-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	1	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Adverse drug reaction, Dyskinesia, Dystonia, Gaze palsy

**Symptom Text:** Dystonic reaction treated with IV Benadryl then PO Valium in ER. Second ER visit 2/18/07 treated with Cogentin. Symptoms resolved after 12 days. 03/21/07-records received from ER facility for services provided on 3/18 and 3/21/07-DX:Dystonic reaction. HX: involuntary spasms, seen in ER day prior. DX at that time dystonic reaction. treated with benadryl and valium. Had 5 doses of valium, now spasms with eyes rolling. Current medications Lexapro. Allergy: Phenergan (dystonic and psychotic reaction). Neuro exam normal. Spasms observed, eye rolling. DC with cogentin. 2/21/07 seen in ER DX: dystonic medication versus vaccine reaction. Neuro exam normal. No spasm observed. Schedule MRI. 04/11/07-records received from ER for DOS 2/16/07-placed on Lexapro 2 weeks prior to ER visit. C/O erratic jerking moments. Upper body and shoulders. Voluntary control of arms and shoulders, legs and neck intact. HX depression. Additional findings: Facial and left arm muscles contracting spontaneously. DX: Dystonic drug reaction. Discontinue Lexapro.

**Other Meds:** Lexapro

**Lab Data:** MRI 3/2/07 WNL records received 4/11/07-Labs WNL

**History:** Depression

**Prex Illness:** Depression

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1189

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274397-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	07-Mar-2007	13-Mar-2007	6	20-Mar-2007	22-Mar-2007	IL		03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0243U	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Agitation, Anxiety, Chest discomfort, Dizziness, Heart rate increased, Injection site rash, Tremor, Unevaluable event

**Symptom Text:** None Stated 04/02/07-records received from facility. Developed rash around injection site, pulse 100, felt shaky, tightness in chest and heart felt like it was racing. Feels anxious, agitated, lightheaded. PE:WNL. DX: Anxiety disorder.

**Other Meds:**

**Lab Data:** CBC, CRP normal

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274401-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	03-Oct-2006	03-Oct-2006	0	20-Mar-2007	23-Mar-2007	VA		23-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Syncopal episode after dose #2 of Gardasil vaccine.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274437-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
9.0	F	21-Mar-2007	21-Mar-2007	0	21-Mar-2007	22-Mar-2007	NV		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea, Pallor, Vomiting

**Symptom Text:** Approximately 5 minutes after administration my child complained of nausea and dizziness, she appeared pale. About 10 min later she vomitted. About 15 min after administration she felt ok.

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:** none~~NULL~~In Patient|none~~NULL~~In Sibling1|none~~NULL~~In Sibling2

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274457-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
10.0	F	12-Mar-2007	13-Mar-2007	1	21-Mar-2007	22-Mar-2007	LA		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1312F	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0960F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral, Skin warm

**Symptom Text:** Arm red, warm, swollen 8cmx8cm.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274461-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	09-Nov-2006	11-Nov-2006	2	21-Mar-2007	22-Mar-2007	CA		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2557AA	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1932AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash papular, Rash pruritic

**Symptom Text:** Itchy rash on both deltoids started 2 days after immunizations received. Rash is fine and papular.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274463-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	26-Jan-2007	10-Mar-2007	43	21-Mar-2007	22-Mar-2007	CO		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Ear pain, Facial palsy, Influenza, Lacrimation increased, Otitis media acute, Swelling face

**Symptom Text:** Patient received first dose of HPV on 1/26/07, then around 2/24/07 experienced flu symptoms which resolved. Then 3/10/07 experienced right sided facial swelling, right eye tearing, right ear pain. Seen by MD 3/12/07 and diagnosed with Acute Otitis Media and Bell's Palsy. MRI scheduled but not completed yet. Question related Bell's Palsy to vaccination?

**Other Meds:** Levlén OCP

**Lab Data:**

**History:** Condyloma acuminatum

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274468-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	14-Mar-2007	15-Mar-2007	1	21-Mar-2007	22-Mar-2007	IL		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0243V	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on arm (not at injection site) on hands and feet-resolving.

**Other Meds:** Advair PRN

**Lab Data:**

**History:** Asthma, Seasonal allergies (dogs and horses per mom)

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274470-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	13-Mar-2007	13-Mar-2007	0	21-Mar-2007	22-Mar-2007	NY		22-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2456AA	5	Right arm	Unknown	
	MNQ	AVENTIS PASTEUR	U1967AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0186U	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Neck pain, Pain in extremity

**Symptom Text:** Severe arm and neck pain, chest tightness, 2 hour post vaccine. No prior history of asthma, abdominal pain. Seen in the ER and discharged with Albuterol.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1197

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274472-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	09-Mar-2007	10-Mar-2007	1	21-Mar-2007	22-Mar-2007	NY		22-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Pharyngolaryngeal pain, Pyrexia

**Symptom Text:** Headache, nausea, fever and continued headache. High fever (temp 105F). Onset of fever 12 hours later same day complained of sore throat.

**Other Meds:** NONE

**Lab Data:** White blood cells 13.8 after 86 sc, Negative rapid strep.

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274560-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		22-Mar-2007	23-Mar-2007	CA		23-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1920AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Disturbance in attention, Dizziness, Headache

**Symptom Text:** Pt reported that approximately 24hrs after receiving the vaccinations she had a headache, dizziness. Went home, took shower, slept through the night. The next day she didn't remember much of the previous day. Feels she continues to have trouble absorbing subjects at school. Feels she is gradually getting better.

**Other Meds:** No

**Lab Data:**

**History:** None

**Prex Illness:** On menses. No known illness

**Prex Vax Illns:** No~~NULL~~In Patient|No~~NULL~~In Sibling1|No~~NULL~~In Sibling2

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274570-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	16-Mar-2007	17-Mar-2007	1	22-Mar-2007	23-Mar-2007	NH		23-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Headache, Nausea

**Symptom Text:** Diarrhea, Nausea, headache

**Other Meds:** Vitamin OTC supplements

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1200

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274572-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	02-Feb-2007	02-Feb-2007	0	16-Mar-2007	23-Mar-2007	MD	WAES0702USA03856	26-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0012U	1	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Inappropriate schedule of drug administration, Injection site pain

**Symptom Text:** Information has been received from a registered nurse concerning a 14 year old female with no medical history and no allergies who on 02-FEB-2007 was vaccinated with a second dose of HPV (lot # 655503/00120), intramuscularly. There was no concomitant medication. On 02-FEB-2007 the patient experienced intermittent headache and soreness at the injection site of the left arm. The patient was examined by the physician on 20-FEB-2007 and was recommended Tylenol. It was noted that the first dose of HPV was received on 27-OCT-2006. At the time of the report, the patient was considered to be not recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274573-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	11-Jan-2007	11-Jan-2007	0	16-Mar-2007	23-Mar-2007	MI	WAES0702USA03905	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vaginal haemorrhage

**Symptom Text:** Information has been received from a nurse, via a company representative, concerning a 13 year old female patient who on 11-JAN-2007 was vaccinated with the first dose, 0.5ml, IM of HPV. The nurse reported that the patient had developed vaginal bleeding that had "varied from light to heavy and has been continuous since the date of administration." The nurse reported that the patient had been referred to an OBGYN for further evaluation. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274574-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	21-Dec-2006	21-Dec-2006	0	16-Mar-2007	23-Mar-2007	TX	WAES0702USA03916	23-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site, Pain in extremity

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 19 year old female with a history of abnormal papanicolaou smear who on 21-DEC-2006 was vaccinated IM in left deltoid with her first dose of HPV, lot # 653736/0689F. Concomitant therapy included Yasmin and Prozac. She experienced severe pain in the arm with the first dose. This reaction was reported at the time of her second vaccination. On 21-FEB-2006 her second dose of HPV, lot # 655617/1447 was administered via gluteus. No symptoms were reported at that time. The patient was reported as recovered on an unspecified date. Additional information has been requested.

**Other Meds:** Yasmin, Prozac

**Lab Data:** UNK

**History:** Papanicolaou smear abnormal

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274575-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	--	WAES0702USA03948	10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site swelling, Paraesthesia

**Symptom Text:** Information has been received from a nurse concerning a 22 year old female with a history of "problems and reactions" to previous vaccinations who was vaccinated with a first dose of HPV. Subsequently, the patient developed swelling around the injection site. The patient was placed on unspecified therapy, and subsequently, recovered. On an unspecified date, the patient was vaccinated with a second dose of HPV. It was reported that the patient experienced a "tingly" sensation in her arm. The patient was treated with unspecified therapy, and subsequently, recovered from the "tingly" sensation. It was reported that the patient had a medical history of similar symptoms after previous vaccinations. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** NONE

**History:** vaccination adverse event

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274576-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	--	WAES0702USA03949	23-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a nurse concerning an 18 year old female who, on an unspecified date, was vaccinated intramuscularly with a first dose of HPV. Subsequently, on an unspecified date, the patient developed a rash. The patient did not seek medical attention. Subsequently, on an unspecified date, the patient recovered. No product quality complaint was involved. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274577-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	CA	WAES0702USA03997	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Sensory disturbance

**Symptom Text:** Information has been received from a nursing supervisor concerning a female (age not reported) who on an unspecified date was vaccinated with HPV. Subsequently, the patient reported that her "arm felt dead". At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274578-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	CA	WAES0702USA03998	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Sensory disturbance

**Symptom Text:** Information has been received from a nursing supervisor concerning a female (age not reported) who on an unspecified date was vaccinated with HPV. Subsequently, the patient reported that her "arm felt dead". At the time of this report, the outcome of the event was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274579-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	--	WAES0702USA04000	23-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Presyncope

**Symptom Text:** Information has been received from a certified medical assistant (C.M.A) concerning a female patient who was vaccinated with a 0.5 mL dose of HPV, (lot # not reported). Subsequently the patient experienced pain at the injection site lasting for about a week. It was reported that the patient almost passed out from the pain. The C.M.A also reported that approximately 19 other patients experienced pain at the injection site lasting for about a week. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274580-1      **Related reports:** 274580-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	06-Nov-2006	Unknown		16-Mar-2007	23-Mar-2007	TX	WAES0702USA04012	23-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation irregular

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female who on 06-NOV-2006 and on 09-JAN-2007 was vaccinated with a first and second dose of HPV. Subsequently the patient experienced irregular menstrual bleeding. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1209

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274580-2      **Related reports:** 274580-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	06-Nov-2006	06-Nov-2006	0	07-May-2007	08-May-2007	TX	200701447	08-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0954F	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menorrhagia, Menorrhagia, Menstruation irregular

**Symptom Text:** Initial report received on 26 April 2007 from another manufacturer, report number WAES0702USA04012. The initial reporters to this manufacturer was a physician and a registered nurse. Verbatim from report: "Initial and follow-up information has been received from a physician and a registered nurse concerning a 13 year old Hispanic female student with allergic rhinitis, otitis media, asthma and history of cleft palate repair who on the morning of 06-NOV-2006 was vaccinated in the left arm with a dose of Gardasil (yeast) lot #653938/0954F. Concomitant therapy included MENACTRA, hepatitis A Virus vaccine and varicella virus vaccine live. After the patient's first dose of Gardasil (yeast) her menstrual cycle started and lasted about 2-3 weeks. On 09-JAN-2007, she was vaccinated in the right arm with the second dose of GARDASIL (yeast). In late February 2007, the patient's menstrual cycle lasted weeks and she experienced heavy bleeding. In follow-up information received on 22-FEB-2007 the physician reported that patient's mother alleges that since her daughter started GARDASIL (yeast) her periods became irregular and long. Her period in January was 15 days. The mother requested a gynecology consult. The reporter felt that irregular and long menstrual bleeding was an other important medical event. Additional information is not expected."

**Other Meds:**

**Lab Data:**

**History:** The patient had past medical history of cleft palate with repair, and concurrent conditions of asthma, rhinitis allergic, and otitis media.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274581-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	20-Feb-2007	21-Feb-2007	1	16-Mar-2007	23-Mar-2007	MD	WAES0702USA04016	23-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Nausea

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on 20-FEB-2007 was vaccinated with a 0.5 mL first dose of HPV. The patient was concomitantly vaccinated with a dose of Boostrix. On 21-FEB-2007 the patient experienced nausea and a headache. The patient sought unspecified medical attention. On 22-FEB-2007, the headache was clearing and the nausea was gone. Additional information has been requested.

**Other Meds:**

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1211

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274582-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	21-Feb-2007	21-Feb-2007	0	16-Mar-2007	23-Mar-2007	--	WAES0702USA04019	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fall, Head injury, Loss of consciousness

**Symptom Text:** Information has been received from a health care professional concerning a 25 year old female with no medical history and no allergies who on 21-FEB-2007 was vaccinated with HPV (lot # 653736/0014U), intramuscularly. There was no concomitant medication. Later that evening she passed out. She hit her head when she fell to the floor. It was reported to be unknown if treatment was required. She called the doctor this morning and was taking the day off from work. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274583-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	13-Feb-2007	13-Feb-2007	0	16-Mar-2007	23-Mar-2007	NC	WAES0702USA04025	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Urticaria

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female with no past medical history and no allergies who on 13-FEB-2007 was vaccinated with HPV (0.5 ml) (lot # 653736/0014U), intramuscularly. Concomitant medication included Loestrin. On 13-FEB-2007, "about half hour to hour after vaccination" the patient experienced "shortness of breath" per the patient. About two hours afterwards, the patient was "fine." The nurse mentioned that the patient was anxious about needles and attributed the symptoms to anxiety. On 19-FEB-2007 the patient developed hives on her elbows and knees. On 22-FEB-2007 the hives had spread "systemically" to her face, ribs, arms and legs. The patient was ordered on Benadryl by her other physician. The symptoms had not resolved. No further information was available. Additional information has been requested.

**Other Meds:** Loestrin

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274584-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	IN	WAES0702USA04028	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urinary tract infection

**Symptom Text:** Information has been received from a health professional concerning an 18 year old female who on an unspecified date was vaccinated with a first dose of HPV. The patient was due to her second dose of HPV, and she developed a urinary tract infection. The patient sought unspecified medical attention. At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1214

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274585-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	20-Feb-2007	20-Feb-2007	0	16-Mar-2007	23-Mar-2007	AZ	WAES0702USA04041	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pruritus, Injection site swelling, Urticaria

**Symptom Text:** Information has been received from a physician assistant concerning a 22 year old female with penicillin allergy who on 20-FEB-2007 was vaccinated with a first dose of HPV. On 20-FEB-2007 she developed itching, erythema and swelling at the injection site. On 21-FEB-2007 she developed hives on her abdomen, thighs and chest upon awakening. When she was seen by the physician assistant on 21-FEB-2007 the swelling and redness at the injection site was gone and the patient commented that the hives were less than before. Her prescriber put her on Zyrtec (10 mg) daily for the hives. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274586-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	20-Feb-2007	20-Feb-2007	0	16-Mar-2007	23-Mar-2007	NY	WAES0702USA04052	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Lymph node pain, Lymphadenopathy, Nausea

**Symptom Text:** Information has been received from a physician concerning a 25 year old female secretary with on medical history or allergies, who on 20-FEB-2007 was vaccinated IM into the left arm with a 0.5 ml dose of HPV. Concomitant therapy included Depo-Provera. On approximately 20-FEB-2007, the patient experienced soreness at injection site. On 21-FEB-2007 for that day only the patient experienced nausea. On the morning of 22-FEB-2007 the patient noticed what looks similar to lymph nodes that are enlarged, tender, and swollen by the wrist of the arm in which the vaccine was administered. Unspecified medical attention was sought. No diagnostic laboratory studies were performed. At the time of this report the patient recovered from all events but had not recovered from soreness at the injection site. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Depo-Provera

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274587-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	12-Feb-2007	12-Feb-2007	0	16-Mar-2007	23-Mar-2007	--	WAES0702USA04055	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 16 year old female with penicillin allergy who on 12-FEB-2007 was vaccinated with a dose of HPV (lot #653736/0014U). There was no concomitant medication. On 12-FEB-2007 the patient developed large hives on her arms, trunk and face. Medical attention was sought and the patient was treated with Benadryl 100 mg. There were no laboratory or diagnostic tests performed. On 13-FEB-2007, the patient recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Penicillin allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274588-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	--	WAES0702USA04067	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician's office concerning a 16 year old female who was vaccinated with a dose of HPV. Subsequently, the patient fainted. The patient did not seek medical attention. The patient's outcome was unknown. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274589-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	22-Feb-2007	22-Feb-2007	0	16-Mar-2007	23-Mar-2007	CO	WAES0702USA04070	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** information has been received from a consumer concerning her 19 year old daughter who on 22-FEB-2007 was vaccinated with her second dose of HPV. Concomitant therapy included unspecified birth control. On 22-FEB-2007 the patient experienced "a lot of pain and was in tears" after receiving HPV. Unspecified medical attention was required. It was also reported that the patient experienced "a little pain" after the first dose of HPV was administered. At the time of the report, the patient's pain persisted. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274590-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	MI	WAES0702USA04082	26-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician concerning her daughter who was vaccinated with a dose of HPV during her Christmas holiday break from college. After the vaccination, the patient walked to the reception desk and fainted. The patient awoke by herself. Unspecified medical attention was sought. It was reported that the patient was embarrassed, then walked out to the car with her parents. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274591-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	23-Mar-2007	CA	WAES0702USA04084	26-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a nurse concerning a female patient (age unknown) who, on an unspecified date, was vaccinated with a dose of HPV. Subsequently, on an unspecified date, the patient passed out after receiving the vaccine. The nurse reported that the patient had not eaten. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274592-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	17-Nov-2006	19-Nov-2006	2	16-Mar-2007	26-Mar-2007	--	WAES0702USA04100	26-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea

**Symptom Text:** Information has been received from a registered nurse concerning a female with asthma who on 17-NOV-2006 was vaccinated with the first dose of Gardasil. On 19-NOV-2006, the patient experienced shortness of breath and chest pain. The patient recieved unspecified treatment at the clinic where she was employed. It was reported that the patient attended work the following day, although, had recurrence of shortness of breath. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1222

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274593-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	28-Mar-2007	--	WAES0702USA04115	06-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Pain in extremity, Paraesthesia, Skin burning sensation, Vaccine positive rechallenge

**Symptom Text:** Information has been received from a female nurse practitioner consumer through the pregnancy registry who on unspecified dates was vaccinated with the first and second doses of Gardasil (0.5 ml). Subsequently the patient reported that she had recently become pregnant. The patient also reported that she experiences burning, pain, and nerve tingling in her arm "soon after" receiving the second dose of Gardasil. The patient reported that she had a similar experience to a lesser degree following the first vaccination with Gardasil. It was thought that the pregnancy occurred after the above events. Unspecified medical attention was sought. The patient subsequently recovered from the burning, pain, and nerve tingling in her arm "a short time after each injection." Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1223

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274594-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	16-Feb-2007	16-Feb-2007	0	16-Mar-2007	26-Mar-2007	--	WAES0702USA04212	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Inappropriate schedule of drug administration, Lip swelling, Neck pain, Pharyngolaryngeal pain

**Symptom Text:** Information has been received from a consumer concerning her 12 year old daughter with a history of surgery for birth defects and allergic to erythromycin who on 15-JAN-2007 and 16-FEB-2007 was vaccinated with a first and second dose of Gardasil, respectively. There was no concomitant medication. On 22-FEB-2007 "last night", the consumer's daughter experienced headache, sore throat, neck pain and her lips were swollen. No medical attention was sought. No laboratory studies were performed. At the time of this report, the consumer's daughter had not recovered. It was also reported that she tolerated her first of the vaccine with any events. The consumer plans on having her daughter receive the third dose of the vaccine. No product quality complaint was involved. Additional information is not expected.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** Birth defects; Surgery

**Prex Illness:** Allergic reaction to antibiotics

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1224

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274595-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	20-Dec-2006	06-Jan-2007	17	16-Mar-2007	26-Mar-2007	PA	WAES0702USA04217	06-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1974AB		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0960F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Diarrhoea, Facial palsy, Facial palsy, Herpes zoster oticus, Herpes zoster oticus

**Symptom Text:** Information has been received from a registered nurse concerning a 11 year old female who was vaccinated with a dose of Gardasil. Concomitant therapy administered at the same time at a different anatomical site included a dose of MENACTRA. Illness at the time of vaccination included herpes simplex on the lip. On 09-JAN-2007, the patient was seen in the office and was diagnosed with herpes zoster otitis which progressed to a diagnosis of Bell's palsy and Ramsay-Hunt Syndrome on 15-JAN-2007. At time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested. 03/28/07-records received for DOS 1/16/07 DX: Bell's Palsy. Ramsay Hunt Syndrome. PH:1/9/07-Seen by PMD to treat shingles in right ear with acyclovir. TX stopped on 1/16/07 due to bells palsy. Right side facial droop difficulty eating. C/O headache throughout with shingles. 1/16/07-stomach cramps, diarrhea. Symptoms resolved 2/8/07.

**Other Meds:**

**Lab Data:**

**History:** UNK

**Prex Illness:** Herpes on lip

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274596-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	09-Feb-2007	22-Feb-2007	13	16-Mar-2007	28-Mar-2007	--	WAES0702USA04221	28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness, Pyrexia

**Symptom Text:** Information has been received from a consumer concerning her daughter, an 18 year old female patient who on 09-FEB-2007 was vaccinated with the first dose of Gardasil. The caller reported that on 10-FEB-2007, her daughter "had a TB test administered. "On 22-FEB-2007 the patient experienced fever and flu-like symptoms. The patient sought unspecified medical attention. Additional information is not expected.

**Other Meds:** MANTOUX SKIN TEST

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274597-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	20-Feb-2007	20-Feb-2007	0	16-Mar-2007	28-Mar-2007	NY	WAES0702USA04224	28-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Head injury, Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a 24 year old female patient who on 20-FEB-2007 was vaccinated with an 0.5 ml dose, IM, of HPV. there was no concomitant medication. On 20-FEB-2007 the nurse reported that the patient "fainted while walking to the waiting room," although the nurse further clarified that the patient "did not lose consciousness, but she hit her head." The patient recovered, and was released to her parents. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274598-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	29-Jan-2007	29-Jan-2007	0	16-Mar-2007	28-Mar-2007	NY	WAES0702USA04255	28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Concussion, Head injury, Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female with no pertinent medical history and no drug reactions or allergies who on 29-JAN-2007 was vaccinated intramuscularly with a 0.5 mL dose of HPV (Lot unspecified by reporter). There was no concomitant medication. On 29-JAN-2007 the patient fainted while walking to the waiting room. The patient hit her head on the floor and suffered a concussion. The patient was rushed to an emergency room in an ambulance. She was release later that day. At the time of the report, the patient had recovered. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274599-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	Unknown	Unknown		16-Mar-2007	28-Mar-2007	--	WAES0702USA04284	28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a Certified Medical assistant (C.M.A) concerning an 18 year old female patient who was vaccinated with her first dose of HPV. The patient called the office back within 24 hours reporting a large rash on her back. Concomitant therapy included albuterol. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** albuterol

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274600-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	28-Mar-2007	MO	WAES0702USA04285	28-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased

**Symptom Text:** Information has been received from a physician concerning a female with papilloma viral infection who was vaccinated intramuscularly with a first dose of HPV. The next day, the patient developed a high temperature if 103 degrees F. Unspecified medical attention was sought. Subsequently, the patient recovered. The physician plans to continue the series of HPV. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** body temp, 103 degr

**History:** Ppailoma viral infection

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1230

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274612-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Jan-2007	01-Jan-2007	0	23-Mar-2007	26-Mar-2007	--	WAES0703USA02141	26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Abdominal pain, Ovarian cyst, Ovarian cyst ruptured, Vomiting

**Symptom Text:** Information has been received from an office receptionist concerning a 12 year old female who in January 2007 was vaccinated with the first dose of Gardasil. Concomitant mediation was not reported. In January 2007, the developed an ovarian cyst that ruptured 10 days after receiving the first dose of Gardasil. Initially, the patient started vomiting for a few days and then there was significant abdominal pain. The patient was examined and diagnosed with ruptured ovarian cyst. The patient's ovarian cyst and ruptured ovarian cyst persisted and were considered to be disabling. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** ultrasound 01/??/07 - results not reported

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274631-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Mar-2007	22-Mar-2007	0	23-Mar-2007	26-Mar-2007	MA		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness

**Symptom Text:** Patient had complaints of lightheadedness/dizziness approx. 5-10 minutes after injection. Lasted for approx. 5 minutes. Patient was seated, cold cloth applied to neck and wrists, given water to drink. s/s resolved with intervention and seating. Patient with no other complaints.

**Other Meds:** Orthotricyclen-lo

**Lab Data:** N/A

**History:** no allergies, dysmenorrhea, H. Pylori 4-2006, mono 4-2006,

**Prex Illness:** none T 98.1, patient was seen on 03-14-2007 for viral pharyngitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1232

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274635-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	22-Mar-2007	22-Mar-2007	0	23-Mar-2007	26-Mar-2007	WI		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2457AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1426F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure, Chills, Confusional state, Dizziness, Muscle contracture, Oxygen supplementation, Pallor, Paraesthesia, Paraesthesia, Paraesthesia oral, Posture abnormal, Sensation of heaviness, Unresponsive to stimuli

**Symptom Text:** Adacel given first, appeared fine. HPV then given and within a minute or two, client's chin fell to chest while arm contracted at elbow up off lap. She did not respond to name or shaking of shoulders for approximately one minute (B/P 100/60, pulse 64). Then became aroused, although very confused and unsure where she was. Called out for her mom and asked where she was and said she felt dizzy. Client then assisted off chair to floor. Became extremely pale, c/o lips tingling, B/P 130/64 at 1800. While resting c/o "heavy head" feeling and paresthia in R arm, R and L hands and feet as well as c/o of chills. At 1805 EMS called and responded by 1810 (B/P 130/66, RR 18 at 1805). Given oxygen per EMS. Client transported to ER. Client discharged from ER within a couple hours. Parent contacted at 2000 and states client was "fine now". Returned to school on 3/23/07 per mother.

**Other Meds:** None

**Lab Data:**

**History:** None noted on vaccine history form completed by mother before immunizations given

**Prex Illness:** No

**Prex Vax Illns:** NONE per parent~~NULL~~In Patient|NONE per parent~~NULL~~In Sibling1|NONE per parent~~NULL~~In Sibling2

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274637-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	20-Mar-2007	21-Mar-2007	1	23-Mar-2007	26-Mar-2007	MA		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Nausea, Pyrexia

**Symptom Text:** Patient called office with complaints of feeling feverish,dizziness,headache, and nausea. Onset 24-28 hours after injection. Symptoms lasted approx 24 hours. Patient used Tylenol with good effect.

**Other Meds:** none

**Lab Data:** none

**History:** Allergies:PCN-rash, Peanuts-hives

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274638-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	11-Jan-2007	16-Jan-2007	5	23-Mar-2007	26-Mar-2007	MA		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Herpes zoster, Tremor, Vomiting

**Symptom Text:** Patient states awoke during night with trembling, dizziness, vomiting x's 1 approx 5 days after injection#1. Pt with IDDM, BS elevated at that time. Episode lasted approx two hours. Also with similar complaints after Injection #2, will report as separate event. Of note, pt diagnosed with Shingles on 3-5-07.

**Other Meds:** Seasonale(OCP), Novalog 1unit/20gm carbs, Lantus 9units @HS, Zoloft 100mg

**Lab Data:** none

**History:** IDDM onset 6-2005, Celiac Sprue 7-2006

**Prex Illness:** Viral pharyngitis and ear pain at time of injection. T 98.7

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274639-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	13-Mar-2007	17-Mar-2007	4	23-Mar-2007	26-Mar-2007	MA		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Tremor, Vomiting

**Symptom Text:** Patient awoke during night with shakiness, headache, and vomited x's one 3 days after vaccination with second dose of Gardasil. Episode lasted approx one hour. Pt has IDDM, BS normal at that time. Same occurred after dose #1 which was reported as separate event.

**Other Meds:** Seasonal (OCP), Novalog 1unit/20 gm carbs, Lantus 9 units @ HS, Zoloft 100mg.

**Lab Data:** none

**History:** IDDM onset 6-2005, Celiac Disease onset 7-06

**Prex Illness:** Had been diag with Shingles on 3-5-07. Felt well at time of vaccination. T 98.0

**Prex Vax Illns:** Same symptoms~Human Papillomavirus Recombinant Vaccine, Quadrivalent (Gardasil)~1~19~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274646-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	21-Mar-2007	21-Mar-2007	0	24-Mar-2007	26-Mar-2007	NC		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0244U	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** She ran a fever of 101 F for 24 hours beginning beginning 4-6 hours after the administration of the second dose of the vaccine.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274660-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	16-Jan-2007	Unknown		23-Mar-2007	26-Mar-2007	FL		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1162F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy

**Symptom Text:** We are reporting that the patient became pregnant after receiving 1st dose of Gardasil. her last menstrual period was 1/17/07. She reported pregnancy to us on 3/1/07. Her EDC is 10/24/07. She received Gardasil on 1/16/07.

**Other Meds:** NONE

**Lab Data:**

**History:** Allergic to Amoxicillin

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274661-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	19-Mar-2007	19-Mar-2007	0	23-Mar-2007	26-Mar-2007	CA		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperhidrosis, Nausea, Syncope

**Symptom Text:** Fainting, sweating, nausea

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274663-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
9.0	F	08-Mar-2007	20-Mar-2007	12	23-Mar-2007	26-Mar-2007	MI		26-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1447F	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abasia, Cyanosis, Joint swelling, Pharyngolaryngeal pain, Pyrexia, Rash, Serum sickness

**Symptom Text:** fever, rash, swollen joints (ankles, elbows, shoulders), can't walk, sore throat, toes blue. Probable Serum sickness

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274672-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	12-Mar-2007	13-Mar-2007	1	23-Mar-2007	26-Mar-2007	FL		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug hypersensitivity, Erythema, Pruritus, Swelling, Swelling face

**Symptom Text:** Patient called 3/15/07. Patient states the morning after she received her 2nd dose of Gardasil, when she woke up her face and neck was red and cheeks were puffy and also itchy. Patient did state she was in the sun x 45 minutes after she left our office- was using a new sunblock x 4days. Patient states swelling and redness was gone by the next day. No treatment.

**Other Meds:** YAZ

**Lab Data:**

**History:** Ibuprofen, Seasonal allergies

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274676-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
48.0	F	19-Mar-2007	19-Mar-2007	0	23-Mar-2007	28-Mar-2007	MD		28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0088V	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Hypoaesthesia, Mobility decreased, Pain in extremity

**Symptom Text:** Right hand soreness and numbness, afebrile, pain with movement limits use of hand, no weakness. Right knee aching, worse with waking. BP 139/93, pulse 97

**Other Meds:** Lisinopril celera

**Lab Data:** Normal blood work, normal EKG

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274678-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	06-Mar-2007	06-Mar-2007	0	23-Mar-2007	26-Mar-2007	PA		26-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2638AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Both arm and elbow itchy.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274697-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	21-Feb-2007	27-Feb-2007	6	16-Mar-2007	29-Mar-2007	CO	WAES0702USA04286	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Food allergy, Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 17 year old female patient with allergies to cast and scallops who on 21-FEB-2007 was vaccinated with a dose of Gardasil. Concomitant therapy included NYQUIL. 20 hours later, the patient developed hives. Unspecified medical attention was sought. The patient's hives persisted. The reporter indicated the patient had hives from the vaccine. Additional information has been requested.

**Other Meds:** NYQUIL

**Lab Data:** Unknown

**History:**

**Prex Illness:** Allergic to cats; Food allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1244

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274698-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	12-Feb-2007	12-Feb-2007	0	16-Mar-2007	29-Mar-2007	OK	WAES0702USA04298	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza like illness, Pyrexia, Rash

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 24 year old female with no pertinent medical history and no history of drug reactions/allergies who on 12-FEB-2007 was vaccinated with first dose of Gardasil (lot # not reported) 0.5 ml IM. Concomitant therapy included YASMIN and ULTRAM. On 12-FEB-2007, the patient developed a rash on her chest, low grade fever and she felt like she had the flu after receiving the first immunization with Gardasil. Unspecified medical attention was sought. On 13-FEB-2007, the patient recovered. No other information was available at the time of reporting. Additional information has been requested.

**Other Meds:** YASMIN, ULTRAM

**Lab Data:** Temperature measurement 2/12/07 low grade fever

**History:** None

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1245

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274699-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Feb-2007	22-Feb-2007	0	16-Mar-2007	29-Mar-2007	--	WAES0702USA04299	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a nurse practitioner concerning a 17 year old female with a cold at the time of the vaccination and unspecified if history of drug reaction /allergies who on 22-FEB-2007 was vaccinated with first dose of Gardasil (lot # not reported) IM. Concomitant therapy included NYQUIL for the cold. On approximately 22-FEB-2007, within 12 to 18 hours of being vaccinated, the patient experienced hives which started on his hips and chest and then spread to her neck and face. Medical attention was sought. The outcome of the hives was not reported. No further information was available at the time of reporting. Additional information has been requested.

**Other Meds:** NYQUIL

**Lab Data:** Unknown

**History:** Cold

**Prex Illness:** Cold

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1246

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274700-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	14-Dec-2006	27-Dec-2006	13	16-Mar-2007	29-Mar-2007	--	WAES0702USA04301	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity, Syncope

**Symptom Text:** Information has been received from a mother concerning her 18 year old daughter who on 14-DEC-2006 was vaccinated with Gardasil (lot # not reported) IM. Concomitant therapy included "TENUS therapy unspecified and hepatitis A virus vaccine (unspecified)" date not provided. The mother reported that her daughter fainted and also experienced pain in her arm after receiving Gardasil. The onset date was reported as 24-Dec-2006. At the time of reporting, the patient had recovered. Additional information has been requested.

**Other Meds:** (therapy unspecified)

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1247

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274701-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Jan-2007	01-Jan-2007	0	16-Mar-2007	29-Mar-2007	NY	WAES0702USA04306	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a physician concerning a female (demographics not provided) who on an unspecified date in January 2007, was vaccinated with Gardasil (lot # not provided). That same day the patient experienced dizziness after the vaccination. At the time of this report the patient had not recovered from the dizziness. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1248

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274702-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	06-Sep-2006	06-Sep-2006	0	16-Mar-2007	29-Mar-2007	IL	WAES0702USA04311	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Chest pain, Nausea

**Symptom Text:** Information has been received from a nurse a the daughter of a female patient (demographics not provided) who on 06-SEP-2006 was vaccinated with the first dose of Gardasil (Lot # not provided). The mother reported to the nurse that on 06-SEP-2006 after receiving the vaccination her daughter developed an elevated temperature (actual measurement not provided), nausea and chest pain. The mother reported to the nurse that she gave her daughter Benadryl (dose not provided). It was reported that the nausea, elevated temperature and chest pain resolved "in about three days". Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1249

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274703-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	12-Feb-2007	13-Feb-2007	1	16-Mar-2007	29-Mar-2007	--	WAES0702USA04312	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>		<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.		NULL		Unknown		Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Feeling hot, Headache, Inappropriate schedule of drug administration, Motion sickness, Nausea, Pyrexia

**Symptom Text:** Information has been received from a nurse concerning a 27 year old female who on 12-FEB-2007 was vaccinated in the left deltoid with the first dose of Gardasil (lot # not provided). Subsequently, on 13-FEB-2007 the patient reported that her "face felt hot", she had a fever, nausea and headache. On 23-FEB-2007 the patient reported that she had an additional symptom similar to motion sickness. The patient sought unspecified medical attention. At the time of this report the patient has not recovered from the events. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274704-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	14-Feb-2007	22-Feb-2007	8	16-Mar-2007	02-Apr-2007	CA	WAES0702USA04326	02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0014U		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Axillary mass, Axillary pain

**Symptom Text:** Information has been received from a registered nurse concerning a 17 year old female who on 14 Feb 2007 was vaccinated IM in the left deltoid with a 0.5mL dose of Gardasil vaccine. There was no concomitant medication. On 22 Feb 2007 the patient "developed a painful lump underneath the arm pit of the same injection arm". The nurse reported that the patient was told to follow up with the physician as soon as possible. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274705-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	14-Feb-2007	14-Feb-2006	-365	16-Mar-2007	02-Apr-2007	KY	WAES0702USA04332	07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral

**Symptom Text:** Information has been received from a health professional ("nurse"), via a company representative concerning a 15 year old female who on approximately 14 Feb 2007 ("sometime last week") was vaccinated IM with a second dose of Gardasil vaccine (yeast) (the patient's first vaccination date was not reported). Concomitant suspect vaccinations included a dose of Varicella and hepatitis A vaccine (inactive). On approximately 14 Feb 2006 ("sometime last week"), the instant after getting the vaccinations, the patient developed a "swallowed" red arm 8-9cm long and 6 cm wide. At the time of the report, it was unknown if the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** immunization

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274706-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	23-Feb-2007	23-Feb-2007	0	16-Mar-2007	02-Apr-2007	--	WAES0702USA04340	02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Paraesthesia, Paraesthesia

**Symptom Text:** Information has been received from a registered nurse concerning a female patient who on 23 Feb 2007 was vaccinated with the first dose of Gardasil. On 23 Feb 2007, after the vaccination, the patient passed out and experienced a tingling sensation in her extremities. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274707-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	21-Feb-2007	Unknown		16-Mar-2007	02-Apr-2007	--	WAES0702USA04343	02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Malaise

**Symptom Text:** Information has been received from a registered nurse concerning a 13 year old female who on 21 Feb 2007 was vaccinated with 0.5ml dose of Gardasil. Concomitant therapy included Adacel. Subsequently the patient "felt sick" and passed out. It was reported that the patient was at home when she passed out but it was unknown how long after she received the vaccination. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274708-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	Unknown	Unknown		16-Mar-2007	02-Apr-2007	--	WAES0702USA04351	02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Information has been received from an office manager concerning a 12 year old female who on an unspecified date was vaccinated with the first dose of Gardasil, injection. Concomitant medication was not reported. Subsequently on an unspecified date, the patient experienced a rash over body and legs that caused severe itching after Gardasil vaccine was administered. On an unspecified date, the patient sought unspecified medical attention. The patient's rash over body and legs that caused severe itching persisted. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274709-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	02-Apr-2007	CA	WAES0702USA04365	02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a nurse concerning a female patient (age unknown) who, on an unspecified date, was vaccinated with a dose of Gardasil. Subsequently, on an unspecified date, the patient passed out after receiving the vaccine. The nurse reported that the patient had not eaten. At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274710-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0702USA04371	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a consumer concerning her daughter, a female patient who was vaccinated with the first dose of Gardasil. Subsequently the patient "broke out in hives after initial dose." It is unknown if the patient recovered. The patient sought unspecified medical attention. Additional information is not expected.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274711-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	03-Feb-2007	22-Feb-2007	19	16-Mar-2007	02-Apr-2007	MP	WAES0702USA04391	02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Photosensitivity reaction, Rash pruritic, Uveitis

**Symptom Text:** Information has been received from a registered nurse concerning her daughter, a 17 year old female patient, with a history of a "hive like reaction" after receiving a dose of MMR (vaccine) when she was 1 year old," who on 03 Feb 2007 was vaccinated with the first dose of Gardasil. There was no concomitant medication. Following the vaccination, on 22 Feb 2007, the nurse reported that her daughter developed uveitis with photosensitivity and an itchy rash to her legs, arms and trunk. The nurse confirmed that the uveitis was treated with prednisone eye drops, and the condition "improved." The nurse stated that the rash on her daughter's legs, arms and trunk had not resolved. Additional information has been requested.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** rash urticaria-like, drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1258

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274712-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	15-Feb-2005	15-Feb-2007	730	16-Mar-2007	02-Apr-2007	NY	WAES0702USA04396	02-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure normal, Diarrhoea, Dizziness, Fall, Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a 21 year old female patient with autoimmune hepatitis, who on 15 Feb 2005 was vaccinated with a dose, 0.5ml, IM, of Gardasil. Concomitant suspect therapy included Adacel, and other concomitant medication included birth control pills, prednisone, vitamins (unspecified) and calcium (unspecified). The nurse reported that on 15 Feb 2007, "20 hours later," the patient "felt lightheaded and passed out. She came to and when she got up she passed out and fell to the floor." The nurse further stated that "both episodes were very brief." On approximately 16 Feb 2007 ("later") the patient "had one episode of diarrhea." On the morning of 16 Feb 2007, the nurse stated that the patient was seen by the doctor and "blood pressure was normal and injection site looked fine. No treatment required." At the time of this report, the patient had recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:** NONE

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274713-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0702USA04415	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician who reported that her daughter was vaccinated with her second dose of HPV and experienced pain during the injection. The patient stated there was no pain when she received the first dose of HPV. Unspecified medical attention was sought by the patient. The patient's outcome was unknown. No further information is available.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1260

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274714-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Jan-2007	01-Jan-2007	0	16-Mar-2007	29-Mar-2007	--	WAES0702USA04505	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Face injury, Haemorrhage, Syncope

**Symptom Text:** Information has been received from a nurse practitioner concerning a female (age not reported) with a history of "becomes sqeemish after being administered shots" who on approximately 01-JAN-2007 (about 8 weeks ago) was vaccinated with the first dose of HPV. Concomitant medication was not reported. On approximately 01-JAN-2007 (about 8 weeks ago), the patient fainted in the elevator after being administered the HPV and she hit her nose which started to bleed. The patient sought unspecified medical attention and was given an x-ray which showed that her nose was not broken. The patient was recovering from the events. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** x-ray, 01/01/07, nose not broken

**History:** Post procedural nausea

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274715-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	16-Jan-2007	Unknown		16-Mar-2007	29-Mar-2007	NY	WAES0702USA04529	29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Rash generalised, Rash maculo-papular

**Symptom Text:** Information has been received from a physician concerning a 19 year old female who on 14-NOV-2007 and 16-JAN-2007 was vaccinated intramuscularly with a 0.5 mL dose of HPV. On 16-JAN-2007, concomitant therapy included a second dose of varicella. Subsequently, on an unspecified date, the patient developed a generalized body rash (20-30 lesions) which were macular papules/erythema and were mainly on the upper extremities and some on the abdomen. There were none on the hands or feet or in the mouth. The patient did not have a temperature or lymph swelling. The papules/erythema were non-painful and not itchy. The physician stated that it did not present like chicken-pox. Routine blood work was performed (results not provided). At the time of this report, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

**Other Meds:**

**Lab Data:** diagnostic laboratory, routine blood work

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274716-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0702USA04535	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Information has been requested from a registered nurse concerning a female patient between the ages of 11 to 13 who within the last 3 months was vaccinated intramuscularly with a 0.5mL dose of HPV. Subsequently the patient experienced dizziness to the point of losing consciousness. The event lasted for a matter of seconds. The patient was well enough to leave in a few minutes. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274717-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0702USA04536	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Information has been received from a registered nurse concerning a female patient between the ages of 11 to 13 who within the last 3 months was vaccinated intramuscularly with a 0.5 mL dose of HPV. Subsequently the patient experienced dizziness to the point of losing consciousness. The event lasted for a matter of seconds. The patient was well enough to leave in a few minutes. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274718-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	01-Dec-2006	20-Jan-2007	50	16-Mar-2007	29-Mar-2007	VA	WAES0702USA04572	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Menorrhagia, Menstruation irregular, Vaginal odour

**Symptom Text:** Information has been received from a consumer concerning her daughter, an 11 year old female patient who in approximately December 2006 ("about two months ago"), was vaccinated with the first dose of HPV (yeast). There was no concomitant medication. On approximately 20-JAN-2007 ("next menses"), the mother reported her daughter's "menses was longer than usual," and lasted for six days. The mother reported her daughter's menses usually "last three days." She also reported the menses was "very heavy and had a foul odor." The patient did not seek medical attention. It was unknown if the patient recovered. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274719-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	02-Nov-2006	23-Nov-2006	21	16-Mar-2007	29-Mar-2007	CT	WAES0702USA04576	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0868F	1	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperaesthesia, Injection site pain, Muscle disorder

**Symptom Text:** Information has been received from a Health care Professional concerning a 26 year old female police officer with muscle sensitivity who on 02-NOV-2006 was vaccinated in left deltoid with a 2nd dose of HPV, lot # 653736/0868F. On 23-NOV-2006 the patient was sore at muscle site on an off for 3 days, and she still noticed sensitivity three weeks post injection. No medical attention was sought. The patient reported as recovered. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Myalgia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274720-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	16-Mar-2007	29-Mar-2007	--	WAES0702USA04630	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician assistant (PA) concerning a female patient who in "early" December 2006, was vaccinated with the first dose of HPV (yeast). The PA reported that the patient "did not have any symptoms except" what the PA stated was "normal pain at the moment of injection." The patient sought unspecified medical attention.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274721-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Feb-2007	22-Feb-2007	1	16-Mar-2007	29-Mar-2007	--	WAES0702USA04636	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0186U		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria, Vomiting

**Symptom Text:** Information has been received from a Physician Assistant (P.A.) concerning a 20 year old female with a history of hives once a year who on 21-FEB-2007 was vaccinated IM with a dose of HPV, lot # 655618/0786U. On 22-FEB-2007 the patient developed hives over her entire body and vomiting. The reporter also noted that in addition to her history of hives, members of her family had a stomach virus with vomiting so it was unclear if her symptoms were from the vaccine. Diphenhydramine hydrochloride (BENADRYL) was ordered for the hives. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Hives

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274722-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	28-Nov-2006	29-Nov-2006	1	16-Mar-2007	29-Mar-2007	NM	WAES0702USA04640	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Injection site pain

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 17 year old female with a cardiac murmur who on 28-NOV-2006 was vaccinated IM with her first dose of HPV, lot #654540/0800F. On 29-FEB-06 the patient experienced minor soreness around the injection site. The patient did not return for her 2nd dose until 27-FEB-2007. The patient recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Cardiac murmur

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274723-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	05-Apr-2007	NY	WAES0702USA04654	05-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Crying, Pain, Pain in extremity

**Symptom Text:** Information has been received from a nurse practitioner and a licensed practical nurse concerning a teenage female (age not reported) who on an unspecified date was vaccinated with 0.5 mL of Gardasil. Subsequently, the patient ended up crying and reported she had pain, when the vaccine was being administered, either left or right arm and had some pain afterwards. Unspecified medical attention was sought. At the time of this report, the patient had recovered from the events (date unknown). Additional information has been requested.

**Other Meds:** unknown

**Lab Data:** unknown

**History:** unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274724-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	NY	WAES0702USA04655	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Crying, Pain

**Symptom Text:** Information has been received from a nurse practitioner and a licensed practical nurse concerning a teenage female (age not reported) who on an unspecified date was vaccinated with 0.5 mL of Gardasil. Subsequently, the patient ended up crying and reported she had pain, when the vaccine was being administered, either the left or right arm and had some pain afterwards. Unspecified medical attention was sought. At the time of this report the patient had recovered from the events (date unknown). Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274725-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	01-Nov-2006	Unknown		16-Mar-2007	29-Mar-2007	IL	WAES0702USA04734	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fungal infection

**Symptom Text:** Information has been received from a consumer concerning her 11 year old daughter with asthma and sulfonamide allergy and a history of yeast infections who in approximately November 2006, was vaccinated with a first dose of Gardasil. Concomitant therapy included ALLEGRA, SINGULAIR, ADVAIR, NASONEX, PROZAC. Subsequently, it was reported that the patient's "yeast infection has become more severe." Unspecified medical attention was sought. At the time of the report, the patient had not recovered. Additional information has been requested.

**Other Meds:** ALLEGRA, SINGULAIR, ADVAIR, NASONEX, PROZAC

**Lab Data:** Unknown

**History:** Yeast infection

**Prex Illness:** Asthma, Sulfonamide allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274726-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	NC	WAES0702USA04736	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1447F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Complex regional pain syndrome

**Symptom Text:** Initial and follow-up information has been received from a physician concerning a female who was vaccinated with a 0.5 ml dose of Gardasil (lot #655617/1447F). Subsequently, 2 days after vaccination, the patient experienced "RSD reaction" that started in her upper extremities and then moved to her lower extremities. The patient is undergoing a neurology work-up. At the time of the follow-up report, the patient had not recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1273

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274727-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	28-Dec-2006	Unknown		16-Mar-2007	29-Mar-2007	NJ	WAES0703USA00002	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Adverse event, Neck pain, Pain in extremity

**Symptom Text:** Information has been received from a registered nurse concerning a 14 year old female with asthma who on 26-OCT-2006 was vaccinated with the first 0.5 ml dose of Gardasil, (Lot # 653735/0688F). On 12-28-06, the patient was vaccinated with the second 0.5 ml dose of Gardasil (Lot # "0916F"). The nurse reported that the patient had adverse experiences after vaccination. The patient experienced neck pain. Also, the patient's arm "had hurt all the way down, off and on". At the time of the report the patient's symptoms began after the first and second dose of Gardasil. At the time of the report, the symptoms had not resolved. The nurse also mentioned that the patient participated in gymnastics. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274728-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0703USA00042	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation delayed

**Symptom Text:** Information has been received from a licensed practical nurse (LPN) concerning an approximately 13 year old ("about 13 years of age") female patient who was vaccinated with a dose of Gardasil. Subsequently the nurse reported that the patient's period (menstrual cycle) is "a little over a week late." At the time of this report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1275

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274729-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	27-Dec-2006	27-Dec-2006	0	16-Mar-2007	29-Mar-2007	--	WAES0703USA00057	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaemia, Dizziness, Loss of consciousness, Menorrhagia

**Symptom Text:** Information has been received from a nurse practitioner (NP) concerning a 14 year old female patient with an allergy to wool, who on 27-DEC-2006 was vaccinated with a dose of Gardasil (Lot # 653735/0688F). Concomitant therapy included DEPO-PROVERA, also administered on 27-DEC-2006. In approximately December 2006 ("since vaccination"), the patient "experienced anemia, dizziness, and heavy menstrual cycles." The NP also stated that the patient reported she "felt like she was going to pass out, but did not report passing out." The NP added that the "patient is receiving iron to treat the anemia." Diagnostic labs were performed (date not specified) including a complete blood count (CBC) (result not provided), hemoglobin 10.8 (unit not provided), and hematocrit 31.7 (unit not provided). At the time of this report, the patient had not recovered. Additional information has been requested.

**Other Meds:** DEPO-PROVERA

**Lab Data:** hemoglobin 01?/??/07 10.8, complete blood cell 01?/??/07, hematocrit 01?/??/07 31.7

**History:**

**Prex Illness:** Allergy to wool

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274730-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	21-Feb-2007	23-Feb-2007	2	16-Mar-2007	28-Mar-2007	FL	WAES0703USA00058	28-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Pain in extremity, Pyrexia, Swelling

**Symptom Text:** Information has been received from a physician, via a company representative concerning a female patient who on approximately 21 Feb 2007 ("last week") was vaccinated with the first dose of Gardasil. The physician reported that the "patient came back a few days after first dose of (Gardasil) and complained arm pain, swelling, fever and nausea" (approximately 23 Feb 2007). The physician confirmed that the patient had recovered "after a few days" (approximately 26 Feb 2007). The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1277

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274731-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Dec-2006	Unknown		16-Mar-2007	29-Mar-2007	IL	WAES0703USA00074	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 16 year old female patient with depression who on 28-DEC-2006 was vaccinated IM with her first dose of Gardasil, lot #654389/0961F. Concomitant therapy included CONCERTA and DEPO-PROVERA. The patient developed a generalized "hive like rash" after her first dose of Gardasil. The nurse reported that the rash "comes and goes". Unspecified medical attention was sought. The patient had not recovered as of the report date. Additional information has been requested.

**Other Meds:** DEPO-PROVERA, CONCERTA

**Lab Data:** Unknown

**History:**

**Prex Illness:** Depression

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274732-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Feb-2007	28-Feb-2007	2	16-Mar-2007	29-Mar-2007	MN	WAES0703USA00084	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Erythema nodosum, Pain, Skin lesion

**Symptom Text:** Information has been received from a Licensed Practical Nurse (L.P.N.) concerning an 18 year old female patient who on 26-FEB-2007 was vaccinated with the first dose of Gardasil. Concomitant therapy included ORTHO-CYCLEN. On 28-FEB-2007 the patient developed red, painful lesions on her feet. The physician characterized the above lesions as similar to erythema nodosum. The physician ordered erythrocyte sedimentation rate (ESR) measurement, the result of which had not yet been obtained. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** ORTHO-CYCLEN

**Lab Data:** erythrocyte - result has not yet been obtained

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1279

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274733-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	28-Feb-2007	28-Feb-2007	0	16-Mar-2007	29-Mar-2007	CA	WAES0703USA00085	08-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0012U	0	Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Agitation, Dizziness, Nausea

**Symptom Text:** Information has been received from a health professional concerning a 17 year old female patient with history of acne and dyspepsia who on 28-FEB-2007 was vaccinated IM with her first dose of Gardasil lot #655503/0012U. Concomitant therapy included PREVACID, RETIN-A and CLEOCIN. The patient reported that she felt dizzy, nauseated and agitated starting 30 minutes after receiving the infection. The physician advised the patient to rest, monitor symptoms and call the office if no improvement. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** CLEOCIN, PREVACID, RETIN-A

**Lab Data:** Unknown

**History:**

**Prex Illness:** Acne; Dyspepsia

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274734-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Jan-2007	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0703USA00090	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blister, Herpes zoster, Pain, Rash

**Symptom Text:** Information has been received from the mother of a female consumer who in January 2007, was vaccinated with a dose of Gardasil. The patient experienced pain, a rash and then full blown blisters. She went to her physician and was diagnosed as shingles. The patient's outcome was unknown. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274735-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	23-Feb-2007	23-Feb-2007	0	16-Mar-2007	29-Mar-2007	NY	WAES0703USA00107	08-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0014U	0	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pruritus, Injection site rash

**Symptom Text:** Information has been received from a registered nurse concerning a female with high grade cervical dysplasia who on 23-FEB-2007 was vaccinated intramuscularly, into the left deltoid, with a first 0.5 ml dose of Gardasil (lot #653736/0014U). There was no concomitant medication. A few days after the vaccination, the patient developed a red, itchy, bumpy rash at the injection site. Unspecified medical attention was sought. There were no laboratory or diagnostic tests performed. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:** Cervical dysplasia

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274736-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	18-Dec-2006	Unknown		16-Mar-2007	29-Mar-2007	CA	WAES0703USA00109	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Back pain, Chills, Dizziness, Injection site pain, Nausea, Pruritus, Pyrexia

**Symptom Text:** Information has been received from a nurse practitioner concerning a 26 year old female with no pertinent medical history who on 18-DEC-2006 was vaccinated intramuscularly, into the left deltoid with a first 0.5 ml dose of Gardasil (lot # "0604F"). Concomitant therapy included vitamins (unspecified). Subsequently the patient experienced soreness at the injection site, sacral back pain, mild low abdominal cramping, nausea, generalized itchiness, mild dizziness and "felt feverish with chills." Unspecified medical attention was sought. There were no laboratory or diagnostic tests performed. The patient recovered in 1 week without treatment. Additional information has been requested.

**Other Meds:** vitamins (unspecified)0

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274737-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	21-Feb-2007	21-Feb-2007	0	16-Mar-2007	29-Mar-2007	NJ	1WAES0703USA0021	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Information has been received from a health professional concerning her 16 year old daughter who on 21-FEB-2007 was vaccinated with a first dose of Gardasil. On 21-FEB-2007 the patient experienced a bad headache. She was given two ADVIL and her headache went away the following day. On 21-FEB-2007, the patient recovered. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1284

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274738-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0703USA00291	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation delayed

**Symptom Text:** Information has been received a licensed practical nurse (LPN) concerning an approximately 13 year old ("about 13 years of age") female patient who was vaccinated with a dose of Gardasil. Subsequently the nurse reported that the patient's period (menstrual cycle) is "a little over a week late." At the time of this report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1285

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274739-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	MI	WAES0703USA00329	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a dose of Gardasil. Subsequently the patient experienced dizziness and sought unspecified medical attention. No further information was provided. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1286

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274740-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	MI	WAES0703USA00330	29-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a dose of Gardasil. Subsequently the patient experienced dizziness and sought unspecified medical attention. No further information was provided. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274741-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	CA	WAES0703USA00741	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Musculoskeletal stiffness, Neck pain

**Symptom Text:** Information has been received from a physician via a company representative concerning a female in her early 20's who, on an unspecified date, was vaccinated with a dose of Gardasil. It was reported that the patient experienced neck pain and stiffness after the injection. The pain was reported to have lasted much longer than expected. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274742-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0703USA00754	08-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>		<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.		NULL		Unknown		Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician's assistant concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil (lot # not reported). Concomitant therapy was unspecified. The patient sought unspecified medical attention. Subsequently, the patient experienced a rash. The specifics of the rash were not reported. The outcome of the rash was not reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274743-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	14-Dec-2006	14-Dec-2006	0	16-Mar-2007	29-Mar-2007	--	WAES0703USA00931	29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1162F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injected limb mobility decreased, Pain in extremity, Pyrexia

**Symptom Text:** Information has been received from a physician concerning an 18 year old female student (weight 131#, height 66.5") who on 14-DEC-2006 at 2 pm was vaccinated with the first dose of Gardasil (lot #654540/1162F), IM in the right arm. Concomitant therapy included Menactra (lot #41974ab), IM in the left arm. On approximately 14-DEC-2006, the patient developed fever T > 100 within 24 hours of vaccination, her arm was very sore and she "could not use for 48 hours". Subsequently on 16-DEC-2006, the patient recovered from fever T > 100, arm was very sore and could not use arm for 48 hours. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274744-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	12-Feb-2007	12-Feb-2007	0	16-Mar-2007	29-Mar-2007	CA	WAES0703USA00940	29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Computerised tomogram, Head injury, Headache, Syncope

**Symptom Text:** Information has been received from a physician concerning a female who on approximately 12-FEB-2007 was vaccinated intramuscularly with a dose of Gardasil. On approximately 12-FEB-2007 the patient fainted after the administration of Gardasil. It was reported that this patient may have fainted while on the way to the car and hit her head at an unspecified area. Medical attention was sought and the patient's mother was requesting a computed axial tomography because the patient was experiencing bad headaches. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274745-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	12-Feb-2007	12-Feb-2007	0	16-Mar-2007	29-Mar-2007	CA	WAES0703USA00941	30-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Head injury, Headache, Syncope

**Symptom Text:** Information has been received from a physician concerning a female who on approximately 12-FEB-2007 was vaccinated intramuscularly with a dose of HPV. On approximately 12-FEB-2007 the patient fainted after the administration of HPV. It was reported that this patient may have fainted while on the way to the car and hit her head at an unspecified area. Medical attention was sought and the patient's mother was requesting a computed axial tomography because the patient was experiencing bad headaches. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274746-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Mar-2007	29-Mar-2007	--	WAES0703USA01022	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain, Pain in extremity

**Symptom Text:** Information has been received from a family nurse practitioner (FNP) concerning numerous patients who on an unspecified dates were vaccinated with HPV (lot # not reported). Subsequently, the patients experienced stinging and sore arm after the vaccination. The outcome of the stinging and sore arm was not reported. No other information was available at the time of reporting. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274747-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	PA	WAES0703USA01074	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1427F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness

**Symptom Text:** Information has been received from a health professional concerning a female who was vaccinated with IM with a 0.5 ml dose of Gardasil (lot 654885/1424F # or lot # 655619/1427F). Subsequently within a few minutes the patient experienced dizziness and felt as if she was going to faint. The patient did not faint and was not sent to the hospital. The patient laid down for a few minutes and had something to drink. The patient recovered on an unspecified date. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274748-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	PA	WAES0703USA01075	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1427F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness

**Symptom Text:** Information has been received from a health professional concerning a female who was vaccinated with IM with a 0.5 ml dose of HPV (lot 654885/1424F # or lot # 655619/1427F). Subsequently within a few minutes the patient experienced dizziness and felt as if she was going to faint. The patient did not faint and was not sent to the hospital. The patient laid down for a few minutes and had something to drink. The patient recovered on an unspecified date. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274749-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		16-Mar-2007	29-Mar-2007	PA	WAES0703USA01076	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1427F		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness

**Symptom Text:** Information has been received from a health professional concerning a female who was vaccinated with IM with a 0.5 ml dose of HPV (lot 654885/1424F # or lot # 655619/1427F). Subsequently within a few minutes the patient experienced dizziness and felt as if she was going to faint. The patient did not faint and was not sent to the hospital. The patient laid down for a few minutes and had something to drink. The patient recovered on an unspecified date. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1296

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274750-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
60.0	F	30-Oct-2006	30-Oct-2006	0	16-Mar-2007	29-Mar-2007	WA	WAES0701USA03988	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Chills, Hyperhidrosis, Inappropriate schedule of drug administration, Influenza, Lymphadenopathy, Musculoskeletal stiffness, Myalgia

**Symptom Text:** Initial and follow-up information has been received from a nurse practitioner concerning a 60 year old white female cigarette smoker (40 cigarettes per day) with hypothyroidism who on 30-OCT-2006 was vaccinated, into the right "glute" with a first dose of HPV (lot # 653978/0955F). Concomitant therapy included levothyroxine Na (SYNTHROID). On 04-NOV-2006 the patient experienced stiff neck, myalgia, mild chills, sweats and temperature of 101. On 06-NOV-2006 the patient experienced enlarged cervical lymph nodes. Subsequently, the patient recovered. It was reported that the patient thought that she had the flu. On 12-JAN-2007 the patient was vaccinated, into the right "glute" with a second dose of HPV (lot # 654389/0961F). On 17-JAN-2007 the patient experienced stiff neck, myalgia, mild chills, sweats and temperature of 101. On 19-JAN-2007 the patient experienced enlarged cervical lymph nodes. The nurse practitioner felt that the patient had an "exaggerated immune response." At the time of the report, the patient's stiff neck and myalgia and mild chills and sweats and temperature of 101 and enlarged cervical lymph nodes persisted. The patient refused her third vaccination. No further information is available.

**Other Meds:** Synthroid

**Lab Data:** body temp 11/04/06 101; body temp, 01/17/07 101; serum C-reactive 01/22/07 14.5; serum alkaline 01/22/07 106

**History:** Hypothyroidism; Cigarette smoker

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1297

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274754-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	Unknown	Unknown		26-Mar-2007	27-Mar-2007	OH	WAES0702USA03451	27-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a physician, for the Pregnancy registry for Gardasil, concerning a 26 year old female with pertinent medical history and drug reactions/allergies unspecified who on an unspecified date was vaccinated with first dose of Gardasil (lot # not reported) injection. On an unspecified date, the patient was vaccinated with second dose of Gardasil (lot # not reported) injection. Concomitant therapy was unspecified. Approximately two weeks after receiving the second dose of vaccine, the patient learned that she was pregnant. The patient sought medical attention, she reported the pregnancy to the physician's office. The date of last menstrual period was not reported. The third dose of Gardasil will not be given to the patient during her pregnancy. The patient has not had any adverse experiences to date. Additional information was received from the physician who reported that the patient had a miscarriage. No further information was available at the time of reporting. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274755-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Jan-2007	22-Jan-2007	0	26-Mar-2007	27-Mar-2007	VA	WAES0702USA01337	27-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0868F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion induced, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 15 year old female student who on 22-JAN-2007 was vaccinated intramuscularly in the left arm with a 0.5ml first dose of Gardasil (lot #653736/0868F). On 02-FEB-2007, it was discovered that the patient was pregnant. At the time of this report, the patient's last menstrual period was unknown. The patient sought unspecified medical attention and she was referred to an obstetrician/gynecologist. A pregnancy test was performed. On an unspecified date, the pregnancy was terminated. At the time of this report, the outcome was unknown. No product quality complaint was involved. Upon internal review, pregnancy was terminated was considered to be an other important medical event. Additional information is not expected.

**Other Meds:** UNK

**Lab Data:** beta-human chorionic

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1299

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274756-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
35.0	F	24-Jan-2007	24-Jan-2007	0	26-Mar-2007	27-Mar-2007	FR	WAES0703USA03854	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abortion missed, Drug exposure during pregnancy, Inappropriate schedule of drug administration

**Symptom Text:** Information has been received from a health professional concerning a pregnant 35 year old female with a history of missed miscarriage who on 24-JAN-2007 was vaccinated intramuscularly with a first dose of Gardasil. The site of administration was not reported. concomitant therapy included Echinacea (unspecified), FUNGUSTATIN, ZIRTEK which the patient took as self medication from 12-JAN-2007 to 24-JAN-2007 because she believed she had a possible fungal infection. It was reported that the patient was unaware that she was pregnant at the time of vaccination. The first day after her last menstruation period was 31-DEC-2006 and the patient's expected date of delivery was 07-OCT-2007. The patient realized that she was pregnant on 31-JAN-2007. Approximately 4 days later, the patient experienced a "missed miscarriage." This diagnosis was made by the reporting physician herself. At the time of this report, the outcome was unknown. The reporting physician specified that the miscarriage was not related to therapy with Gardasil. It was also specified that FUNGUSTATIN had not been prescribed by a physician and that it was self-administered by the patient. Upon internal review, miscarriage was considered an other important medical event. Other business partner number included E2007-01696. No further information is available. The case is closed.

**Other Meds:** ZIRTEK 12Jan07 - 24Jan07, echinacea (unspecified) 12Jan07 - 24Jan07, fluconazole 12Jan07 - 24Jan07

**Lab Data:** UNK

**History:** Abortion missed

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1300

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274775-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	15-Feb-2007	16-Feb-2007	1	26-Mar-2007	28-Mar-2007	MI		28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dyspnoea, Electrocardiogram normal, Heart rate increased, Middle insomnia, Nausea, Night sweats, Tachycardia

**Symptom Text:** History of racing heart since getting vaccine 2/20/07. Short of breath-sent to cardiologist ECG doppler normal. Back again 3/16/07 missed 5 days of school. Coughing waking at night, night sweats, nausea.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274777-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	19-Mar-2007	20-Mar-2007	1	26-Mar-2007	28-Mar-2007	NY		03-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TD	AVENTIS PASTEUR	AC52B014AA	5	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB143BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	01870	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash generalised

**Symptom Text:** rash-red spots with white centers all over.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274788-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	15-Mar-2007	15-Mar-2007	0	26-Mar-2007	28-Mar-2007	CA		28-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	02002AC	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0187U	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Fall, Syncope

**Symptom Text:** After getting 1 Menactra vaccine to her Left deltoid and 2 HPV vaccines to her Right deltoid. Patient fainted and fell down to the floor, nonconscious. Approx 2 min she became alert and her Blood pressure 90/60. 911 was called and she was brought to hospital in stable condition.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274790-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	06-Mar-2007	09-Mar-2007	3	26-Mar-2007	28-Mar-2007	VA		28-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2638AA	0	Left arm	Intramuscular	
	FLU	AVENTIS PASTEUR	U2307AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00886	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral, Pain in extremity

**Symptom Text:** R arm redness, pain, swelling. Shortly after.

**Other Meds:** Adderall

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE/Well child

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1304

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274837-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Mar-2007	26-Mar-2007	0	26-Mar-2007	27-Mar-2007	VA		27-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	SP 2631AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	M 0688F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperhidrosis, Pallor, Presyncope

**Symptom Text:** BECAME DIAPHOETIC AND VERY PALE. NEAR SYNCOPE

**Other Meds:** NONE

**Lab Data:**

**History:** MIGRAINES

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1305

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274938-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	11-Jan-2007	11-Jan-2007	0	27-Mar-2007	28-Mar-2007	GA	WAES0703USA02391	28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy, Urine human chorionic gonadotropin negative

**Symptom Text:** Information has been received from a 20 year old female with an allergy to Zomig and a history of multiple miscarriages. On 11-JAN-2007 the patient was vaccinated with her first dose of Gardasil when she was 4 and a half weeks pregnant. The patient took a urine Human chorionic gonadotropin (HCG) test in the doctor's office that said she was not pregnant, and they administered the vaccination on day. On 17-JAN-2007 the patient discovered she was pregnant. On 21-JAN-2007 she had a miscarriage. Medical attention was sought. Her outcome was unknown. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** urine beta-human 01/11/07 - Not pregnant

**History:** Miscarriage

**Prex Illness:** Pregnancy NOS (LMP = Unknown) Drug hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274940-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	29-Nov-2006	Unknown		27-Mar-2007	28-Mar-2007	GA	WAES0703USA03531	03-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hip arthroplasty

**Symptom Text:** Information has been received from a female who on 29-NOV-2006 was vaccinated with Gardasil. At the time of reporting, the patient had not yet received her second dose of Gardasil due to hip replacement surgery. Additional information has been requested. Upon internal review, hip replacement surgery was considered to be an other important medical event.

**Other Meds:** UNK

**Lab Data:**

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1307

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274941-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	13-Mar-2007	13-Mar-2007	0	27-Mar-2007	28-Mar-2007	FR	WAES0703USA04220	28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0572F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Agitation, Hypotension, Loss of consciousness, Nausea, Neurological examination, Tonic convulsion

**Symptom Text:** Information has been received from a health professional concerning a 15 year old female who on 13-MAR-2007 was vaccinated IM into the arm with a first dose of Gardasil (lot # 655376/0572F, batch # NE45050). About 5-10 minutes after the vaccination the patient developed symptoms of tonic convulsions and was unconsciousness for about 1-2 minutes. After recovery the patient developed hypotension and felt nauseas for about 20 minutes. The patient recovered completely. It was reported that the patient is tall and slim and was very excited before vaccination. It was also noted that her sister has a history of hydrocephalus and epilepsy. A neurologic check is planned. Other business partner numbers included E2007-01613.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** UNK

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274942-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		27-Mar-2007	28-Mar-2007	AZ	WAES0703USA04238	28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a medical assistant through a pregnancy registry concerning a 19 year old female with a history of miscarriage who was vaccinated with the first dose of Gardasil. It was reported that later the patient found out that she was pregnant. The patient was 2 months pregnant at the time of the vaccination. It was reported that the patient miscarried 2 weeks after the vaccination. At the time of the report it was unknown, if the patient recovered. Upon internal review, it was determined that miscarried was an other important medical event. Additional information has been requested.

**Other Meds:** UNK

**Lab Data:** UNK

**History:** Miscarriage

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274951-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	26-Mar-2007	26-Mar-2007	0	27-Mar-2007	29-Mar-2007	MO		29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00440	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Nausea, lightheaded x 5 min right after injection.

**Other Meds:**

**Lab Data:** None

**History:** Get lightheaded with blood draws

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1310

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274953-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	06-Mar-2007	07-Mar-2007	1	27-Mar-2007	29-Mar-2007	AZ		04-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2115AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Back pain, Back pain, Body temperature, Bronchitis, Convulsion, Discomfort, Dizziness, Fall, Headache, Hyperventilation, Lack of spontaneous speech, Mental status changes, Nystagmus, Pyrexia, Stridor, Syncope, Tetany, Viral infection

**Symptom Text:** 1:30 Backache, headache, dizziness, generalized discomfort in clinic - call to facility for clarification of side effects, referred to Family Practice - developed stridor, nystagmus - transferred to facility reported at 4:30. Admitted to ICU. Discharged facility 3/9/07. 04/02/07-records received from facility-Fever and altered neurological status. Temp 101.2. Fell at clinic. Fainted. Presented to ER with nystagmus with mainly her gaze toward the right. Not speaking Hyperventilating. Fever a few days ago and had been sick with viral syndrome. PE pupils equal round reactive to light but she had nystagmus frequently every few seconds and mainly seemed with a right. Required interpreter but she had no spontaneous speech. Carpal pedal spasm. DC Summary for DOS 3/7-3/9/07. DC DX:Diseases disorders of nervous system. Convulsions, Tetany, bronchitis, nystagmus, altered mental status, hyperventilation, headache, lumbago, fever.

**Other Meds:**

**Lab Data:** Done in hospital LP: clear fluid, 1 WBC, 0 RBC, Glucose WNL at 56, protein 19. WBC 16.3, 90% neutrophil. Influenza A and B negative. EEG: mildly abnormal EEG due to excessive presence of beta activity which could be drug related. The lack

**History:**

**Prex Illness:** Very minimal URI symptoms

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274955-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	U	22-Mar-2007	22-Mar-2007	0	27-Mar-2007	29-Mar-2007	PA		29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0088U	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Lightheaded then passed out for less than 10 seconds.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274964-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	16-Mar-2007	17-Mar-2007	1	27-Mar-2007	29-Mar-2007	MN		29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	08005	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Herpes zoster

**Symptom Text:** Herpes Zoster of R upper chest & shoulder

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274968-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	22-Feb-2007	23-Feb-2007	1	27-Mar-2007	29-Mar-2007	MI		29-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site nodule, Injection site pain, Injection site pruritus

**Symptom Text:** Pt received #3 Gardasil on 2/22/07. L arm small red dot after shot. On 2/23/07 she started to get larger with raised area on 2/24/07. Size of (2) quarters, itching on/off with minimal pain. On 3/15/07 22mm bump felt under the skin but not raised.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1314

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274970-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	13-Mar-2007	13-Mar-2007	0	27-Mar-2007	29-Mar-2007	OR		29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Herpes simplex, Nausea, Pyrexia

**Symptom Text:** Pt felt nauseous after receiving vaccine. Developed temperature >102. Continued with a fever 102 deg -103.5 F x 5 days. Developed "fever blisters" in mouth. Saw a provider at hospital ED. Treated with Doxycycline.

**Other Meds:** None

**Lab Data:** Lab work done at hospital no results available

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274971-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
10.0	F	05-Mar-2007	Unknown		27-Mar-2007	29-Mar-2007	MI		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1892AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration

**Symptom Text:** None Menactra given 2 mo early

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 274972-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	11-Jan-2007	11-Jan-2007	0	27-Mar-2007	29-Mar-2007	NY		29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain

**Symptom Text:** Pt received Gardasil vaccine 1/11/07 at 100PM - Developed c/o chest pain late evening & went to hospital ER. Pt brought this to our attention 3/12/07 when she was scheduled for her second vaccination - dose not given. No intervention other than Advil given in ER.

**Other Meds:** None

**Lab Data:** Chest Xray & EKG within normal limit, Dedimer normal

**History:** Allergy Penicillin

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275007-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	23-Mar-2007	24-Mar-2007	1	27-Mar-2007	28-Mar-2007	NY		28-Mar-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Myalgia, Neck pain, Pain in extremity, Pain in extremity

**Symptom Text:** APPROX. 24 HOURS AFTER VACCINE BEGAN WITH MUSCULAR NECK,BACK,LEG AND ARM PAIN.

**Other Meds:** PREVICID 30 MG DAILY

**Lab Data:**

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1318

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275023-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
77.0	M	06-Feb-2007	06-Feb-2007	0	16-Mar-2007	30-Mar-2007	CA	WAES0702USA00873	08-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARZOS	MERCK & CO. INC.	1476F		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Incorrect drug dosage form administered

**Symptom Text:** Information has been received from a health professional concerning a 77 year old male with no known allergies who on 06-FEB-2007 was vaccinated IM in the right arm with a 1 ml dose of Zostavax (lot # 656412/1476F). The Zostavax was reconstituted with Gardasil (lot # 654741/1208F) and the combined product was administered to the patient. It was reported that the patient was on an unspecified concomitant medication. No symptoms have been reported. Unspecified medical attention was sought. There was no product quality complaint involved. Additional information has been requested.

**Other Meds:** (therapy unspecified)

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1319

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275050-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		16-Mar-2007	16-Apr-2007	AZ	WAES0702USA03477	16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARZOS	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Accidental exposure, Wrong drug administered

**Symptom Text:** Information has been received from a health professional concerning a patient who was vaccinated with a dose of Zostavax that was reconstituted with Gardasil. No symptoms were noted. The office manager reported it was human error. The vaccine was administered by a medical assistant who was working in the office as a temp and was unfamiliar with the office and the vaccine. There was no product quality complaint involved. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275070-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	02-Mar-2007	13-Mar-2007	11	28-Mar-2007	29-Mar-2007	NY		29-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01880	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Day after receiving Gardasil noted hives throughout body which increased over weekend. Prescribed Keflex and Benadryl.

**Other Meds:** Othrotrecyclen Lo

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275111-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		29-Mar-2007	30-Mar-2007	NC	WAES0703USA03783	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Diarrhoea, Haematochezia, Pain, Pyrexia, Renal failure acute

**Symptom Text:** Information has been received from a physician concerning a 13 year old female who, on an unspecified date, was vaccinated intramuscularly with a second dose of Gardasil. Within 24-48 hours, the patient experienced fever, achiness and diarrhea. The physician reported that 1-2 days later, the patient developed blood in the stool and was admitted to the hospital. The physician reported that the patient was diagnosed with acute kidney failure and was still hospitalized. At the time of this report, the patient's fever, achiness and acute kidney failure persisted. Fever, achiness and acute kidney failure were considered to be immediately life-threatening and disabling. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275112-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	19-Mar-2007	19-Mar-2007	0	29-Mar-2007	30-Mar-2007	CA	WAES0703USA04361	30-Mar-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anxiety, Convulsion, Loss of consciousness, Pain

**Symptom Text:** Information has been received from a physician, via a company representative, concerning a 13 year old female patient, who on 19-MAR-2007 was vaccinated with the first dose, IM, of Gardasil. The physician reported that "approximately 3 minutes after receiving the first dose of the vaccine, the patient passed out," and then "experienced a seizure that lasted approximately 2 minutes." The physician stated that the seizure was probably related to pain or anxiety, and indicated that the patient's status had improved after she received therapy (therapy unspecified). Seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275145-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	26-Mar-2007	26-Mar-2007	0	29-Mar-2007	30-Mar-2007	ME		05-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01884	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Paraesthesia, Paraesthesia

**Symptom Text:** Elbows bilateral tingling and numb. No shortness of breath, respiratory distress

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275151-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	06-Mar-2007	Unknown		29-Mar-2007	30-Mar-2007	MD		02-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Condition aggravated, Juvenile arthritis, Varicella

**Symptom Text:** Spoke with patient mother 3/13/07. Patient appeared to have what was thought to be chicken pox. Her rheumatologist did bloodwork and thinks that the vaccine flared up her Juvenile rheumatoid arthritis. Mother will call back with results of test and results from visit at John Hopkins.

**Other Meds:** Claritin D

**Lab Data:** Bloodwork done by rheumatologist

**History:** Amoxicillin

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275181-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	21-Mar-2007	23-Mar-2007	2	29-Mar-2007	30-Mar-2007	NY		30-Mar-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0244U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Swelling face

**Symptom Text:** Patient received 1st dose of Gardasil on 3/21/07 no co's voiced at time of injection. On Friday evening 3/23/07 patient noted face to be red and swollen, symptoms disappeared after 2 hours. On Monday 3/26/07, pateint noted same red, swollen face after ingesting glass of white wine with dinner, again symptoms lasted about 2 hours. Patient did not take any other medication during this time frame, nor had she used any new soaps/make up.

**Other Meds:**

**Lab Data:**

**History:** seasonal allergies

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275225-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	21-Mar-2007	21-Mar-2007	0	30-Mar-2007	02-Apr-2007	MA		03-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2141AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1426F		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fall, Head injury, Headache, Muscle twitching, Pallor, Staring

**Symptom Text:** Received immunizations at approximately 6:50PM, went to waiting room where brother and sister saw her fall to floor hitting her head (?left side) on a wooden playbox. They said she just stared for about 5 seconds then left arm / shoulder was twitching when RN arrived, patient was conscious and in a chair. She was pale, P68 at a FBV minutes, before 7pm, BP was 108/78, P78 standing. She was still dizzy and c/o headache, so ambulance was called. She was observed in ER and discharged home.

**Other Meds:** None

**Lab Data:** Accucheck 149, via normal EKG normal > Done at medical center

**History:** allergies - Erythromycin, Acanthosis nigricans, overweight

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1327

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275249-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
10.0	F	19-Mar-2007	19-Mar-2007	0	30-Mar-2007	02-Apr-2007	AL	WAES0703USA04310	02-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0013U	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash, Rash generalised

**Symptom Text:** Information has been received from a registered nurse concerning a 10 year old female with a penicillin allergy who on 19-MAR-2007 was vaccinated IM with a 0.5 ml second dose of Gardasil (Lot# 654741/0013U). There was no concomitant medication. On 19-MAR-2007 the patient developed a rash all over her body, especially near the injection site. The nurse reported that the patient was given BENADRYL for the rash. The patient went to see her pediatrician who reportedly prescribed the patient with prednisone an ZYRTEC. It was also reported that the patient did not have a reaction to her first dose of Gardasil. At the tiem of the report, the patient was recovering. The nurse felt that the patient's rash was an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:** Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275250-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	15-Mar-2007	18-Mar-2007	3	30-Mar-2007	02-Apr-2007	--	WAES0703USA04262	02-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Gait disturbance, Pain in extremity

**Symptom Text:** Information has been received from a physician concerning her 18 year old daughter with penicillin and sulfonamide allergy, attention deficit/hyperactivity disorder, anxiety and migraine who on 15-MAR-2007 was vaccinated, intramuscularly, with a dose of Gardasil. Concomitant therapy included TOPAMAX, STRATTERA and ZOLOFT. On 18-MAR-2007 the patient experienced "soreness in her legs" and her "knees and ankles began to hurt." The patient took ibuprofen for the symptoms. On 20-MAR-2007, the patient was not able to attend school. It was reported that she was "not walking normally" and "walking like an old lady." Unspecified medical attention was sought. There was no laboratory or diagnostic test performed. At the time of the report, the symptoms had not resolved. The physician considered "knees and ankles began to hurt" and "soreness in her legs" to be disabling events.

**Other Meds:** STRATTERA, ZOLOFT, TOPAMAX

**Lab Data:** None

**History:**

**Prex Illness:** Penicillin allergy; sulfonamide allergy; Attention deficit/hyperactivity disorder; Anxiety; Migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1329

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275251-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	15-Mar-2007	15-Mar-2007	0	30-Mar-2007	02-Apr-2007	CA	WAES0703USA03961	02-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Activities of daily living impaired, Muscle twitching, Musculoskeletal stiffness, Pain in extremity, Tourette's disorder

**Symptom Text:** Initial and follow-up information has been received from a Medical Assistant concerning a 17 year old female patient who on 15-MAR-2007 was vaccinated IM with her first dose of Gardasil, lot #654702/0011U. The reporter reported soon after the injection "her arm hurt really bad" and was stiff. On 16-MAR-2007 the patient developed sporadic twitching of her whole body. The reporter stated that the patient "looked as if she had Tourette syndrome. " On 17-MAR-2007 the patient was examined in the emergency room and was released a few hours later. She was examined by her primary physician and gynecologist. She had an appointment with a neurologist. She has not had any improvement in her symptoms of sporadic twitching, however arm pain and stiffness were subsiding. The reporter considered the events to be disabling because the patient was unable to perform her activities of daily living for a week. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275299-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	26-Mar-2007	28-Mar-2007	2	31-Mar-2007	02-Apr-2007	KY		10-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNSURE	2	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pruritus, Injection site swelling, Injection site warmth, Oedema peripheral, Paraesthesia, Paraesthesia

**Symptom Text:** Gardasil give in Right Deltoid on Monday March 26. On Wed, March 28, patient reported itching, swelling and redness in Right upper arm. 4 1/2 inch by 5 inch red, swollen, hot area noted on upper right arm. Taken to see MD on Thursday March 29. Patient started on Omnicef 300mg BID, Zyrtec 10mg QD, cool compresses and Advil PRN. On Saturday, March 31, Patient began complaints of tingling in fingers of Rt. hand. Rt. arm 3-4 cm larger than left arm. Called Dr. instructed to elevate arm and give Advil around the clock. Report increase swelling or symptoms to physician.

**Other Meds:** Previcid, Yaz

**Lab Data:**

**History:** Reflux

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275308-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	30-Mar-2007	Unknown		30-Mar-2007	03-Apr-2007	NE		03-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Seizure anoxic, Syncope vasovagal

**Symptom Text:** Vasovagal response VS Reflex anoxic seizure

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275310-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	13-Mar-2007	14-Mar-2007	1	30-Mar-2007	03-Apr-2007	FL		03-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	A17714A	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1427F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Chills, Dizziness, Headache, Pharyngolaryngeal pain, Pyrexia, Vomiting

**Symptom Text:** Received Gardasil and Menactra on same day 3/13/07 at a routine physician. Approximately 12 hours later, she began with fevers, chills, headache, dizziness, sore throat & abdominal pain, vomited x 1

**Other Meds:** None

**Lab Data:** Rapid Strep test (-), rapid influenza test (-)

**History:** Left Choroidal fissure brain cyst - stable in size

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1333

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275314-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	30-Mar-2007	30-Mar-2007	0	30-Mar-2007	03-Apr-2007	SC		03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Injection site pain, Syncope

**Symptom Text:** Dizziness, Syncope recovered in few minutes. Patient also complained of severe pain at Vaccine site. Tylenol PO given.

**Other Meds:** None

**Lab Data:** Glucose 96, B/P 104/86, Sat 99%, pulse 75

**History:** None, NKDA, H/O Reflux

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275365-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	15-Jan-2007	15-Jan-2007	0	02-Apr-2007	03-Apr-2007	--	WAES0703USA03948	03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Unknown	Intramuscular	

**Seriousness:** PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Hypokinesia, Pain in extremity

**Symptom Text:** Information has been received from a physician concerning an 18 year old female with AMOXIL allergy who on 15-JAN-2007 was vaccinated with the first dose of Gardasil (lot #655619/1427F), IM, 0.5 ml. Concomitant therapy included hormonal contraceptives (unspecified). On 15-JAN-2007, the patient experienced prolonged left arm pain and limitation of movement secondary to arm pain following the first dose of Gardasil. No redness or swelling was noted. A shoulder x-ray was negative. The patient was treated with an unspecified NSAID's (non-steroidal, anti-inflammatory drug) and was referred to a neurologist. At the time of the report, the patient's prolonged left arm pain persisted and was considered to be disabling. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** joint X-ray 01/15/07 negat

**History:**

**Prex Illness:** Penicillin allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275366-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	05-Mar-2007	05-Mar-2007	0	02-Apr-2007	03-Apr-2007	MA	WAES0703USA03899	03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0186U		Left arm	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Discomfort, Hypokinesia, Injected limb mobility decreased, Injection site pain

**Symptom Text:** Information has been received from an RN concerning a 26 year old female patient who on 05-MAR-2007 was vaccinated IM in left deltoid with a dose of Gardasil, lot #655618/0186U. Concomitant therapy included unspecified birth control pills. The nurse indicated that the patient has experienced soreness at the injection site from the dose of Gardasil since 05-MAR-2007, and described the symptoms as "uncomfortable". The patient is a dancer and cannot lift her arm. Medical attention was sought and Advil was taken for the symptoms. The patient's symptoms have improved but they have not resolved. The nurse felt that the patient's symptoms were disabling because she was unable to work as a dance instructor and cannot keep her arm up over her head. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275373-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	22-Mar-2007	24-Mar-2007	2	02-Apr-2007	03-Apr-2007	CT	CT200705	03-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0244U	0	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Rash macular, Rash pruritic

**Symptom Text:** Pt seen at office on 3/26/07 c/o itchy rash to face. Reports XS began 2 days previously. Seen by DR noted macular rash face and neck and ordered Benadryl, Prn.

**Other Meds:** Albuterol inhaler, Prevacid

**Lab Data:** None

**History:** Allergy Codeine (GI upset), HX GERD and exercise induced asthma.

**Prex Illness:** on 3/22/07 for epistaxis S/P trauma nose

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275377-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	12-Mar-2007	12-Mar-2007	0	02-Apr-2007	04-Apr-2007	IN		07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U	1	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB129AA	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Convulsion, Syncope

**Symptom Text:** Syncope and short syncopal seizure after Gardasil x2

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275392-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	07-Feb-2007	01-Mar-2007	22	02-Apr-2007	03-Apr-2007	VA		03-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1447F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Complained of rectal condyloma within 3 weeks of getting vaccine. No exposure there.

**Other Meds:**

**Lab Data:** None exam

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1339

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275428-1 (D)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Mar-2007	07-Mar-2007	6	02-Apr-2007	03-Apr-2007	NY		03-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	0943R	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1280F	1	Right arm	Intramuscular	

**Seriousness:** DIED, SERIOUS

**MedDRA PT** Aopsy, Myocarditis, Ventricular tachycardia

**Symptom Text:** presented to ED with Ventricular tachycardia. Preliminary autopsy finding of myocarditis

**Other Meds:**

**Lab Data:**

**History:** aortic and mitral valve insufficiency, unknown aetiology

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1340

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275438-1 (D)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	12-Mar-2007	26-Mar-2007	14	02-Apr-2007	03-Apr-2007	CA		19-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	

**Seriousness:** DIED, SERIOUS

**MedDRA PT** Coronary artery thrombosis, Echocardiogram abnormal, Pulmonary embolism, Sudden cardiac death, Thrombosis

**Symptom Text:** Given Gardasil vaccine dose #1 3/12/07. No adverse reaction reported. Collapsed and died on 3/26/07 secondary emboli (records unavailable). 4/3/07 T/C to coroners bureau to request prelim COD. Spoke w/investigating deputy who stated autopsy done at Medical Center. T/C to physician at Medical Center who is actually a cardiologist, not pathologist, who had responded to the code & pronounced. Spoke w/secretary who states from Death Certificate COD is sudden cardiac death and pulmonary embolism. Echocardiogram revealed very enlarged right ventricle & small left ventricle as well as large blood clots within both the right atrium & right ventricle. Letter faxed to pathology department to request final autopsy report.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275444-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	U	Unknown	Unknown		02-Apr-2007	05-Apr-2007	FL		05-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypotension, Loss of consciousness

**Symptom Text:** Patient passed out. Blood pressure remained too low for patient to get off floor for 1% 1/2 hrs.

**Other Meds:** allergy to penicillin

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1342

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275476-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	12-Mar-2007	23-Mar-2007	11	03-Apr-2007	12-Apr-2007	MS		12-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	SMALL	WYETH PHARMACEUTICALS, INC	4020076	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0011U	0	Left arm	Unknown	
	ANTH	EMERGENT BIOSOLUTIONS	FAV103	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Back pain, Pyrexia, Rash pruritic

**Symptom Text:** 1-2 wk-fever, lower back pain, lower abdominal pain. 23-MAR-broke out in small red bumps that got bigger and itched really bad.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275483-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	27-Mar-2007	28-Mar-2007	1	03-Apr-2007	05-Apr-2007	PA		06-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01888U	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain

**Symptom Text:** 16 Year old female received a 2nd dose of Gardasil vaccination next morning she woke up with generalized body aches.

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1344

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275510-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		03-Apr-2007	04-Apr-2007	FR	WAES0703USA04719	04-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Cold sweat, Dyspnoea, Injection site pain, Malaise, Sensation of foreign body

**Symptom Text:** Information has been received from a company representative via a physician's office concerning a 17 year old female who on an unspecified date was vaccinated with the first dose of Gardasil. Concomitant medication was not reported. Subsequently on an unspecified date, immediately following vaccination, the patient complained about injection site pain. The patient left the practice together with her mother. About 15 minutes post vaccination, the patient and her mother returned. At that time, the patient complained about feeling unwell and an intense global feeling in her pharynx. The patient felt like not being able to breath. The patient was treated with corticosteroids. After about 1 hour, the patient recovered from the global feeling in her pharynx but was asthenic and showed cold sweat. The patient was admitted to the hospital. The patient recovered after two days and was discharged from the hospital. Other business partner numbers included E2007-01818. Additional information is not expected.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1345

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275511-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Mar-2007	22-Mar-2007	0	03-Apr-2007	04-Apr-2007	FR	WAES0703USA05195	07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	IPV	UNKNOWN MANUFACTURER	Z0868		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0903F		Unknown	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	Z0868		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Cough, Injection site pruritus, Medication error, Pruritus, Visual disturbance, Vomiting, Wrong drug administered

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who on 22-MAR-2007 was vaccinated IM into the right arm with a first dose of Gardasil (lot# 654948/0903F; batch# NE35170). concomitant suspect therapy included given on 22-MAR-2007 included an IM into the left arm booster dose of REPEVAX (batch# Z0868). About 30 minutes later, the patient developed pruritis first at the left than at the right injection site. The patient experienced "subjective" unspecified visual disturbance for a short time. Subsequently, she vomited 5 times and experienced a dry cough and felt weak. the patient's mother brought her back to the practice. She was treated with antihistamines, prednisolone (100 mg) and inhalative salbutamol. Within about 2 hours the patient recovered. It was reported that all previous vaccinations were well tolerated. The reporter felt that pruritis at the injection site, visual disturbance, vomited 5 times, dry cough and weak were considered to be other important medical events. Other business partner numbers include: E200701842. No further information is available. The file is closed.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275542-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	27-Mar-2007	29-Mar-2007	2	03-Apr-2007	05-Apr-2007	NY		06-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Skin burning sensation, Urticaria

**Symptom Text:** Bethany went tanning at tanning bath, has tanned previous to vaccine. Did not use sun tanning lotion. 2 hrs post tanning after showering noticed hives on chest, breasts and armpits. C/O burning and itching, pt instructed no tanning until further notice per doctor. No other c/o symptoms. Hives lasted 8 hr then disappeared.

**Other Meds:** Estrostep 28

**Lab Data:**

**History:** NKA

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1347

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275552-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	26-Mar-2007	28-Mar-2007	2	03-Apr-2007	04-Apr-2007	TX		04-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Rash maculo-papular, Rash pruritic

**Symptom Text:** Patient developed itchy, maculopapular rash on the palms 2 days after Gardasil was administered. Sje also had temp of 102 which lasted less than 1 day duration. Po benadryl given.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275559-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	26-Mar-2007	27-Mar-2007	1	03-Apr-2007	04-Apr-2007	PA		04-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B009AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0186U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash papular

**Symptom Text:** patient developed a skin colored papular nonpruritic rash on arms and face 5 days after receiving hpv and tdap vaccines. came to the doctors to be evalauted for the rash. no other symptoms or sequelae

**Other Meds:**

**Lab Data:** none

**History:** nickel and lactose allergies

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275562-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	30-Mar-2007	03-Apr-2007	4	03-Apr-2007	04-Apr-2007	ME		04-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Local reaction, Urticaria

**Symptom Text:** LOCAL REACTION WITH URTICARIA

**Other Meds:** mIRENA iud

**Lab Data:**

**History:** CODEINE,SULFA,CEFZIL

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1350

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275584-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Mar-2007	01-Mar-2007	0	04-Apr-2007	05-Apr-2007	--	WAES0703USA05676	05-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Chest discomfort, Dyspnoea, Erythema, Erythema, Injection site pain, Injection site swelling, Oxygen supplementation

**Symptom Text:** Information has been received from a registered nurse (a school nurse), via a company representative, concerning a 16 year old female patient, who in March 2007, was vaccinated with a dose, 0.5ml, IM, of Gardasil. The nurse reported that on the following day, the patient developed swelling and pain at the injection site, chest tightness, shortness of breath and facial redness, and was transported by ambulance to the emergency room. The nurse stated that treatment included oxygen, and epinephrine injection, and prednisone. Following treatment "the patient's symptoms resolved and the patient completely recovered." The nurse considered the events to be life threatening and disabling. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275591-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		19-Mar-2007	17-Apr-2007	--	WAES0702USA04415	17-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Information has been received from a physician who reported that her daughter was vaccinated with her second dose of Gardasil and experienced pain during the injection. The patient stated there was no pain when she received the first dose of Gardasil. Unspecified medical attention was sought by the patient. The patient's outcome was unknown.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275618-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	04-Apr-2007	04-Apr-2007	0	04-Apr-2007	16-Apr-2007	WI		16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	02400	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Neck pain, Paraesthesia

**Symptom Text:** Pain from injection site extending into neck. Paresthesia in hand.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275622-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	21-Feb-2007	22-Feb-2007	1	04-Apr-2007	16-Apr-2007	AZ		23-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2209AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1209F	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0263U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Hypotonia, Muscular weakness, Neurological examination, Pain in extremity, Physiotherapy, Urinary tract infection

**Symptom Text:** Pt c/o pain and weakness in Lt arm persistent since admin. of vaccine in Lt arm. Dr notes pt has decrease muscle strength in Lt arm unable to make a fist and decrease tone in Lt arm. 4/10/07 Received medical records from PCP which include vax records & reveal that on day of vax patient experienced UTI s/s, UA was done & patient started on antibiotics. Returned to PCP on 4/4/07 w/complaints of left arm weakness since vax. Exam revealed decreased left arm muscle strength. Patient was unable to make a fist w/left hand & had decreased muscle tone in left arm. Received neuro & PT referrals.

**Other Meds:** Minocycline, Dafferin gel

**Lab Data:** Dr examined referred to PT and neurology consult.

**History:** None

**Prex Illness:** U.T.I.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275623-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
0.0	F	17-Oct-1994	Unknown		04-Apr-2007	16-Apr-2007	CO		06-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	0908F	1	Right arm	Subcutaneously	
	MNQ	AVENTIS PASTEUR	U1875AA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1427F	0	Left leg	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB143BA	0	Right leg	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Injection site erythema, Injection site swelling, Oedema peripheral

**Symptom Text:** Right upper arm swelled and turned red. Was given on ABD, steroid and pain killer about Fri PM 13/30/07. Seen again by NP - no meds given at that time. Arm by 4-1-07 was red and swollen from elbow to shoulder and was resolving.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275629-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		05-Apr-2007	09-Apr-2007	--	WAES0703USA04205	09-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a medical office receptionist who saw a news report in which it was reported that a female patient who was vaccinated with Gardasil experienced a seizure. She had no further information and reported she only saw part of the news report. Upon internal review, seizure was considered an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275630-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	07-Feb-2007	07-Feb-2007	0	05-Apr-2007	06-Apr-2007	--	WAES0703USA05393	06-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Foetal heart rate abnormal

**Symptom Text:** Information has been received from a 24 year old female with no drug reactions or allergies and no pertinent medical history who on 07-FEB-2007 was vaccinated with the first dose of Gardasil. There was no concomitant medication. The patient reported that she was pregnant when she received her first injection of Gardasil. The patient reported that she did have an appointment with OB/GYN and the physician did not hear a heartbeat and she was therefore being referred for an ultrasound. The patient stated that her physician advised her to continue the injections with Gardasil, but the patient decided not to get the other two shots. Upon internal review it was determined that "physician did not hear a heartbeat" was considered an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1357

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275631-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	02-Feb-2007	01-Dec-2006	-63	05-Apr-2007	09-Apr-2007	PA	WAES0703USA05511	07-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Arthralgia, Dizziness, Headache, Loss of consciousness, Vision blurred

**Symptom Text:** Information has been received from a physician concerning a 13 year old female who on 18-DEC-2006 was vaccinated with a first dose of Gardasil (lot #654389/0961F). There was no concomitant medication. Subsequently, the patient experienced hip, knee and ankle pain. In January 2007, the patient began to experience occasional episodes of blurry vision. On 02-FEB-2007, the patient was vaccinated with a second dose of Gardasil. It was reported that the patient's symptoms "severely worsened" following the second dose of Gardasil and the patient also experienced lightheadedness and increase in headaches. The patient was seen by an orthopedic physician on 02-FEB-2007. Unspecified laboratory and diagnostic tests were performed (results not reported). On 07-FEB-2007 the patient experienced "one episode of blacking out." The patient saw a neurologist on 20-MAR-2007. At the time of the report, the patient had not recovered. The reporting physician considered the events to be disabling as the patient was unable to participate in ballet or dancing classes. Additional information has been requested.

**Other Meds:** None

**Lab Data:** diagnostic laboratory - results not reported

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275639-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	15-Mar-2007	23-Mar-2007	8	05-Apr-2007	16-Apr-2007	NC		16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0955F	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Bone pain, Myalgia, Tendonitis

**Symptom Text:** myalgias, bone pain, tendonitis

**Other Meds:**

**Lab Data:**

**History:** Amox, itching; hx eczema, hay fever

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275693-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	16-Feb-2007	Unknown		05-Apr-2007	16-Apr-2007	NJ		16-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		00140	1	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Limb discomfort, Pain

**Symptom Text:** c/c-pain-odd sensation in legs-first dose-adm by Gyn (MD) November 2006. 2nd dose-adm by PMD-Feb 2007- Symptoms-started Feb2-have increased since

**Other Meds:**

**Lab Data:** labs done 3-30-2007

**History:** NONE

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275694-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	02-Apr-2007	02-Apr-2007	0	05-Apr-2007	16-Apr-2007	CA		16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2659AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0181U		Left arm	Unknown	
	MNC	UNKNOWN MANUFACTURER	U2221BA		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Pallor, Pyrexia

**Symptom Text:** Mother explained when child woke up 4-3-07 a day after immunization she noticed her skin was pale, weak and has fever.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275701-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	07-Mar-2007	Unknown		06-Apr-2007	09-Apr-2007	FR	WAES0704POL00002	09-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Peritoneal abscess, Polycystic ovaries

**Symptom Text:** Information has been received from a physician concerning a 13 year old female who on approximately 07-MAR-2007 was vaccinated with Gardasil. In March 2007, the patient experienced polycystic ovaries and peritoneal abscess (10 centimetres in diameter) and was hospitalized. The patient was treated with antibiotic intravenously. After treatment with antibiotic the diameter of the abscess was about 3 centimetres. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275702-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	01-Feb-2007		06-Apr-2007	09-Apr-2007	MN	WAES0703USA05521	09-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Information has been received through the pregnancy registry from a physician concerning a female teenager who was vaccinated with a first dose of Gardasil without the knowledge that she was pregnant. It was found out that the patient was pregnant after the administration of the vaccine. Later the patient had a miscarriage. As per the reporter, the miscarriage happened "last month or so." Medical attention was sought. The patient was recovering. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:**

**Prex Illness:** Pregnancy NOS (LMP=unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275703-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	26-Mar-2007	Unknown		06-Apr-2007	09-Apr-2007	--	WAES0703USA05647	09-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Abdominal pain

**Symptom Text:** Information has been received from a pharmacist (PharmD) concerning a female (age unknown) patient who on 26-MAR-2007 was vaccinated with a dose of Gardasil which was thought by the reporter to be her initial dose. Subsequently, on an unspecified date, the patient experienced generalized abdominal pain and was hospitalized on 29-MAR-2007 to rule out appendicitis. The pharmacist stated that all of the patient's test have come back normal but could not identify specifically what tests or labs were performed. It was noted that the patient was treated with IV fluids and pain medication as needed. At the time of this report, the patient had not recovered. No product quality complaint was involved. The reporter considered generalized abdominal pain to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** diagnostic laboratory - normal

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1364

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275704-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	13-Mar-2007	13-Mar-2007	0	06-Apr-2007	09-Apr-2007	FL	WAES0703USA05514	09-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Emergency care examination, Fatigue, Neurological examination

**Symptom Text:** Information has been received from a physician concerning a 24 year old white female with no pertinent medical history who on 13-MAR-2007, at 08:30, was vaccinated, into the right deltoid, with a first dose of Gardasil (lot #657006/0188U). Concomitant therapy included ZYRTEC-D, AMBIEN CR and ALEVE. On 13-MAR-2007, at approximately 19:00, the patient had a seizure while driving. The patient went to the emergency room and underwent unspecified blood tests and a computed axial tomography (results not reported). On 14-MAR-2007, the patient was too tired to go to work. The patient was advise to follow-up with a neurologist. It was recommended that the remainder of Gardasil series was held until neurologic work up was complete. Upon internal review, the patient's seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** ZYRTEC-D; AMBIEN CR; ALEVE

**Lab Data:** computed axial 03/13/07 - results not reported; diagnostic laboratory 03/13/07 - results not reported

**History:** None

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1365

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275705-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	16-Jan-2007	26-Feb-2007	41	06-Apr-2007	09-Apr-2007	FR	WAES0703USA05447	10-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0902F	0	Unknown	Intramuscular			

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Burning sensation, Escherichia infection, Herpes simplex, Rash pustular, Skin fissures, Superinfection, Vaginal inflammation, Vulvovaginal discomfort

**Symptom Text:** Information has been received from a gynaecologist concerning a 17 year old female who on 16-JAN-2007 was vaccinated with the first dose of Gardasil, (lot #654884/0902P, batch #NE24240), IM into the upper arm. Concomitant medication was not reported. On 26-FEB-2007, the patient experienced rhagades, pustules and burning feeling of vulva. On 28-FEB-2007, the patient developed severe inflammation of introitus vaginae. The patient was admitted to hospital on 02-MAR-2007. Severe herpes simplex genitalis and a superinfection with Escherichia coli were diagnosed. the patient was treated with acyclovir and antiinfectives. On an unspecified date, the following laboratory tests were performed leukocytes 6.4 nl, hemoglobulin 13.6 g/dl, hematocrit 39.5%, thrombocytes 251.000 micro/L, IgM positive, IgG positive, vaginal smear showed Escherichia coli and HSV-PCR diagnosed herpes simplex type I. On 07-MAR-2007, the patient was discharged from the hospital. Subsequently on an unspecified date, the patient recovered completely from herpes simplex type I and superinfection. On 19-MAR-2007, the patient received the second dose of Gardasil which was well tolerated (up to the reporting date). File closed. No further information is available.

**Other Meds:** Unknown

**Lab Data:** cervical smear 02?Mar07- Comment: showed Escherichia coli; HSV type and/or 2 identification PCR 02?Mar07 - Comment: Type I diagnosis made by HCR-PCR; WBC count 02?Mar07 6.4 nl; hematocrit 02?Mar07 39.5%; hemoglobin 02?Mar07 13.6 g/dl; plat

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275706-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		06-Apr-2007	09-Apr-2007	--	WAES0703USA05352	09-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Guillain-Barre syndrome

**Symptom Text:** Information has been received from a nurse concerning a female (age not reported) who on an unspecified date was vaccinated with a dose of Gardasil. Subsequently the patient developed Guillian-Barre syndrome. At the time of this report, the outcome was unknown. Upon internal review, Guillian-Barre syndrome was considered an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275707-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		06-Apr-2007	09-Apr-2007	--	WAES0703USA05351	09-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a nurse concerning a female (age not reported) who on an unspecified date was vaccinated with a dose of Gardasil. Subsequently the patient experienced "ongoing seizures". Upon internal review, the patient's seizures were considered an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275708-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	22-Mar-2007	22-Mar-2007	0	06-Apr-2007	09-Apr-2007	--	WAES0703USA04990	09-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Convulsion, Emergency care examination, Injection site irritation, Loss of consciousness

**Symptom Text:** Information has been received from a certified nurses aid concerning a 19 year old female who on 22-MAR-2007 was vaccinated with the first dose of Gardasil. Concomitant medication was reported as none. On 22-MAR-2007, the patient experienced burning feeling at the injection site, the patient passed out and had a seizure for about 10 minutes. An ambulance was called and the patient was rushed to the emergency room. The outcome and causality of the events were not reported. Burning feeling at the injection site, passed out and seizure were considered to be other important medical events. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275712-1 (S) **Related reports:** 275712-2; 275712-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	03-Apr-2007	03-Apr-2007	0	06-Apr-2007	12-Apr-2007	FL		13-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U226AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Computerised tomogram abnormal, Fall, Head injury, Headache, Neck pain, Subarachnoid haemorrhage, Syncope, Unresponsive to stimuli

**Symptom Text:** Fainted within 10 min of receiving vaccines and fell backward and hit head on carpeted floor was unresponsive for 20-30 seconds. Complained of headache and neck pain. Transported to ER - CT showed traumatic subarachnoid hemorrhage. Transferred to PICU

**Other Meds:**

**Lab Data:**

**History:** Allergic to penicillin

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275712-2 (S) **Related reports:** 275712-1; 275712-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	02-Apr-2007	02-Apr-2007	0	13-Apr-2007	16-Apr-2007	FL	WAES0704USA00912	01-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Dizziness, Fall, Head injury, Intensive care

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 13 year old female patient with a history or vasovagal response to vaccine who on 02-APR-2007 was vaccinated with a first dose 0.5 mL of Gardasil. Concomitant therapy included Menactra. On 02-APR-2007 the patient felt dizziness and fell on the ground. The patient was hospitalized in intensive care for head injury but did not require any surgery. At the time of this report patient was still in the hospital and had not recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:** Vasovagal reaction

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1371

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275712-3 (S) **Related reports:** 275712-1; 275712-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	02-Apr-2007	02-Apr-2007	0	04-May-2007	07-May-2007	FL	200701352	07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Dizziness, Fall, Head injury

**Symptom Text:** Initial report received on 19 April 2007 from another manufacturer, report# WAES0704USA00912. The initial reporter to this manufacturer had been a health care professional. Verbatim from the report: "Information has been received from a Registered nurse (R.N.) concerning a 13 year old female patient with a history of vasovagal response to vaccine who on 02-APR-2007 was vaccinated with a first dose of 0.5 mL of Gardasil. Concomitant therapy included MENACTRA. On 02-APR-2007 the patient felt dizziness and fell on the ground. The patient was hospitalized in intensive care for head injury but did not require any surgery. At the time of this report patient was still in the hospital and had not recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** Vasovagal reaction

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275734-1      **Related reports:** 275734-2; 275734-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	03-Apr-2007	03-Apr-2007	0	06-Apr-2007	09-Apr-2007	MD		10-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TTOX	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	NULL	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chromatopsia, Dyspnoea, Hypotension, Injection site pain, Oral pain, Pharyngolaryngeal pain, Photopsia

**Symptom Text:** Within one minute following injections, Bonnie experienced flashing lights in her eye; could only see in bright primary colors; had extreme trouble breathing; experienced pain in top of mouth and throat; pain at injection site; blood pressure was low. Symptoms started to subside after injection of Epinephrine and use of Nebulizer. She has no history of food or pollen allergies.

**Other Meds:** none

**Lab Data:**

**History:** Previous reaction to DPT vaccine (seizure)Previous reaction to dental sealants (multiple canker sores, unexplained muscle twitching, rash on trunk of body)Previous reaction to sulfa based eye drops prescribed for pinkeye

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1373

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275734-2 (S) **Related reports:** 275734-1; 275734-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	03-Apr-2007	03-Apr-2007	0	11-Apr-2007	12-Apr-2007	MD	WAES0704USA00708	13-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0091U	0	Unknown	Unknown	
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Hypotension, Paraesthesia oral, Throat irritation, Vision blurred

**Symptom Text:** Information has been received from a physician, concerning a 14 year old female patient with a drug hypersensitivity to pertussis and a sulfonamide allergy, who on 03-APR-2007 was vaccinated with the first dose of Gardasil (Lot # 655322/0091U) (dose and route not provided). Concomitant vaccines administered on 03-APR-2007 included MENACTRA. On 3-APR-2007, the patient experienced blurry vision, tingling in her mouth and throat, and low blood pressure (not specified) "within 30 seconds of vaccination with Gardasil. "The patient was given epinephrine and albuterol in the physician's office, and was then sent to the ER. Treatment in the ER included steroids (unspecified). The physician indicated that the patient recovered on the same day, 03-APR-2007. The physician considered the blurry vision, tingling of the mouth and throat, and low blood pressure to be disabling, life threatening, and an other medical event. Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:**

**Prex Illness:** Drug hypersensitivity; sulfonamide allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1374

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275734-3 (S) **Related reports:** 275734-1; 275734-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	03-Apr-2007	03-Apr-2007	0	04-May-2007	07-May-2007	MD	200701349	07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Hypotension, Paraesthesia, Paraesthesia oral, Vision blurred

**Symptom Text:** This case was received from another manufacturer (reference number WAES0704USA00708) on 19 April 2007. The following information is verbatim as it appears in the other manufacturer's report: "This is in follow-up to report(s) previously submitted on 4/10/2007. Information has been received from a physician, concerning a 14 year old female patient with a drug hypersensitivity to pertussis and a sulfonamide allergy, who on 03-APR-2007 was vaccinated with the first dose of Gardasil (Lot# 65532210091U) (dose and route not provided). Concomitant vaccines administered on 03-APR-2007 included tetanus toxoid and MENACTRA. On 03-APR-2007, the patient experienced blurry vision, tingling in her mouth and throat, and low blood pressure (not specified) "within 30 seconds of vaccination with Gardasil. The patient was given epinephrine and albuterol in the physician's office, and was then sent to the ER. Treatment in the ER included steroids (unspecified). The physician indicated that the patient recovered on the same day, 03-APR-2007. Follow up information from the physician indicated that at the time of vaccination, the physician was "unaware of the reactions the patient had experienced following exposure to the pertussis vaccine and sulfa as these occurred when the patient was a small child." The physician clarified that he did not consider the events to be life threatening, but confirmed that the patient would not receive additional doses of Gardasil. The physician considered the blurry vision, tingling of the mouth and throat, and low blood pressure to be life threatening, and an other medical event. Additional has been requested.

**Other Meds:**

**Lab Data:**

**History:** Drug hypersensitivity to pertussis; Sulfonamide allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1375

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275740-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	18-Dec-2006	19-Dec-2006	1	08-Apr-2007	09-Apr-2007	PA		10-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Arthralgia, Dizziness, Groin pain, Headache, Loss of consciousness, Pain, Physiotherapy, Vision blurred

**Symptom Text:** SYMPTOMS: Groin/hip, knee, ankle pain (began following Gardasil Vaccine Shot #1 12/18/06; severely worsened following Gardasil Vaccine Shot #2 2/2/07) Light-headedness, increased headaches (began following Gardasil Vaccine Shot #1; increased following Gardasil Vaccine Shot #2) Episodes of blurred vision (occasional episodes Jan thru present 2007) One episode of "blacking out" while in shower (Feb 2007) Swelling in knees TREATMENT: Been under the care of orthopaedic sports medicine doctor since 2/2/07 Had series of Xrays. hips, knees, ankles --- nothing out of the ordinary shown Participated in 6 weeks physical therapy --- pain increased to point of discontinuing PT at suggestion of physical therapist and orthopaedic doctor Had blood work done. --- nothing out of the ordinary shown Met with Dr. neurologist 3/20/07 --- office tests show nothing out of the ordinary. prescribed change in diet and charting of headaches. follow-up appt in early May Began Ibuprofen therapy (4x per day for 2 weeks) for swelling and hips/knees/ankles as prescribed by orthopaedic doctor on 3/21/07. follow-up appt 4/6/07. Next step: schedule appointment with rheumatologist; begin physical therapy again as prescribed by orthopaedic doctor

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1376

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275779-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	28-Nov-2006	31-Jan-2007	64	09-Apr-2007	10-Apr-2007	IL	WAES0704USA00075	11-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a consumer and a licensed practical nurse, through the pregnancy registry, concerning a 23 year old female, who was vaccinated on 28-SEP-2006 with the first dose of Gardasil, and on 28-NOV-2006 with the second dose of Gardasil (Lot # 653735/0688F). There was no concomitant medication. The nurse reported that on 26-FEB-2007 (consumer reported as 13-MAR-2007, "some time after"she received the second dose) the patient had a miscarriage. The date of the last LMP was approximately 31-JAN-2007 ("late January"). According to the consumer, lab diagnostic tests included "several blood tests, ultrasounds, vaginal probe" (results not provided). On 29-MAR-2007, the third dose of Gardasil (Lot # 654389/0961F) was administered to the patient, and the nurse reported the patient "was fine" at that visit. The miscarriage was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Diagnostic laboratory 02/26/07, gynecological 02/26/07, ultrasound 02/26/07

**History:**

**Prex Illness:** Pregnancy NOS (LMP = 1/31/2007)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1377

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275780-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Jan-2007	Unknown		09-Apr-2007	10-Apr-2007	FR	WAES0704USA00470	11-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0902F		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Generalised erythema, Injection site discolouration, Pruritus generalised

**Symptom Text:** Information has been received from a gynaecologist concerning a 17 year old female with a history of contraception use who on 23-JAN-2007 was vaccinated with Gardasil (lot # 654884/0902F; batch # NE24240) into the left upper arm (number in the series not reported). Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. On 23-JAN-2007, the same day, the patient experienced generalized pruritus and redness, She was treated with antihistamines and recovered on 24-MAR-2007. On an unspecified date in 2007, the patient developed a "white spot" (diameter approximately 4 cm) in the area of the injection site . At the time of reporting, the white spot was ongoing. This was supposed to be a "persisting damage". The events were ongoing to be serious as Other Important Medical Events. File closed. Other business partner numbers included: E2007-01992. No further information is available.

**Other Meds:** hormonal contraceptives (unspecified) Unk - Unk

**Lab Data:** None

**History:** Contraception

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275805-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	06-Apr-2007	07-Apr-2007	1	09-Apr-2007	11-Apr-2007	CO		11-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Head injury, Nausea, Vertigo

**Symptom Text:** Patient reported "dizziness", "room spinning", some nausea symptoms beginning 11 hours after administration of vaccine. Dizziness woke patient during the night due to severity. Symptoms were continuing at time of discussion with patient at approximately 56 hours after administration. Symptoms worsen with position change, movement. Patient also reports striking top of head in a swimming pool approximately 4 hours after receiving vaccination. Patient will see MD if symptoms do not improve.

**Other Meds:** None known

**Lab Data:**

**History:** None known

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275812-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	04-Apr-2007	04-Apr-2007	0	09-Apr-2007	17-Apr-2007	AL		17-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Gluteous maxima	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** 1 1/2 hr after patient received Gardasil injection, pt developed "worse headache I ever had." lasting several hours.

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1380

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275814-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	09-Apr-2007	09-Apr-2007	0	09-Apr-2007	17-Apr-2007	OK		17-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	12142AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anxiety, Fall, Loss of consciousness, Syncope

**Symptom Text:** Approx 2-3 min after vaccine admin, pt experienced syncope episode with 2-3 sec loss of consciousness and fall to ground from own height. Pt had not eaten that day and had expressed anxiety re: immuniz. prior to event vs immediately after event BP-110/70; P-130/min, R-24/min, O2 sat 98%. Placed pt in recumbent position and gave her mild to drink. Fs OS-109 mg/dl. Fully recovered w/in 10 min BP-100/70; P-88/mm; R-16/mn O2 Sat 99%. Recovered at 11:55 in stable condition.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275815-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	03-Feb-2007	03-Feb-2007	0	09-Apr-2007	17-Apr-2007	MO		17-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Hyperhidrosis, Pharyngeal oedema

**Symptom Text:** Within 1 hr after pt left office per pt she experienced dizziness, sweating, SOB and throat swelling. Pt had to use albuterol inhaler.

**Other Meds:** Zyrtec, Albuterol inhaler

**Lab Data:** none

**History:** Asthma, Seasonal Allergies

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1382

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275819-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	30-Mar-2007	01-Apr-2007	2	09-Apr-2007	17-Apr-2007	NC		17-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1213F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration

**Symptom Text:** 5cc of erythema/induration right u pper arm. Claritin, cool compresses.

**Other Meds:** none

**Lab Data:**

**History:** obesity

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275823-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	14-Mar-2007	23-Mar-2007	9	09-Apr-2007	17-Apr-2007	MI		17-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1149F	1	Left arm	Subcutaneously	
	TDAP	AVENTIS PASTEUR	C2492BA	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1892AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** On 3/23/07, had "bump" with 2 smaller bumps" on labia. 3-24-07 another appeared, but "first was almost gone" Referred to private physician.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275829-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	04-Apr-2007	04-Apr-2007	0	09-Apr-2007	17-Apr-2007	FL		17-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1932AB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Gait disturbance, Hypotension, Pallor, Syncope

**Symptom Text:** Dizziness, pt stated that she was feeling tired, faint, could not walk, almost passed, pale face, low blood pressure. But she was conscious the whole time. The whole episode happened about 10 minutes after receiving the vaccines. She was monitored in the office until she was feeling better. She walked out of the office at 1230 PM. Received the shots at 1140.

**Other Meds:**

**Lab Data:** Blood Glucose (normal)

**History:** None/NKDA

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275830-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	12-Jan-2007	12-Jan-2007	0	09-Apr-2007	17-Apr-2007	FL		17-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2117AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fall

**Symptom Text:** At the check out patient was standing and then fell on the floor was taken to the room. She was awake, alert, vital signs were normal, stayed in the room for 15-20 minutes and left when she felt better.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275899-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	12-Mar-2007	19-Mar-2007	7	10-Apr-2007	11-Apr-2007	PA	WAES0704USA00353	11-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Feeding disorder, Movement disorder, Tic

**Symptom Text:** Information has been received from a physician concerning a 15 year old female patient with Opitz syndrome (hypertelorism-hypospadias), Turner's syndrome and migraines who was on 12-MAR-2007 vaccinated with a first dose of Gardasil, lot #654389/0961F (dose not reported). Concomitant therapy included TOPAMAX, fentanyl and other "unknown medications". On 19-MAR-2007 the patient developed a movement disorder characterized by "verbal and bodily" tics. On 20-MAR-2007 patient was hospitalized and treated with IV fluids. Unspecified laboratory tests were normal. She was seen by a neurologist who felt her tics were volitional because she could stop them when asked. Another neurologist felt the tics were not volitional because they occurred in her sleep. At the time of this report, the patient had not recovered. The physician considered the events to be disabling since she was unable to feed herself. Additional information has been requested.

**Other Meds:** (therapy unspecified), fentanyl, TOPAMAX

**Lab Data:** Unknown

**History:**

**Prex Illness:** Turner's syndrome; Migraine; Hypertelorism

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275915-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	02-Apr-2007	02-Apr-2007	0	10-Apr-2007	17-Apr-2007	IN		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U	2	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Skin laceration

**Symptom Text:** Student received Gardasil at 1500 on 4/2/07 - tolerated vaccine well - returned to dorm - subsequently passed out in dorm bathroom causing laceration to head.

**Other Meds:** None

**Lab Data:**

**History:** Allergic to Ceclor

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275921-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	Unknown	Unknown		10-Apr-2007	17-Apr-2007	TX		18-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0244U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Arthralgia, Musculoskeletal pain, Pain in extremity

**Symptom Text:** On 3-24 07 patient developed pain on her left shoulder /left elbow/left knee / left shin/and left ankle (no arthritis) (injection was left arm)

**Other Meds:** Gynazole vaginal cream

**Lab Data:**

**History:** Acne

**Prex Illness:** Yeast vaginitis

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1389

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275935-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	10-Apr-2007	10-Apr-2007	0	10-Apr-2007	11-Apr-2007	CA		11-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** 10 minutes after administration of Gardasil in left deltoid, patient reported feeling a little dizzy. She was seated and instructed to hold her head down between her knees, with some improvement. Vital signs included B/P 76/50 (left arm) [B/P from 20 minutes earlier was 98/70]. Patient was monitored for 45 minutes, given Gatorade 12 oz and 16 oz water. Symptoms of dizziness completely resolved, with persistent stable B/P in the 90s/60s, both arms, sitting and standing.

**Other Meds:** None

**Lab Data:**

**History:** NKA/NKDA

**Prex Illness:** UTI

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275951-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	03-Apr-2007	07-Apr-2007	4	11-Apr-2007	18-Apr-2007	OH		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	03844	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	00014	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Broke out with rash and hives 4-7-07 x 3 days.

**Other Meds:**

**Lab Data:**

**History:** Med allergy to Sulfa

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275961-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Feb-2007	18-Mar-2007	18	10-Apr-2007	17-Apr-2007	NJ		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B014AA	5	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB143BA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Grand mal convulsion, Headache, Hypoaesthesia, Nausea

**Symptom Text:** 22 Days after receiving the above vaccines, she experienced numbness in her right hand and a headache and nausea. The next morning those symptoms were resolved. After being awake for 10 minutes she had a grand mal seizure. Duration 2-3 minutes. Emergency evaluation revealed a normal exam. PMH - significant for epilepsy. Dx 11/05 on Lamictal last seizure 1/06.

**Other Meds:** Lamictal

**Lab Data:** EEG --> B/L abnormal activity

**History:** Epilepsy, recurrent headaches

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1392

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275989-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	29-Jan-2007	08-Feb-2007	10	11-Apr-2007	12-Apr-2007	NY	WAES0704USA00603	13-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Diplopia, Optic neuritis, Vision blurred

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 16 year old female with no pertinent medical history who on 29-JAN-2007 was vaccinated, intramuscularly , into the left deltoid, with a 0.5 ml dose of Gardasil (lot #"1424K"). There was no concomitant medication. On 08-FEB-2007 the patient developed optic neuritis, blurred vision and double vision and was hospitalized. The patient was discharged from the hospital on 13-FEB-2007 when her vision returned to normal. At the time of the report, the patient was recovering under the care of a retinologist. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Unknown

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275990-1 (D)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		11-Apr-2007	12-Apr-2007	--	WAES0704USA00721	13-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** DIED, ER VISIT, SERIOUS

**MedDRA PT** Death, Thrombosis

**Symptom Text:** Information has been received from a physician's assistant (PA), via a company representative, concerning a female patient who was vaccinated (date unspecified) with a dose of Gardasil the PA reported that "the patient died of a blood clot 3 hours after getting the Gardasil vaccine." The PA clarified that the patient was not vaccinated at her office. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1394

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275991-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		11-Apr-2007	12-Apr-2007	TN	WAES0704USA00736	13-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cervical dysplasia, Cervical dysplasia, Condition aggravated

**Symptom Text:** Information has been received from a physician concerning a 19 year old female patient, sexually active for less than 1 year, who in December 2006 was vaccinated with a first dose of Gardasil. A papanicolaou smear (PAP) test was done on the same day as the vaccination and the results showed cervical intraepithelial neoplasia (CIN) 2 or 3. After her second injection with Gardasil vaccine (yeast) she required conization due to the rapid development of CIN. Human Papillomavirus (HPV) types were unknown. The physician felt that rapid development of CIN was an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** colposcopy, Pap test 12/??/06 - Results showed CIN 2 or 3

**History:**

**Prex Illness:** Sexually active; Cervical intraepithelial neoplasia II

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275992-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	04-Mar-2007	Unknown		11-Apr-2007	12-Apr-2007	TN	WAES0704USA00776	13-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

**MedDRA PT** Stevens-Johnson syndrome

**Symptom Text:** Information has been received from a physician concerning a friend of a friend's 11 or 12 year old daughter who on approximately 04-MAR-2007 ("about 1 month ago") was vaccinated with a first dose of Gardasil. In approximately March 2007, the patient developed Stevens-Johnson Syndrome and was hospitalized. Her recovery status was unknown at the time of the report. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1396

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275993-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	26-Mar-2007	26-Mar-2007	0	11-Apr-2007	12-Apr-2007	VA	WAES0704USA00946	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0243U		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Computerised tomogram normal, Dizziness, Fall, Head injury, Loss of consciousness, Neck injury, Pyrexia

**Symptom Text:** Information has been received from a licensed practical nurse (LPN), via company representative, concerning a 16 year old female patient with a sulfonamide allergy, who on 26-Mar-2007 was vaccinated with a dose of 0.5ml, IM, of Gardasil (Lot # 656372/0243U). Concomitant therapy included LOESTRIN. The nurse reported that on 26-MAR-2007, "about 15 minutes" after the vaccination, the patient felt dizzy, passed out, "hitting her face and head as she fell." The patient was taken to the ER, and was treated wit intravenous fluids and TYLENOL. A computed tomography (CT) was performed to evaluate for head and neck injury; the CT result was negative. The nurse added that the patient also developed a low grade fever (date not specified). At the time of this report, the nurse indicated that the patient had recovered from the events. Felt dizzy, passed out, hitting her face and head as she fell, and low grade fever were considered to be an other important medical event. Additional information has been requested.

**Other Meds:** LOESTRIN

**Lab Data:** Head computed axial 03/26/07 - Negative

**History:**

**Prex Illness:** Sulfonamide allergy

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1397

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275994-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		11-Apr-2007	12-Apr-2007	FR	WAES0704USA01086	13-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Erythema multiforme

**Symptom Text:** Information has been received from a pediatrician concerning an adolescent female who was vaccinated, intramuscularly, into the upper arm, with a first dose of Gardasil. Approximately 3 week after the vaccination the patient experienced erythema exsudativum multiforme and was hospitalized. She was treated with intravenous corticosteroids. Subsequently, the patient recovered (exact duration not reported). No further information is available. Other business partner numbers included E2007-02193.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 275999-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	20-Mar-2007	22-Mar-2007	2	11-Apr-2007	16-Apr-2007	--		16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Abdominal pain, Mental disorder, Nausea, Vomiting

**Symptom Text:** A 17-year-old female who was brought to the emergency room because of progressively worsening right-sided abdominal pain since the day before her admission. She developed some nausea and had emesis in the emergency room. No previous history of abdominal pain. Additionally, she had received an injection of Gardasil three to four days prior to onset of these symptoms. She has no fever and no chills, No chest pain. Nausea and vomiting, as stated. No diarrhea. She did have a normal bowel movement yesterday. Her periods had been regular until she was started on Depo-Provera. No fever. No chills. No significant weight changes. No history of diabetes. Mental health problems as stated earlier.

**Other Meds:**

**Lab Data:** Her blood pressure is 118/79, temperature 36.7, pulse 81 and respirations 22. HEAD, EARS, EYES, NOSE AND THROAT Unremarkable. Conjunctivae are pink. Buccal mucosa are moist. No cervical lymphadenopathy. Thyroid not palpable. CHEST Clear to

**History:** Her medical history includes a long psychiatric history with anxiety and panic disorder, posttraumatic stress disorder and attachment disorder. No known medication allergies. The family history is not known. She is adopted. She has been adopted since age 5. No history of alcohol or tobacco.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276004-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	04-Apr-2007	04-Apr-2007	0	11-Apr-2007	18-Apr-2007	WI		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	02440	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Neck pain, Paraesthesia

**Symptom Text:** Pain from injection site extending into neck. Paraesthesia in hand.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276006-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Mar-2007	Unknown		11-Apr-2007	18-Apr-2007	OH		18-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0187U	2	Right arm	Intramuscular	HPV4 UNK	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Medication error

**Symptom Text:** Inadvertently gave the 3rd dose 2 days after the 2nd dose (of Gardasil).

**Other Meds:**

**Lab Data:** None

**History:** ANA (+), arthritis

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276013-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	13-Mar-2007	13-Mar-2007	0	11-Apr-2007	18-Apr-2007	OR		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1426F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia, Rash, Urticaria

**Symptom Text:** Moderate Fever, widespread rash/hives

**Other Meds:** Effexor XR 150 mg; Lexapro 10 mg; Ortho Evra Patch

**Lab Data:** None

**History:** Allergy Augmentin and Penicillin

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1402

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276037-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	27-Mar-2007	29-Mar-2007	2	11-Apr-2007	12-Apr-2007	AZ		12-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	SMALL	WYETH PHARMACEUTICALS, INC	4020076	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	
	ANTH	EMERGENT BIOSOLUTIONS	FAV106	0	Left arm	Subcutaneously	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Erythema, Insomnia, Lymph node pain, Lymphadenopathy, Nausea, Pruritus, Pyrexia, Rash generalised, Vomiting

**Symptom Text:** 29 Mar 07 developed rash all over body that lasted approx. 3 days/ took benedryl or claritin for releif. 3Apr 07 lymph nodes became tender and enlarged. 5 Apr 07 lymph nodes hot, red, sore, and itchy accompanied by nausea, vomiting, diarrhea, and fever that desipated on 8 Apr 07. some lymph nodes are still enlarged and have had a hard time sleeping through the night since I received the vaccinations.

**Other Meds:** Macrobid- UTI preventative, Naproxen- PRN for pain

**Lab Data:** none

**History:** Med allergies: Morphine, Codeine, Demoral, Penicillin

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276042-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	11-Apr-2007	11-Apr-2007	0	11-Apr-2007	12-Apr-2007	FL		12-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Confusional state, Crying, Fall, Head injury, Loss of consciousness

**Symptom Text:** APPROXIMATELY 10 MINUTES AFTER VACCINE ADMINISTRATION CLIENT PASSED OUT FALLING AND HITTING HER HEAD. CLIENT AROUSED IN A FEW SECONDS. VITAL SIGNS CHECKED. APPROXIMATELY 20 MINUTES LATER CLIENT REPORTED FEELING ANXIOUS AND CONFUSED, CRYING, AMBULANCE CALLED

**Other Meds:** NONE KNOWN

**Lab Data:** TRANSFERRED BY AMBULANCE TO MORTON PLANT HOSPPER MOTHERS REPORT: CLIENT GIVEN IV FLUIDS AND CT SCAN. MOTHER REPORTS CT SCAN NORMAL BUT DID NOT R/O OR CONFIRM CONCUSSION CLIENT RELEASED FROM HOSPITAL AROUND NOON. MOTHER REPORTS ED RECOMMEN

**History:** NONE KNOWN

**Prex Illness:** NONE KNOWN

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276063-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	05-Apr-2007	05-Apr-2007	0	11-Apr-2007	18-Apr-2007	RI		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1300F	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0011U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Hyperhidrosis, Pallor, Pharyngolaryngeal pain, Syncope, Tremor

**Symptom Text:** 2-3 min after receiving vaccination while standing had syncopal episode, sweaty, shaking sore throat white lips after 5-10 mins. 12 cups of H2O felt better BP 90/60 BP normal taken prior to exam 106/62 P 80

**Other Meds:**

**Lab Data:** none

**History:** anaphylaxis to bees (epi pen)

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276064-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Mar-2007	22-Mar-2007	0	11-Apr-2007	18-Apr-2007	RI		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypotension, Loss of consciousness

**Symptom Text:** Passed out in hallway after receiving vaccine. BP 90/30 then elevated to 98/60 took 15 mins to be able to sit up BP normal taken prior to exam 94/60 P 84

**Other Meds:**

**Lab Data:** none

**History:** Ceclor allergy (rash)

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1406

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276065-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Mar-2007	22-Mar-2007	0	11-Apr-2007	18-Apr-2007	RI		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1300F	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0011U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure normal, Fall, Heart rate normal, Syncope

**Symptom Text:** Syncopal episode appr 5-7 mins after administration of IM Gardasil. Fell at our check out window with no alerts anyone- BP 116/80 BP normal/prior to exam 120/80 P. 92

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276066-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	20-Mar-2007	20-Mar-2007	0	11-Apr-2007	18-Apr-2007	RI		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperhidrosis, Hypotension, Pallor, Syncope

**Symptom Text:** Administered vaccine with on incidents. Suddenly with in 2-3 mins. became faint, sweaty, pale layed pt down on exam table. Responded immediately BP 98/56 AP 68. Observation, cool drink rest no further incidence-discharged with mom (did not drug herself).

**Other Meds:** Doxycycline 1xd on/off for ache

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276069-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	Unknown	Unknown		11-Apr-2007	18-Apr-2007	MO		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	14478	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** Left arm started hurting 3 days after HPV #2 administration. Continued with pain in arm 1 month after administration of shot

**Other Meds:**

**Lab Data:** ultrasound

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1409

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276081-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	01-Jan-2007	01-Jan-2007	0	12-Apr-2007	13-Apr-2007	FL	WAES0704USA01018	13-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Areflexia, Gait disturbance, Incorrect route of drug administration, Muscular weakness, Muscular weakness, Pain, Paraesthesia, Sciatic nerve neuropathy, Sensory disturbance, Similar reaction on previous exposure to drug

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with migraines and tension headaches who in January 2007, was vaccinated intramuscularly into the right leg (also reported as "buttocks") with a first dose of Gardasil. Concomitant therapy included amitriptyline (manufacturer unknown and rizatriptan benzoate. In March 2007, a second dose of Gardasil was administered intramuscularly into the left leg (also reported as "buttocks"). The physician reported that "a few days to a week after each dose the patient developed a sciatic neuropathy". It was further reported that the neuropathy of the right leg had resolved completely over a few weeks (approximately January 2007 or February 2007). The neuropathy of the left leg had improved, but has not resolved. The physician noted that the patient was still having weakness in the left leg and loss of deep tendon reflex at the level of the left ankle. She also had sensory complaints and tingling when touched at the lateral distal lower extremity. The pain was improved however. The patient was reported to still have a limp. It was also reported that the patient was able to attend school but was unable to participate in physical activities due to the sciatic neuropathy. The physician felt that the patient's experiences were disabling. Additional information has been requested.

**Other Meds:** amitriptyline hydrochloride,MAXALT(RIZATRIPTAN BENZOATE)

**Lab Data:** None

**History:**

**Prex Illness:** Migraine, Tension headache

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1410

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276104-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
39.0	F	05-Sep-2006	05-Sep-2006	0	09-Apr-2007	07-May-2007	CO	WAES0611USA02401	07-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0696F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Agitation, Inappropriate schedule of drug administration, Underdose

**Symptom Text:** Initial and follow up information has been received from a health professional concerning a 39 year old whit female patient with NKDA and with HPV and with a family history of breast cancer (mother) who on 07, Nov 2006 was vaccinated with a second IM dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 654540/0800F) into the left deltoid. It was reported that the patient jerked her arm away and the needle came out of the patient's arm and did not received a full dose of the vaccine. It was reported that it was "hard to tell how much of the injection was lost." "A 1/3 of the injection came out of the patient's arm and what is left in the vial." It was recommended that the patient get re-vaccinated with dose number 2. The patient was "upset for the inconvenience" and the patient decided to discontinue the injection because she had a "bad experience", she already had HPV and she had trouble getting to the office. No symptoms were noted. A first dose of HPB rL1 6 11 16 18 VLP vaccine (yeast) (lot # 653650/0696F) was given IM into the deltoid on 05, Sep 2006. Additional information is not expected.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Family history of cancer; Papilloma viral infection

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1411

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276105-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	13-Sep-2006	Unknown		09-Apr-2007	07-May-2007	FL	WAES0611USA07318	07-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653650/0640F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Nausea, Otitis media

**Symptom Text:** Information has been received from a registered nurse concerning a 24 year old female who on 13, Sep 2006 and 08, Nov 2006 was vaccinated intramuscularly with a first and second 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 653650/0640F). There was no concomitant medication. In approximately November 2006, the patient became pregnant about 3 weeks before she was vaccinated with her second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient's last menstrual period was 15, Oct 2006 and her estimated due data is 22, Jul 2007. No symptoms were noted. The patient sought unspecified medical attention. Other medications used during pregnancy included amoxicillin (+) clavulanate potassium (AUGMENTIX) started on 28, Nov 2006 875mg, twice a day for otitis media, ampicillin started on 04, Dec 2006 500 mg once a day administered for nausea due to amoxicillin (+) clevulanate potassium (AUGMENTIN), and prenatal vitamins started on 28, Nov 2006. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276106-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	07-May-2007	--	WAES0701USA00301	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pruritus, Injection site swelling

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with pertinent medical history and drug reactions/allergies not reported who in December 2006 (before Christmas) was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast), injection 0.5 mL. Concomitant medication was not reported. Subsequently, on an unspecified date, the patient experienced redness, swelling and itching at injection site. The patient sought unspecified medial attention. The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276107-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Apr-2007	07-May-2007	NY	WAES0701USA01666	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>			<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.			654540/1162F		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Medical device complication

**Symptom Text:** Information has been received from a health professional who reported that a prefilled syringe (Lot # 654540/1162F) malfunctioned and the vaccine sprayed across the room. The patient did not miss being vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1414

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276108-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	20-Nov-2006	20-Nov-2006	0	09-Apr-2007	07-May-2007	NC	WAES0701USA04121	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		653938/0954	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Drug exposure during pregnancy, Nausea, Pregnancy

**Symptom Text:** Information has been received as part of a pregnancy registry from a nurse practitioner concerning a 16 year old female with food allergies to coconut and mushrooms and a of history migraines, streptococcal infection and pharyngitis who on 20, Nov 2006 was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast), 0.5 mL by intramuscular injection, first dose (lot# 6539381/0954F). Concomitant medication included (CLARITIN) and (NASONEX). On 20, Nov 2006, the patient indicated that her last period was one week ago (13, Nov 2006). On 05, Dec 2006, the patient was seen in an clinic with complaints of nausea and dizziness and had a positive urine pregnancy test at that time. On 11, Dec 2006, the patient underwent and ultrasound which revealed that she was 7 1/2 weeks pregnant. CRL 10.4 mm, positive fetal heartbeat. Additional information is not expected

**Other Meds:** Claritin, Nasonex

**Lab Data:** Ultrasound, 12/11/2006, CRL 10.4 mm, positive fetal heartbeat, 7 1/2 weeks pregnant. Urine beta-human , 12/05/2006 posit

**History:** Migraine; Streptococcal infection; Pharyngitis; Pregnancy NOS (LMP = 10/05//2006) Food allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276109-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
38.0	F	22-Jan-2007	22-Jan-2007	0	09-Apr-2007	07-May-2007	--	WAES0701USA04534	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Fatigue, Ocular hyperaemia

**Symptom Text:** Information has been received from a nurse practitioner concerning a 38 year old female with colitis ulcerative and no allergies who on 22, Jan 2007 was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On 22, Jan 2007 the patient had eye redness of the white of the eye, tiredness, fatigue and lightheadedness. As of 05, Feb 2007, the patient's symptoms continued. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:** Colitis ulcerative

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1416

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276110-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	28-Dec-2006	28-Dec-2006	0	09-Apr-2007	07-May-2007	TN	WAES0702USA00159	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		654389/0961F	1	Right arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, No adverse effect

**Symptom Text:** Information has been received from a registered nurse concerning a 14 year old female with no pre-existing conditions who on 29, Nov 2006, was vaccinated with the first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). On 28, Dec 2006, the patient was vaccinated with second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 654389/0961F) IM right arm 30 days after the 1st dose. At the time of the vaccination, the patient had no illness. The patient did not experience adverse effects. No additional information is expected.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1417

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276111-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	16-Feb-2007	16-Feb-2007	0	09-Apr-2007	07-May-2007	AL	WAES0702USA03810	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect route of drug administration, No adverse effect

**Symptom Text:** Information has been received from a nurse that on 16, Feb 2007, they administered a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) in a patient's hip. No adverse event was reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276112-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	07-May-2007	KS	WAES0703USA00199	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician via a company representative concerning a female patient who was vaccinated with the first dose. 0.5 ml, IM, of HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently the patient "developed hives all over her body." At the time of this report, the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276113-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
40.0	F	27-Feb-2007	27-Feb-2007	0	09-Apr-2007	07-May-2007	--	WAES0703USA00227	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Injection site pain

**Symptom Text:** Information has been received from a nurse practitioner (NP) concerning a 40 year old female who on 27, Feb 2007 was vaccinated with the first dose, 0.5 ml, of HPV rL1 6 11 16 18 VLP vaccine (yeast). concomitant therapy included estrogens (unspecified). On 27, Feb 2007, "starting a short time after her first dose, "the NP reported that the patient experienced pain at the injection site. At the time of this report, the patient was recovering from the event. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** estrogens (unspecified)

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1420

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276114-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	15-Feb-2007		09-Apr-2007	07-May-2007	--	WAES0703USA00265	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaemia, Dizziness, Laboratory test

**Symptom Text:** Information has been received from a nurse practitioner concerning a female who was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) first dose. Concomitant therapy included medroxyprogesterone acetate (DEPO-PROVERA). On approximately 15, Feb 2007, the patient experienced continuing dizziness when administered HPV rL1 6 11 16 18 VLP vaccine. A blood test was performed and the patient was found to be anemic. The nurse practitioner was unsure whether to continue further series with HPV rL1 6 11 16 18 VLP vaccine. Unspecified medical attention was sought. As of 01, Mar 2007, the patient's continuing dizziness and anemic persisted. Additional information has been requested.

**Other Meds:** DEPO-PROVERA

**Lab Data:** diagnostic laboratory , anemic

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276115-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Apr-2007	07-May-2007	--	WAES0703USA00294	07-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Facial palsy

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). One day post vaccination with HPV rL1 6 11 16 18 VLP vaccine (yeast, the patient developed facial palsy (not further specified). The patient outcome was not reported. Additional information is not expected.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276116-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00296	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Facial palsy

**Symptom Text:** Information has been received from a physician concerning a patient who was vaccinated with Gardasil. Concomitant therapy included influenza virus vaccine (unspecified). One day post Gardasil, the patient developed facial palsy (not further specified). The patient outcome was not provided. Additional information is not expected.

**Other Meds:** influenza virus vaccine

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276117-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00336	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>		<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.		0187U		Unknown		Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a registered nurse concerning a female who was vaccinated intramuscularly with Gardasil (LOT# 656049/0187U). Subsequently the patient experiences an 8 inch rash on hip area. The patient sought medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1424

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276118-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	12-Feb-2007	12-Feb-2007	0	09-Apr-2007	09-May-2007	IL	WAES0703USA00347	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure fluctuation, Decreased appetite, Dehydration, Dizziness, Headache, Pain, Pain in extremity, Somnolence, Syncope

**Symptom Text:** Information has been received from a consumer concerning her 14 year old daughter who on 12-FEB-2007 was vaccinated with Gardasil (lot # not reported) 0.5 ml IM. There was no concomitant medication. On 12-FEB-2007 the patient experienced her arm hurting really bad after getting the injection and she developed a headache. Three days after the injection, on 15-FEB-2007, the patient experienced fainting, dizziness, headaches, "dehydrating", not eating, everything kind of hurts, and she only wanted to sleep. Her blood pressure was not steady and was all over the place. Medical attention was sought. Orthostatic test was performed. At the time of reporting, the patient had not recovered. Additional information has been requested.

**Other Meds:** None

**Lab Data:** diagnostic procedure 02/15??/07 - "orthostatic test"

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276119-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	26-Feb-2007	27-Feb-2007	1	09-Apr-2007	09-May-2007	--	WAES0703USA00367	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a nurse practitioner concerning a 24 year old female, with no pertinent medical history, who on 26-FEB-2007 was vaccinated with Gardasil (LOT# 654702/0011U). There was no concomitant therapy. On 26-FEB-2007, within 24 hours of Gardasil administration, the patient experienced a rash on her abdomen. The patient had phoned the office to report the rash. The rash was not seen by the nurse practitioner or physician. No prescription medication therapy was provided to the patient. Subsequently, the patient recovered in 1 day. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1426

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276120-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	27-Feb-2007	27-Feb-2007	0	09-Apr-2007	09-May-2007	CA	WAES0703USA00380	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Bone pain, Chills, Dyspnoea, Inappropriate schedule of drug administration, Lethargy, Myalgia, Rash

**Symptom Text:** Information has been received from a physician concerning a 27 year old female with no known drug allergies and a history of a left thrombosis (2001), loop electrosurgical excision procedure for mild dysplasia (06-DEC-2006) and a pregnancy (2001) who was vaccinated intramuscularly on 27-NOV-2006 with the first dose of Gardasil (Lot # not provided). On 27-FEB-2007 the patient was vaccinated intramuscularly in the right deltoid with the second dose of Gardasil (Lot # 654702/0011U). Five to eight hours post vaccination the patient developed a rash on right shoulder that spread up to her neck, myalgia, lethargy, chills, bone aching and mild shortness of breath. It was reported that 48 hours later, the patient returned to her physicians office who recommended treatment with Benadryl. The physician reported that the patient did not take the Benadryl. It was reported that the rash as resolving and the patient. The physician reported that the patient was seen again in his office on 01-MAR-2007 and was still experiencing lethargy and bone pain. The physician also reported that the patient did not have any adverse effects after that the first of Gardasil. He states that he was unsure if the third dose of Gardasil will be administered. Additional information has been rechecked.

**Other Meds:** Unknown

**Lab Data:**

**History:** Thrombosis leg; Loop electrosurgical excision procedure; Dysplasia; Pregnancy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276121-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Feb-2007	01-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00381	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a nurse concerning a female who in February 2007, was vaccinated IM with 0.5 ml Gardasil. In approximately February 2007, the patient developed a flesh-colored, dry, flakey, itchy rash on her face a couple days after administration of Gardasil. The rash resolved in about 5 days. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276122-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00390	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Alopecia, Myalgia

**Symptom Text:** Information has been received from a pediatrician concerning a female who was vaccinated with a 0.5 ml dose of Gardasil. Subsequently the patient experienced muscle aches and hair loss. On 02-MAR-2007, the patient was going to the pediatrician's office for evaluation. the pediatrician reported that the vaccine was administered by the patient's OB/GYN. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276123-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	02-Jan-2007	02-Jan-2007	0	09-Apr-2007	09-May-2007	NY	WAES0703USA00405	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia oral

**Symptom Text:** Information has been received from a certified medical assistant concerning a 22 year old female with an allergy to gluten or wheat who on 02-JAN-2007 was vaccinated intramuscularly with a 0.5 ml (first dose of Gardasil) (lot 654389/0961F). The CMA reported that the patient's tongue felt numb for several days after her first dose of Gardasil. The patient sought unspecified medical attention. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:**

**Prex Illness:** Gluten intolerance; Food allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1430

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276124-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	23-Feb-2007	23-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00421	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Urticaria

**Symptom Text:** Information has been received from a physician assistant concerning a 15 year old "healthy individual" female who on approximately 23-FEB-2007, was vaccinated with Gardasil first dose. On approximately 23-FEB-2007 (also reported as about a week after Gardasil was administered, the patient experienced swelling and hives in her extremities area. The reporting physician assistant does not treat this patient and did not want to be contacted. The treating physician works in the same office as the reporter but also did not want to be contacted as the physician did not feel the events were related. No lab or diagnostic tests were performed. Unspecified medical attention was sought. As of 02-MAR-2007, the patient's swelling and hives in her extremities persisted. No further information is available.

**Other Meds:** Unknown

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276125-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Feb-2007	26-Feb-2007	4	09-Apr-2007	09-May-2007	IL	WAES0703USA00432	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Pyrexia, Rash erythematous, Rash pruritic

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 22-FEB-2007 was vaccinated with a first dose of Gardasil. On approximately 26-FEB-2007, the patient developed fever of 101F that lasted for several days. On approximately 28-FEB-2007, the patient developed a red, itchy rash on the upper body from the waist up. The patient sought unspecified medical attention. At the time of this report, the outcome was unknown. Additional information has been requested.

**Other Meds:** Unk

**Lab Data:** body temp 02/26/07 101 F

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276126-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	01-Dec-2006	Unknown		09-Apr-2007	09-May-2007	TX	WAES0703USA00440	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nodule on extremity, Oedema peripheral, Pruritus

**Symptom Text:** Information has been received from a physician concerning a 23 year old female who in December 2006, was vaccinated into the left arm with a 0.5mL first dose of Gardasil. Subsequently, on an unspecified date, the patient developed a swollen arm (reported via company representative). The physician also reported that the patient developed a "nodule on the left arm under the skin, "a pouch, which intermittently becomes itchy." (date not reported). At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Additional information is not available.

**Other Meds:** Unk

**Lab Data:** Unk

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276127-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	12-Jan-2007	12-Jan-2007	0	09-Apr-2007	09-May-2007	IN	WAES0703USA00443	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0697F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Information has been received from a registered nurse concerning a 22 year old female with an allergy to tetracycline who on 12-JAN-2007 was vaccinated IM with a 0.5 mL first dose of Gardasil (Lot# 653650/0697F). Concomitant therapy included medroxyprogesterone acetate (DEPO-PROVERA). On 12-JAN-2007 the patient developed a 102 degree fever later that evening. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** Depo-Provera

**Lab Data:** body temp 01/12/07 102

**History:** Allergic reaction to antibiotics

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1434

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276128-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	IL	WAES0703USA00447	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Herpes zoster

**Symptom Text:** Information has been received from a pharmacist concerning a 20 year old female with pertinent medical history not reported and drug reactions/allergies reported as none who on an unspecified date was vaccinated with HPV rL1 6 11 18 VLP vaccine (yeast), 0.5 ml, IM. Concomitant medication was not reported. Approximately on week after vaccination, the patient reported that she experienced shingles. The outcome and causality of the event was not reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276129-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	26-Feb-2007	26-Feb-2007	0	09-Apr-2007	09-May-2007	SC	WAES0703USA00461	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a physician via a company representative concerning a "very nervous" 17 year old female who on approximately 26, Feb 2007 ("earlier this week") was vaccinated IM with a 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # not reported). On approximately 26, Feb 2007 ("after injection") the patient fainted. The patient sought unspecified medical attention and was reported as recovered (date not specified). Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** None

**History:** Nervousness

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276130-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Mar-2007	01-Mar-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00483	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site haemorrhage

**Symptom Text:** Information has been received from a physician's assistance concerning a female who on 01-MAR-2007 was vaccinated with Gardasil. On 01-MAR-2007, the patient experienced a little blood at injection site when Gardasil was administered. Unspecified medical attention was sought. The patient's outcome was not reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unk

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276131-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	OH	WAES0703USA00489	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bronchospasm, Dyspnoea

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with 0.5 ml of Gardasil. Subsequently the patient experienced bronchospasm and shortness of breath. The patient was noted to be under a lot of stress "lately". Subsequently, the patient recovered from bronchospasm and shortness of breath. Additional has been requested.

**Other Meds:** Unknown

**Lab Data:** Unk

**History:** Stress

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276132-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	27-Feb-2007	01-Mar-2007	2	09-Apr-2007	09-May-2007	CA	WAES0703USA00515	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pruritus, Injection site rash

**Symptom Text:** Information has been received from a 27 year old female with no allergies who had no problem with her first dose of Gardasil. On 27-FEB-2007 the patient received her second dose of Gardasil via injection. Concomitant therapy included "YAZ" (therapy unspecified). On 01-MAR-2007 the patient experienced bumps and itchiness where she received her Gardasil shot. The patient did not seek medical attention. As of 02-MAR-2007 the patient was not recovered. Additional information has been requested.

**Other Meds:** [therapy unspecified]

**Lab Data:** Unk

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1439

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276133-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	16-Dec-2006	18-Dec-2006	2	09-Apr-2007	09-May-2007	PA	WAES0703USA00597	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	654885/1424F		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a 16 year old female with fibromyalgia, Ehlers-Danlos syndrome, migraine and insomnia and no know drug allergies who on 16, Dec 2006 was vaccinated intramuscularly with a 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 654885/1424F). Concomitant therapy included amitriptyline hydrochloride (AMITRIPTYLIN), ramelteon (ROZEREM), cephalexin (KEFLEX) and fludrocortisone acetate (FLORINEF). On 18, Dec 2006 (also reported as "several hours after receiving HPV rL1 6 11 16 18 VLP vaccine (yeast)") the patient developed mild hives on her neck. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. On 19, Dec 2006 ("by the next morning") the hives resolved without treatment. No further problems were reported. No product quality complaint was involved. Additional information has been requested.

**Other Meds:** AMITRIPTYLIN, KEFLEX, FLORINEF, ROZEREM

**Lab Data:** Unknown

**History:** Fibromyalgia; Ehlers-Danlos syndrome; migraine; Insomnia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1440

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276134-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	01-Sep-2006	01-Sep-2006	0	09-Apr-2007	09-May-2007	--	WAES0703USA00614	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Information has been received from a licensed practical nurse (LPN) concerning her 16 year old daughter who in September 2006, was vaccinated with the first IM dose of Gardasil. Concomitant therapy included "RPN" inhaler. The LPN reported her daughter had been "growing out of rheumatoid arthritis". Within 24 hours, at 0400 hours, the patient experienced nausea and vomiting that lasted for several days. The patient was then fine. In November 2006 or December 2006, the patient received her second IM dose of Gardasil. Within 24 hours, at 0400 hours, the patient experienced vomiting and nausea that lasted for several days. Subsequently, the patient was fine. The patient did not seek medical attention. Additional information has been requested.

**Other Meds:** [therapy unspecified]

**Lab Data:** Unk

**History:** Rheumatoid arthritis

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1441

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276135-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.3	F	08-Feb-2007	22-Feb-2007	14	09-Apr-2007	09-May-2007	FL	WAES0703USA00618	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dermatitis allergic, Pityriasis rosea, Rash, Rash, Rash generalised

**Symptom Text:** Information has been received from a health professional concerning a female who on 08-FEB-2007 was vaccinated intramuscularly with the first dose of Gardasil (lot # 653938/0954F). Subsequently the patient developed a rash on her arm and part of her face on approximately 22-FEB-2007. The rash spread to the rest of her body. The patient was referred to a Infectious Disease specialist and was diagnosed with allergic dermatitis and pityriasis rosea. Throat culture was negative. The patient was treated with hydroxyzine hydrochloride (Atarax). Subsequently, the rash resolved. Additional information has been requested. It was reported that another female in her school class experienced allergic dermatitis with pityriasis rosea after vaccination with Gardasil (WAES0703USA04287)

**Other Meds:** Unk

**Lab Data:** throat culture 02/07

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276136-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	01-Mar-2007	01-Mar-2007	0	09-Apr-2007	09-May-2007	CA	WAES0703USA00629	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Dizziness

**Symptom Text:** Information has been received from a physician concerning a 23 year old female patient who on 01-MAR-2007 was vaccinated with a dose of Gardasil. the patient became dizzy after receiving the injection. She also had stomach cramps when she got home. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1443

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276137-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	15-Dec-2006	15-Dec-2006	0	09-Apr-2007	09-May-2007	MA	WAES0703USA00630	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injected limb mobility decreased, Paraesthesia, Vomiting

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 21 year old female patient with asthma who on 15-DEC-2006 was vaccinated IM in her right arm with a dose of Gardasil, lot #654389/0961F. Concomitant therapy included hormonal contraceptives (unspecified) and albuterol inhaler (unspecified). The patient has had difficulty lifting her right arm since she was immunized in that arm on 15-DEC-2006. The patient also experienced tingling in her arm, nausea, and vomiting after the injection. The patient was treated with physical therapy. The patient had not recovered as of the report date. Additional information has been requested.

**Other Meds:** albuterol; hormonal contraceptives

**Lab Data:** Unknown

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1444

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276138-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00636	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Neuropathy

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with pertinent medical history and drug reactions/allergies not reported who on an unspecified date was vaccinated with the first dose of Gardasil. Concomitant medication was not reported. Subsequently on an unspecified after being administered the first dose of Gardasil, the patient developed neuropathy and was currently seeing a neurologist. The physician was not sure if the neuropathy was caused by Gardasil or not. The outcome of the event was not reported. Additional information has been requested.

**Other Meds:** Unk

**Lab Data:**

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1445

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276139-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	FL	WAES0703USA00664	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Herpes simplex, Herpes virus infection

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated on an unspecified date with her second dose of Gardasil. Approximately a week later, the patient developed herpetic appearing lesions located on the perivulva and/or gynecological area. The patient was diagnosed with type 1 herpes simplex. The patient's outcome was known. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1446

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276140-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00668	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a Nurse Practitioner (N.P.) concerning a female patient in her early 20's who on an unspecified date was vaccinated with her first dose of Gardasil. Five minutes after receiving the injection, the patient fainted. She was given fruit juice. Her outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1447

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276141-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	20-Feb-2007	Unknown		09-Apr-2007	09-May-2007	MD	WAES0703USA00670	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Vomiting

**Symptom Text:** Information has been received through the pregnancy registry from a registered nurse concerning a female who on 20-FEB-2007 was vaccinated with a first dose of Gardasil while she was pregnant. Subsequently the patient experienced vomiting. The patient was seen in the emergency room and treated with unspecified fluids. On an unspecified date, the patient's alpha-human chorionic gonadotropin level was 221,000. At the time of the report, the patient was 4 months gestation. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** serum alpha-human 221.0

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276142-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	15-Feb-2007	16-Feb-2007	1	09-Apr-2007	09-May-2007	NY	WAES0703USA00672	09-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Information has been received from a licensed practical nurse concerning a 16 year old female with seasonal allergy who on 29-AUG-2006 was vaccinated intramuscularly with a first dose of Gardasil. On 06-NOV-2006, the patient was vaccinated intramuscularly with a second dose of Gardasil. It was reported that the patient received the first and second dose without incident. On 15-FEB-2007, the patient was vaccinated intramuscularly with a third dose of Gardasil. Concomitant therapy included Loratadine. On 16-FEB-2007, at midnight, the patient developed nausea and vomiting that lasted until 14:00 and the patient recovered. Unspecified medical attention was sought. Additional information has been requested.

**Other Meds:** Loratadine

**Lab Data:**

**History:** Seasonal allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1449

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276143-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	26-Feb-2007	26-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00680	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a registered nurse concerning a 16 year old female with no previous drug reactions who on 26, Feb 2007, was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) first dose. On 26, Feb 2007, the patient fainted after receiving HPV rL1 6 11 16 18 VLP vaccine (yeast). Unspecified medical attention was sought. The patient recovered from fainting the same day the vaccine was received. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276144-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	05-Mar-2007	05-Mar-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00698	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	653937/0637F	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a pharmacist concerning a 19 year old female with pertinent medical history and drug reactions/allergies reported as none who on 05, Mar 2007 was vaccinated with the second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), ( lot # 653937/0637F). Concomitant medication was reported as none. On 05, Mar 2007, 5 to 10 minutes after receiving the vaccination, the patient fainted. The patient sought unspecified medical attention. The outcome and causality of the event was not reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276145-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	01-Feb-2007	01-Feb-2007	0	09-Apr-2007	09-May-2007	CA	WAES0703USA00708	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Myalgia

**Symptom Text:** Information has been received from a physician concerning a 15 year old female who in February 2007, was vaccinated with a first dose of Gardasil. The physician reported that the patient developed muscle pain, headache and dizziness after receiving the first dose. The patient sought unspecified medical attention. At the time of this report, the outcome was unknown. Additional information has been requested.

**Other Meds:** Unk

**Lab Data:** Unk

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276146-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	04-Jan-2007	11-Jan-2007	7	09-Apr-2007	09-May-2007	MO	WAES0703USA007710	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling abnormal, Nausea, Vertigo

**Symptom Text:** Information has been received from a physician concerning a 21 year old female who on 04, Jan 2007 was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). ON approximately 11, Jan 2007 the patient experienced dizziness. The patient described her dizziness as a "head rush" associated with a feeling of "fuzziness" and a sensation that she was spinning. This feeling may be accompanied by nausea with no vomiting. The dizziness was episodic and lasted for minutes to an hour or so. The dizziness was not positional and did not occur at night. The patient was seen by three physicians and underwent magnetic resonance imaging (MRI). All follow-up examinations and MRI were normal. At the time of this report, the patient had not recovered from the dizziness. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** magnetic resonance, normal

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276147-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	01-Mar-2007	01-Mar-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00727	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vulval disorder

**Symptom Text:** Information has been received from a nurse practitioner concerning a 15 year old female with a history of fever of 102.5 degree a week prior to being vaccinated who on 01-MAR-2007 was vaccinated with Gardasil. In March 2007, soon after vaccination with Gardasil, the patient developed labia lesions. The patient was not sexually active. On 05-MAR-2007, the patient was seen for an office visit. The lesions were cultured and sensitivity of the lesions were negative for bacterial, fungal and viral infections. As of 05-MAR-2007, the patient's labia lesions persisted. Additional information has been requested.

**Other Meds:** Unk

**Lab Data:** diagnostic microbiology 03/07 culture and sensitivity of the lesions are negative for bacterial, fungal and viral infections

**History:** Fever

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276148-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	05-Mar-2007	05-Mar-2007	0	09-Apr-2007	09-May-2007	OH	WAES0703USA00798	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Influenza like illness, Loss of consciousness, Nausea, Pain, Pain

**Symptom Text:** Information has been received from a physician, via a company representative, concerning a female patient, who on 05-MAR-2007 was vaccinated with the first dose of Gardasil. The physician reported that after the vaccination, the patient left the office and lost consciousness momentarily, experiences flu like symptoms including nausea, aches and pains and dizziness." It was unknown if the patient experienced fever. The patient went to the emergency room at 9:30 pm on 05-MAR-2007, "but was admitted into the hospital." Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276149-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	19-Feb-2007	19-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00861	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site

**Symptom Text:** Information has been received from a physician concerning a patient (age and gender unknown) who on 19-FEB-2007 was vaccinated with Gardasil (Lot number 654540/0800F). On 19-FEB-2007 the patient the received vaccine in the bottom. No further information is available.

**Other Meds:** Unk

**Lab Data:** Unk

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1456

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276150-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
36.0	F	02-Jan-2007	02-Jan-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00873	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Menstrual disorder

**Symptom Text:** Information has been received from a 36 female with no pertinent medical history who on 02-JAN-2007 was vaccinated with a first dose of Gardasil. There was no concomitant medication. On 17-JAN-2007 the patient's "period started a week early" and has remained on that schedule. The patient did not seek medical attention. She reported that she would be a few days to a week late receiving her second vaccination of Gardasil because the physician's office was out of stock and had to order more. No further information is available.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276151-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	02-Mar-2007	02-Mar-2007	0	09-Apr-2007	09-May-2007	KS	WAES0703USA00876	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	654510/0962F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female smoker (1/2 pack per day) with genital warts who on 02, Mar 2007 was vaccinated intramuscularly with a 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 654510/0962F). Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO-CYCLEN). On 02, Mar 2007, the patient experienced chest pain several hours post vaccination. The character and location of the chest pain was unknown. On 04, Mar 2007, the patient recovered from chest pain without medical attention on treatment. No further problem reported. Additional information has been requested.

**Other Meds:** ORTHO-CYCLEN

**Lab Data:** None

**History:** Smoker; Genital wart

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276152-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
64.0	M	06-Mar-2007	06-Mar-2007	0	09-Apr-2007	09-May-2007	FL	WAES0703USA00883	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Medication error, Wrong drug administered

**Symptom Text:** Information has been received from a physician concerning a 64 year old male who on 06-MAR-2007 was vaccinated intramuscularly with a 0.5 ml dose of Gardasil instead of Zostavax. It was reported that there was no product confusion and that is was a medication error. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276153-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00915	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, No adverse effect

**Symptom Text:** Information has been received from a registered nurse concerning a female (age not reported) who on an unspecified date was vaccinated with the first dose of Gardasil, 0.5 ml, IM. Concomitant medication was not reported. Subsequently on an unspecified date, the patient did not come in for her 2nd dose of Gardasil on time and the vaccination was given after 2 months. No adverse experiences were noted. Additional information is not expected.

**Other Meds:** Unk

**Lab Data:**

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276154-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00945	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Accidental exposure, Eye irritation, Vision blurred

**Symptom Text:** Information has been received from a medical assistant concerning a female nurse splashed Gardasil in her eyes. Subsequently, the nurse's eyes were blurry and burning (patient outcome not reported). The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1461

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276155-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Dec-2006	01-Dec-2006	0	09-Apr-2007	09-May-2007	--	WAES0703USA00962	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Myalgia, Pain

**Symptom Text:** Information has been received from a physician concerning a female who in December 2006 , was vaccinated with Gardasil 0.5 mL, injection. In December 2006, the patient experienced muscle aches all over, especially in the legs and arms. The patient's muscle aches all over, especially in the legs and arms persisted for 3 months. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unk

**Lab Data:**

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1462

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276156-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	30-Jan-2007	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA00980	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site swelling, Neck mass

**Symptom Text:** Information has been received from a physician concerning a female who on 30, Jan 2007, was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, the patient developed a large lump on her neck and swelling to her thigh at injection site after immunization with HPV rL1 6 11 16 18 VLP vaccine (yeast). Unspecified medical attention was sought. As of 03, Mar 2007, the patient's large lump on her neck and swelling to her thigh at injection site persisted. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1463

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276157-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	26-Feb-2007	26-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00984	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Eye swelling, Pruritus

**Symptom Text:** Information has been received from a registered nurse concerning a 16 year old female with no pertinent medical history and no previous reactions who on 26, Feb 2007, was vaccinated with HPV rL1 06 11 16 18 VLP vaccine (yeast) first dose. Concomitant therapy included hepatitis A vaccine (inactive) (manufacturer unknown), diphtheria toxoid and tetanus toxoid all administered on the same day (26, Feb 2007). The nurse did not know if the vaccines were administered in the same arm as HPV rL1 6 11 16 18 VLP vaccine. ON 26, Feb 2007, the patient developed swelling around both eyes and her face became red and itchy. The patient did not have a fever or any other symptoms. Unspecified medical attention was sought. On 03, Mar 2007, the patient recovered from swelling around both eyes and red and itchy face. Additional information has been requested.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1464

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276158-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	26-Feb-2007	26-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA00994	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Erythema, Headache, Injection site erythema, Injection site pain, Injection site swelling, Oedema peripheral

**Symptom Text:** Information has been received from a registered nurse concerning a 16 year old female with an allergy to amoxicillin (+) clavulanate potassium (Augmentin) who on 26-FEB-2007 was vaccinated with the first IM dose of 0.5 ml of Gardasil (lot # 655849/0263). There was no concomitant medication. Later in the day, on 26-FEB-2007 the patient experienced soreness at the injection site. On 27-FEB-2007 the patient developed arm redness and swelling from injection site to fingertips. There was no itching. The patient also experienced dizziness and headache throughout the day (frequency and duration unknown). The patient took ibuprofen on 28-FEB-2007 for the swelling. The swelling and redness subsided the morning of 01-MAR-2007. The patient was still reporting pain at the injection site and no swelling or redness on 05-MAR-2007. The patient was recovering from dizziness and headache. The patient had not been examined at the office since the vaccination. No lab testing was performed. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:** Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276159-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01012	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cyanosis, Dizziness, Erythema, Hypoaesthesia, Hypoaesthesia, Myalgia, Rash, Skin discolouration

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Ten days after HPV rL1 6 11 16 18 VLP vaccine (yeast) was administered, the patient developed numb fingers and hands, fingers turned red and blue, muscle aches, rash and dizziness. Unspecified medical attention was sought. As of 06, Mar 2007, the patient's numb fingers and hands and fingers turned red and blue, muscle, aches, rash and dizziness persisted. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1466

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276160-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	15-Jan-2007	15-Jan-2007	0	09-Apr-2007	09-May-2007	NE	WAES0703USA01014	09-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	655619/1427F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyskinesia, Pallor, Syncope

**Symptom Text:** Information has been received from a registered nurse concerning an 18 year old female patient who on 15, Jan 2007 was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) (lot # 655619/1427F). Concomitant suspect vaccination included a dose of diphtheria toxoid (=) pertussis acellular 3-component vaccine (+) tetanus toxoid (BOOSTRIX; and a dose of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). On 15, Jan 2007, within 2 minutes after her vaccinations. the patient became pale and fainted. The nurse also reported that while unconscious, the patient had jerking motions which lasted a couple of seconds. The patient was reported to have rested in the office for 15 minutes and then went home recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1467

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276161-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	03-Jan-2007	23-Feb-2007	51	09-Apr-2007	09-May-2007	MD	WAES0703USA01048	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a licensed practical nurse, concerning a 20 year old female patient, who on 03-JAN-2007 was vaccinated with the first dose, 0.5 ml, IM, of Gardasil (Lot # 654389/0961F). There was no concomitant medication. On approximately 23-FEB-2007, the patient developed "hives that started approximately 1 week before her appointment for the second dose (02-MAR-2007). The nurse added that the patient's "primary physician gave her an analgesic" (name unknown). The nurse stated that the patient "still had the hives when she came to the office" for her appointment and reported "the hives were mostly on both arms." The patient "received the second dose" of Gardasil on 02-MAR-2007. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276162-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	21-Feb-2007	21-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA01052	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a physician concerning a female patient who on 21, Feb 2007 was vaccinated with a dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient developed a single hive above her upper lip about 20 minutes after the injection. Unspecified medical attention was sought. The patient recovered. The physician did not know if the event was definitely related to the HPV rL1 6 11 16 18 VLP vaccine (yeast). Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276163-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	MO	WAES0703USA01054	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a first and second dose of Gardasil. The patient developed a rash on her face after 1st injection. She developed a more extensive rash on her face after the 2nd injection. In both instances, the rash was isolated to only the patient's face. The physician was not planning to vaccinate the patient with the 3rd dose due to the adverse experience. Unspecified medical attention was sought. The patient was improving as of the report date. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1470

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276164-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	CT	WAES0703USA01086	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Activities of daily living impaired, Pyrexia

**Symptom Text:** Information has been received from a physician concerning a 15 year old female patient who in January 2007 was vaccinated with a second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient developed a fever of 102.5F for 3 days after her injection. The patient missed one day of school. Unspecified medical attention was sought. The patient recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** body temp, 01/??/07, 102.5

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1471

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276165-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	16-Feb-2007	27-Feb-2007	11	09-Apr-2007	09-May-2007	WI	WAES0703USA01098	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Papilloma viral infection

**Symptom Text:** Information has been received from a physician concerning a 16 year old female with asthma and allergy to "campha" who on 16, Feb 2007 was vaccinated IM with her first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), single dose vial. Concomitant therapy included fluticasone propionate (+) salmeterol xinafoate (ADVAIR) and amphetamine aspartate/amphetamineSO4/dex (ADDERALL TABLETS). On 27, Feb 2007 the patient was tested for HPV and the pap smear results were positive for high risk HPV. Unspecified medical attention was sought. Her outcome was unknown. Additional information has been requested.

**Other Meds:** ADDERALL TABLETS, mg; ADVAIR

**Lab Data:** cervical smear, 02/27/2007, Positive for high risk HPV

**History:** Asthma; Drug hypersensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276166-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	CT	WAES0703USA01104	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with no pertinent medical history who was vaccinated with a second dose of Gardasil. There was no concomitant medication. Subsequently the patient experienced dizziness for three days. Unspecified medical attention was sought. There were no laboratory or diagnostic tests performed. Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276177-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	10-Apr-2007	11-Apr-2007	1	12-Apr-2007	16-Apr-2007	OH		16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	0113U	1	Right arm	Subcutaneously	
	MNQ	AVENTIS PASTEUR	U1968AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0244U	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B011AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration

**Symptom Text:** area of erythema and induration at site of second varicella immunization. 9 by 4 cm. no fever

**Other Meds:**

**Lab Data:** none

**History:** AMOXIL ALLERGY

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1474

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276218-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	12-Feb-2007	12-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA01129	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Head injury, Injection site pain, Injection site reaction, Injection site warmth, Loss of consciousness

**Symptom Text:** Information has been received from a licensed practical nurse concerning an 18 year old female who was vaccinated with Gardasil (Lot# 653735/0688F). On 12-FEB-2007, the patient lost consciousness and hit her head after receiving her first dose of Gardasil. The patient was taken to the emergency room but was not admitted. The patient also developed local site reaction. On 13-FEB-2007, the patient visited the office and complained of pain at the site and it was warm to the touch. Unspecified medical attention was sought. Subsequently, the patient recovered from lost consciousness, hit head, local site reaction and pain and warmth at injection site. Additional information has been requested.

**Other Meds:** Unk

**Lab Data:** Unk

**History:** Unk

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276219-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01131	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) first dose. Subsequently, the patient developed a rash over their entire body. Unspecified medical attention was sought. The patient's outcome was not reported. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1476

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276220-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	07-Mar-2007	07-Mar-2007	0	09-Apr-2007	09-May-2007	SC	WAES0703USA01156	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Headache, Loss of consciousness, Syncope

**Symptom Text:** Information has been received from a nurse concerning a 17 year old female who on 07-MAR-2007 was vaccinated with a 0.5 mL second dose of Gardasil. On 07-MAR-2007, the patient experienced a headache then fainted after receiving the second dose of Gardasil. The patient's blood pressure was slightly elevated while she passed out. The patient was advised to sit down for 15-20 minutes after the Gardasil was administered but refused to be seated to passing out. The patient was taken to the emergency room but refused care. At the time of this report, the outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276221-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01172	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dyspnoea

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) with asthma who on an unspecified date was vaccinated with the second dose of Gardasil, 0.5 ml, once, IM. Concomitant therapy included Advair and unspecified inhaler (therapy unspecified). Subsequently on an unspecified date, the patient experienced chest tightness and shortness of breath a short time after receiving her second dose of Gardasil. The physician reported that the patient self-medicated with her inhaler and her symptoms resolved. Additional information has been requested.

**Other Meds:** (therapy unspecified), ADVAIR

**Lab Data:**

**History:**

**Prex Illness:** Asthma

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1478

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276222-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	01-Dec-2006	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01175	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Smear cervix abnormal

**Symptom Text:** Information has been received from a pharmacist concerning her 19 year old daughter with food allergies who in December 2006, was vaccinated with a first dose of Gardasil. Concomitant therapy included Yaz. The patient had a routine Papanicolaou (pap) test which revealed a few mild abnormal cells. A colposcopy was scheduled. The patient had not recovered as of the report date. Additional information has been requested.

**Other Meds:** YAZ

**Lab Data:** Pap test - a few mild abnormal cells

**History:**

**Prex Illness:** Food allergy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1479

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276223-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01179	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>		<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.		NULL		Unknown		Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Information has been received from a physician concerning a female who was vaccinated with the second dose of Gardasil. Subsequently the patient experienced genital warts. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1480

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276224-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	02-Mar-2007	02-Mar-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA01200	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Presyncope

**Symptom Text:** Information has been received from a certified medical assistant concerning a 22 year old female who on 02-MAR-2007 was vaccinated with second dose of Gardasil, injection (Lot#655503/0012U). Concomitant therapy included Yaz. On 02-MAR-2007, after administration of Gardasil the patient experienced dizziness and was close to fainting. Therapy with human papillomavirus vaccine was discontinued. Subsequently, the patient recovered from dizziness and close to fainting. The product quality complaint unit was not involved. Additional information has been requested. The same source also provided information concerning other patient's experiences (WAES# 0703USA04318 and WAES# 0703USA04319).

**Other Meds:** YAZ

**Lab Data:** Unknown

**History:**

**Prex Illness:** Contraception

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276225-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	06-Feb-2007	26-Feb-2007	20	09-Apr-2007	09-May-2007	--	WAES0703USA01205	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1447F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Neck pain

**Symptom Text:** Information has been received from a physician concerning a 27 year old female who on an unspecified date was vaccinated with the first IM dose of Gardasil (lot# 655617/1447F). On 06-FEB-2007, the patient was vaccinated with the second IM dose of 0.5 ml Gardasil. Concomitant therapy included Percocet. On 26-FEB-2007 the patient called the physician's office with complaints of neck pain. No lab testing was performed. The physician reported that patient refused to take the third dose of 0.5 ml Gardasil due to arthralgia after her second dose. Additional information has been requested.

**Other Meds:** PERCOCET

**Lab Data:** None0

**History:**

**Prex Illness:** Joint disorder

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276226-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	05-Mar-2007	05-Mar-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA01266	09-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a nurse practitioner, via a company representative, concerning a female patient, who on 05-MAR-2007 was vaccinated with the first dose, IM, of Gardasil. Concomitant suspect therapy included Tdap. The nurse practitioner reported that "a patient who received the 1 Gardasil in one arm and the Tdap vaccine in the other arm, fainted within a few seconds after being vaccinated." The nurse practitioner states that "the patient was fine after a minute or so." The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1483

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276227-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
0.3	M	02-Mar-2007	02-Mar-2007	0	09-Apr-2007	09-May-2007	NC	WAES0703USA01289	09-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	PNC	WYETH PHARMACEUTICALS, INC	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	OPV	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	
	IPV	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Medication error, Wrong drug administered

**Symptom Text:** Information has been received from two consumers, the mother and father of a 4 month old male infant, who on 02-MAR-2007 was vaccinated with a single dose Gardasil by mistake. Concomitant therapy included Dtap (unspecified), IPV (unspecified), OPV (unspecified) and Prevnar. The mother and father of the child reported that their son should have received the "HIB" vaccine (not specified) "but instead (was) given (Gardasil)." On 20-MAR-2007, the mother of the infant reported that the child had been experiencing "diarrhea for over a week," and reported that Pedialyte had been ordered. She added that on 16-MAR-2007, the HIB vaccine was administered. The mother stated that her child did "not appear dehydrated," and continued to have "wet diapers." The patient's twin brother also experienced the events as described above after vaccination with Gardasil (WAES # 0703USA01783). Additional information has been requested.

**Other Meds:** hib conj vaccine (unspecified)

**Lab Data:** Unknown

**History:**

**Prex Illness:** Prophylaxis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276228-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	07-Mar-2007	07-Mar-2007	0	09-Apr-2007	09-May-2007	FL	WAES0703USA01294	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a Registered Nurse (R.N.) concerning a 17 year old female patient who on 10-JAN-2007 was vaccinated with her first dose of Gardasil. On 03-MAR-2007 she was vaccinated IM in her left deltoid with her second dose of Gardasil, lot #654540/0800F. Concomitant therapy included oral contraceptives (unspecified). Shortly after the administration of her second dose,

**Other Meds:** hormonal contraceptives

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276229-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	NY	WAES0703USA01300	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Dyskinesia, Tremor, Vomiting

**Symptom Text:** Information has been received from an office receptionist concerning her 19 year old daughter who on an unspecified date was vaccinated with a first dose of Gardasil. The patient's arm was "shaky" after the first injection. On an unspecified date the patient received her 2nd dose of Gardasil. Subsequently, her arm was "jumpy" and she experienced vomiting and diarrhea. Unspecified medical attention was sought. The patient recovered. Additional information has requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1486

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276230-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01306	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Immediate post-injection reaction, Injection site irritation, Injection site pain, Presyncope

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast) first dose. Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid administered right before HPV rL1 6 11 16 18 VLP vaccine. The patient said that while she was being administered the HPV rL1 6 11 16 18 VLP vaccine (also reported as immediately after receiving HPV rL1 6 11 16 18 VLP vaccine), she had stinging and burning sensation (at injection site) and felt as if she was going to faint or pass out. The feeling lasted for approximately fifteen minutes. Thereafter, she felt "okay" Subsequently, the patient recovered. Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276231-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	OH	WAES0703USA01307	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from an office manager concerning a female patient who was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) and fainted after receiving the injection. Unspecified medical attention was sought. The patient recovered. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276232-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01335	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Information has been received from a physician concerning a female patient who was vaccinated with a first dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient developed a rash all over the body after the injection. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276233-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	06-Mar-2007	07-Mar-2007	1	09-Apr-2007	09-May-2007	WI	WAES0703USA01345	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Information has been received from a nurse practitioner concerning a female who on 06-MAR-2007 was vaccinated with the first IM dose of Gardasil. On 07-MAR-2007 the patient experienced rash on her neck. The reporter felt that rash on her neck was not related to Gardasil. Patient outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1490

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276234-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	09-May-2007	--	WAES0703USA01357	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea

**Symptom Text:** Information has been received from an employee at a physician's office concerning a female who in December 2006, was vaccinated with HPV rL1 6 11 16 18 VLP vaccine (yeast), injection. In December 2006, the patient experienced nausea. In December 2006, therapy with human papillomavirus vaccine was discontinued. Subsequently, the patient recovered from nausea. Additional information is not expected.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1491

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276235-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	28-Feb-2007	08-Mar-2007	8	09-Apr-2007	09-May-2007	MA	WAES0703USA01360	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	654389/0961		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menstruation delayed

**Symptom Text:** Information has been received from a registered nurse concerning a 19 year old female patient with seasonal allergies who on 28, Feb 2007 was vaccinated IM with a 0.5 mL dose of HPV rL1 6 11 16 18 VLP vaccine (yeast) lot # 654389/0961F) and has not begun her period. Concomitant therapy included ethinyl estradiol (+) levonorgestrel (AVLANE), as oral contraception, and fluticasone propionate (FLONASE). The nurse reported that the patient took her 3 weeks of active pills and usually begins her period 2 days after beginning the reminder pills. As of 08, Mar 2007 (4 days after beginning the reminder pills), the patient had not begun her period. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** AVLANE; FLONASE

**Lab Data:** None

**History:** Seasonal allergy

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276236-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	25-Jan-2007	04-Feb-2007	10	09-Apr-2007	09-May-2007	LA	WAES0703USA01367	09-May-2007
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anogenital warts

**Symptom Text:** Information has been received from a physician concerning a 24 year old female with no medical history of drug reactions/allergies who on 25, Jan 2007 was vaccinated with the first IM 0.5 ml dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included hormonal contraceptives (unspecified). On approximately 04, Feb 2007, the patient experienced lesions on the external vaginal area. The patient contacted the physician on 26, Feb 2007. Biopsy of the lesions revealed condyloma. No treatment was provided at the time of reporting. The patient had not recovered. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** biopsy, 02/??/07; condyloma

**History:** none

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1493

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276237-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	TX	WAES0703USA01500	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Menorrhagia, Menstruation delayed

**Symptom Text:** Information has been received from a registered nurse concerning a 22 year old "nurse" who works in the same physician's office who was vaccinated with first dose HPV rL1 6 11 16 18 VLP vaccine (yeast). Subsequently, her menstrual cycle did not arrive on time. Her menstruation lasted for 2 weeks and it was a heavier flow. the patient's menstrual cycle ended and then started again. The patient experienced 2 cycles in one month. After her second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast), the patient's menstrual cycle arrived on time but it was a heavier flow. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1494

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276238-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
0.3	M	02-Mar-2007	Unknown		09-Apr-2007	09-May-2007	NC	WAES0703USA01783	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Medication error, Wrong drug administered

**Symptom Text:** Information has been received from two consumers, the mother and father of a 4 month old male infant, who on 02-MAR-2007 was vaccinated with single dose by mistake. Concomitant therapy included Dtap (unspecified), IPV, OPV (unspecified). The mother and father of the child reported that their son should have received the HIB vaccine (not specified) "but instead (was) given Gardasil. On 20-MAR-2007, the mother of the infant reported that the child had been experiencing "diarrhea for over a week," and reported that oral electrolyte maintenance (PEDIALYTE) has been ordered. She added that on 16-MAR-2007, the haemophilus influenza type B vaccine was administered. The mother stated that her child did "not appear dehydrated," and continued to have "wet diapers." The patient's twin brother also experienced the events as described above after vaccination with Gardasil (WAES # 0703USA01289). Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:**

**Prex Illness:** Prophylaxis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276239-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Apr-2007	09-May-2007	OH	WAES0703USA01925	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fall

**Symptom Text:** Information has been received from an office manager concerning a patient who was vaccinated with a first dose of Gardasil. The patient got dizzy and fell after receiving the injection. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276240-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		09-Apr-2007	09-May-2007	NY	WAES0703USA01943	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Dizziness, Eye haemorrhage, Nausea

**Symptom Text:** Information has been received from an office receptionist concerning her 17 year old step daughter who on an unspecified date was vaccinated with first dose Gardasil. The patient experienced extreme nausea, diarrhea and dizziness after the injection. "Patient was vomiting so hard, that the blood vessels in her eyes broke." The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1497

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276241-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Apr-2007	09-May-2007	FL	WAES0703USA02267	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Information has been received from a Licensed Practical Nurse (L.P.N.) concerning a patient who was vaccinated with a first dose of Gardasil. Patient developed hives within 2-3 hours of receiving the injection. The patient's outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276242-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Mar-2007	07-Mar-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA04052	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Pallor

**Symptom Text:** Information has been received from a health professional concerning a 16 year old female who on 07-MAR-2007, was vaccinated with Gardasil (Lot# 654535/0960F). There was no local site reaction but on 07-MAR-2007, the patient became dizzy and pale. The patient had to wait 20 minutes in the waiting room before she was fine (recovered). Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276243-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		09-Apr-2007	04-May-2007	FL	WAES0703USA04287	04-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dermatitis allergic, Pityriasis rosea, Rash generalised

**Symptom Text:** Information has been received from a medical assistant concerning a female with vaccinated with Gardasil. Subsequently the patient developed a rash on her arm and part of the face. The rash spread to the rest of the body. The patient was diagnosed with allergic dermatitis and pityriasis rosea. Patient outcome was unknown. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1500

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276244-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	07-Feb-2007	07-Feb-2007	0	09-Apr-2007	04-May-2007	--	WAES0703USA04318	04-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0012U	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Information has been received from a certified medical assistant concerning a patient with contraception who on 07-FEB-2007 was vaccinated with second dose of Gardasil (Lot#655503/0012U). Concomitant therapy included YASMIN, PAXIL and PROTONIX. On 07-FEB-2007, the patient experienced fainted (patient outcome not provided). Additional information has been requested. The same source also provided information regarding other patients' experiences (WAES#0703USA01200 and WAES#0703USA04319).

**Other Meds:** YASMIN, PROTONIX, PAXIL

**Lab Data:** Unknown

**History:**

**Prex Illness:** Contraception

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276245-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		09-Apr-2007	04-May-2007	--	WAES0703USA04319	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Presyncope, Syncope

**Symptom Text:** Information has been received from a certified medical assistant concerning three patients who were vaccinated with Gardasil. Subsequently, the patients were closed to fainting or fainted (patient outcomes not provided). Attempts are being made obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. The same source provided information concerning the experienced of other patients (WAES#0703USA01200 and WAES#0703USA04318).

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276246-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	19-Feb-2007	19-Feb-2007	0	09-Apr-2007	04-May-2007	--	WAES0703USA04414	04-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site

**Symptom Text:** Information has been received from a physician concerning a patient (age and gender unknown) who on 19-FEB-2007 was vaccinated with Gardasil (Lot number 654540/0800F). on 19-FEB-2007 the patient the received vaccine in the bottom. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276247-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	19-Feb-2007	19-Feb-2007	0	09-Apr-2007	04-May-2007	--	WAES0703USA04415	04-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0800F		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug administered at inappropriate site

**Symptom Text:** Information has been received from a physician concerning a patient (age and gender unknown) who on 19-FEB-2007 was vaccinated with Gardasil (Lot number 654540/0800F). On 16-FEB-2007 the patient the received vaccine in the bottom. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1504

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276248-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	21-Dec-2006	21-Dec-2006	0	09-Apr-2007	09-May-2007	IL	WAES0703USA04432	09-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hot flush, Immediate post-injection reaction, Injection site pain, Nausea

**Symptom Text:** Information has been received from a registered nurse concerning a 20 year old female student who on 21-DEC-2006, at 2:00PM, was vaccinated IM, into the left deltoid, with a first dose of Gardasil (Lot# 653937/0637F). There was no illness at the time of vaccination. On 21-DEC-2006, after the injection, at 2:00PM, the patient became lightheaded and nauseated, "approximately 15 minutes". The nurse also reported the injection was very painful when vaccine contents injected into muscle and the patient had a hot flash. On 23-FEB-2007, at 3:15PM, the patient was vaccinated IM, into the left deltoid, with a second dose of Gardasil (Lot# 654389/0961F). There was no illness at the time of vaccination. The nurse reported that the patient felt a hot flash immediately post injection . The second injection was also said to be very painful when vaccine contents injected into the muscle (not from needle placement), for "five minutes". No further information is expected.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276249-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Feb-2007	01-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA04505	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Rash

**Symptom Text:** Information has been received from a nurse concerning a female who in February 2007, was vaccinated IM with 0.5 mL Gardasil. In approximately February 2007, the patient developed a flesh-colored, dry, flakey, itchy rash on her face a couple days after administration of Gardasil. The rash resolved in about 5 days. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1506

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276250-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Feb-2007	01-Feb-2007	0	09-Apr-2007	09-May-2007	--	WAES0703USA04506	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Musculoskeletal stiffness

**Symptom Text:** Information has been received from a nurse concerning a female who in February 2007, was vaccinated IM with 0.5 mL Gardasil. In February 2007, the morning after receiving Gardasil the patient experienced a stiff neck which was stiff for about a day. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1507

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276251-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
30.0	F	01-Oct-2006	01-Oct-2006	0	09-Apr-2007	09-May-2007	--	WAES0703USA04516	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Medication error, Pain, Pain in extremity

**Symptom Text:** Information has been received from a certified family nurse practitioner (CFNP) concerning a 30 year old female clinic employee who in August 2006 was vaccinated with first dose of Gardasil (lot # not reported). In October 2006, the patient was vaccinated with second dose of Gardasil (lot # not reported). In February 2007, the patient was vaccinated with third dose of Gardasil (lot # not reported). In October 2006, the patient experienced stinging and sore arm after the second vaccination. The patient recovered after three days. In February 2007, the patient again experienced stinging and sore arm after the third vaccination. The patient recovered after three days. Additional information was received from the CFNP via telephone. The sore arm lasted about 3 days. There was no reaction with the first dose which came from a pre-loaded syringe. The second and third doses of vaccine were from a vial. No additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1508

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276252-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
32.0	F	01-Oct-2006	01-Oct-2006	0	09-Apr-2007	09-May-2007	--	WAES0703USA04517	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Medication error, Pain, Pain in extremity

**Symptom Text:** Information has been received from a certified family nurse practitioner (CFNP) concerning a 25 year old female clinic employee who in August 2006 was vaccinated with first dose of Gardasil (lot # not reported). In October 2006, the patient was vaccinated with second dose of Gardasil (lot # not reported). In February 2007, the patient was vaccinated with third dose of Gardasil (lot # not reported). In October 2006, the patient recovered after three days. In February 2007, the patient again experienced stinging and sore arm after the third vaccination. The patient recovered after three days. Additional information was received from the CFNP via telephone. The sore arm lasted about 3 days. There was no reaction with the first dose which came from a pre-loaded syringe. The second and third doses of vaccine were from a vial. No additional information has been received.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276255-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	Unknown	Unknown		13-Apr-2007	16-Apr-2007	--	WAES0704USA01230	16-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diplegia, Guillain-Barre syndrome, Pain

**Symptom Text:** Information has been received from a pediatric physician concerning a 14 year old female who was vaccinated with a dose of Gardasil. Subsequently the patient developed Guillain-Barre syndrome which he thought was "pain and paralysis in the legs" or a "nerve-related syndrome that can last between 6 months to a year." Unspecified medical attention was sought. The patient's outcome was unknown. Upon internal review, Guillain-Barre syndrome was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276262-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	25-Mar-2007	Unknown		13-Apr-2007	16-Apr-2007	--		16-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Angioedema, Urticaria

**Symptom Text:** Patient developed severe urticaria and angioedema starting about 24-48 hours after getting HPV vaccine (First dose). Patient had two E.R. visits. Needs high dose steroids to control angioedema of throat. Problem lasted ten days.

**Other Meds:**

**Lab Data:**

**History:** No previous history of urticaria

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276265-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	29-Mar-2007	29-Mar-2007	0	13-Apr-2007	23-Apr-2007	MD		24-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Nausea, Pyrexia, Vomiting

**Symptom Text:** pt states she had fever, nausea, vomiting and diarrhea for one and half days.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:** fever, nausea, vomiting~Measles Mumps Rubella (Virivac)~~0~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276294-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	Unknown	Unknown		15-Apr-2007	16-Apr-2007	CA		16-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	1	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain in extremity, Vaccine positive rechallenge

**Symptom Text:** intermittent numbness/pain on injection arm. started after the first vaccine 12/15/06, increased in intensity and frequency after 2nd injection 2/27/07.

**Other Meds:** flovent, albuterol

**Lab Data:** none thus far

**History:** none

**Prex Illness:** none. the mfr was Novartis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276300-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	15-Mar-2007	Unknown		13-Apr-2007	19-Apr-2007	DE		19-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Pain in extremity

**Symptom Text:** c/o soreness in arm since injection on 3/15/07. Pt came in 4/13/07 with above symptoms not note to us before this date

**Other Meds:**

**Lab Data:** none

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1514

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276302-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	12-Apr-2007	12-Apr-2007	0	13-Apr-2007	19-Apr-2007	CA		19-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B009AA	0	Right leg	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2158AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0244U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Headache, Vomiting

**Symptom Text:** approx 1 hour after vaccine pt reported headache with temp (had tem 99 deg) per pt mom tem up to 102 approx 4 hour after I 25-vomiting approx 2 hour after I 25

**Other Meds:** none

**Lab Data:** physical exam 4/13/07 with flu scheduled

**History:** none

**Prex Illness:** Temp 99 no other illnesses

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1515

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276314-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		16-Apr-2007	17-Apr-2007	MS	WAES0704USA00624	17-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Information has been received from a nurse practitioner concerning an approximately 16 year old female who was seen in a clinic for a migraine, and subsequently, was vaccinated IM with the first dose of Gardasil. It was reported that the patient developed seizures within 15-20 minutes of vaccination. The clinic called 911, and the nurse practitioner "believed" the patient was taken to the emergency room, although, it was unknown if the patient was hospitalized. It was also reported that the patient had no prior history of seizures, and that the patient's outcome was unknown. Upon internal review, the patient's seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:**

**Prex Illness:** Migraine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1516

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276315-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	20-Dec-2006	01-Jan-2007	12	16-Apr-2007	17-Apr-2007	--	WAES0704USA00625	17-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a registered nurse for the Pregnancy registry for Gardasil concerning a 26 year old female who on 20-DEC-2006 was vaccinated IM with the second 0.5 mL dose of Gardasil. The patient was vaccinated with the first 0.5 mL dose Gardasil (lot # 653937/0637F) on 27-OCT-2006. Concomitant therapy included hormonal contraceptives (unspecified). In January 2007, the patient became pregnant. In March 2007, the patient had a miscarriage at 8 weeks gestation. The patient sought unspecified medical attention. Subsequently, the patient recovered. Upon internal review, the patient's miscarriage was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** hormonal contraceptives

**Lab Data:** Unknown

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown)

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1517

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276328-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
9.0	F	09-Apr-2007	10-Apr-2007	1	16-Apr-2007	19-Apr-2007	MA		20-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Torticollis

**Symptom Text:** Gardasil #1 received 4/9/07 woke up 4/10/07 with acute torticoillis.

**Other Meds:** None

**Lab Data:** None

**History:** 4/2/07 had a febrile illness with vomiting

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1518

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276336-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	12-Mar-2007	19-Mar-2007	7	16-Apr-2007	19-Apr-2007	NJ		20-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1497F	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash papular, Rash pruritic, Rash vesicular

**Symptom Text:** Papular vesicular pruritic rash began 1 week after receiving Varivax booster.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276343-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	26-Mar-2007	Unknown		16-Apr-2007	26-Apr-2007	LA	LA070401	26-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2556AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2061AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Expired drug administered

**Symptom Text:** #2 MMR administered expired lot # MSD 0377R (3/24/07) couldn't update in LINKS

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276349-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	19-Mar-2007	22-Mar-2007	3	16-Apr-2007	26-Apr-2007	MA		26-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Rash macular

**Symptom Text:** on 3/22/07 broke out in rash on right arms, upper chest and neck itchy. on 3/23/07-examined and very faint macular rash on arms, neck, upper trunk, not urticaria

**Other Meds:**

**Lab Data:** Also on OLP (Yaz)

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1521

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276351-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	11-Apr-2007	11-Apr-2007	0	16-Apr-2007	19-Apr-2007	NH	NH0716	20-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2221AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fall, Head injury, Posturing, Staring

**Symptom Text:** Sitting on exam table , received vaccines Gardasil and Menactra. Got down from exam table, stood up and fell forward, hitting forehead on the wall. Nurse pivoted her onto a chair, sitting position. "Patient's eyes were open, back arched, arms straight and posturing" x approximately 3 seconds. Relaxed - still staring, not alert. Nurse and medical student placed her on exam table reclining.

**Other Meds:** None

**Lab Data:** Vital signs stable, neurologically stable, per provider note

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1522

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276352-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	09-Apr-2007	09-Apr-2007	0	16-Apr-2007	19-Apr-2007	NH	NH0717	20-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2221AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fall, Feeling hot, Head injury, Posture abnormal, Tremor

**Symptom Text:** Patient had lab work done 1st (hemoglobin), then received vaccines-Gardasil and Menactra left exam room, walked into waiting room and told mother she felt "hot and dizzy"; "fell over, hit head, eyes remained and open, head arched back, arms shaking. "Episode over within 1-2 minutes.

**Other Meds:** Birth control "patch", Albuterol Inhaler prn

**Lab Data:** Orthostatic vital signs done; stable

**History:** Asthma, Dysmenorrhea, Migraines-Acne

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1523

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276442-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	21-Mar-2007	21-Mar-2007	0	16-Apr-2007	26-Apr-2007	MA		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	V214AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1426F		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fall, Head injury, Headache, Heart rate normal, Muscle twitching, Pallor, Staring

**Symptom Text:** Received immunizations at approximately 6:50 pm, went to waiting room where brother and sister saw her fall to floor hitting her head (L side) on a wooden play box. They said she just stared for about 5 seconds and then L arm/shoulder was twitching when RN arrived, was conscious and in a chair. She was pale, P68 at a few minutes before 7 am. BP 7:10pm 100/70. By 7:25 pm, BP was increased to 78. She was still dizzy and c/o headache, so ambulance was called. She was observed in ER and discharged home.

**Other Meds:** None

**Lab Data:** EKG nl

**History:** Allergies-erythromycin; Medical conditions-acanthosis, overweight

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1524

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276530-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	23-Feb-2007	23-Feb-2007	0	17-Apr-2007	18-Apr-2007	GA	WAES0704USA01566	18-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Fall

**Symptom Text:** Information has been received from a Certified Medical Assistant (C.M.A.) concerning a 14 year old female patient who on 23-FEB-2007 was vaccinated IM with 0.5 mL of Gardasil. On 23-FEB-2007 the patient fell to floor in a seizure like state. After 30 seconds she became conscious. Patient never had a seizure like episode before this incident. Unspecified medical attention was sought by the patient. The patient recovered the same day. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1525

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276531-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	01-Mar-2007	01-Mar-2007	0	17-Apr-2007	18-Apr-2007	--	WAES0704USA01485	18-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Drug administered at inappropriate site, Facial palsy

**Symptom Text:** Information has been received from a certified nurse midwife, via a company representative, concerning a 25 year old female patient who on 01-MAR-2007 was vaccinated in the hip, with the first dose of Gardasil (Lot #02630 - invalid). There was no concomitant medication. The nurse stated that on 27-MAR-2007, the patient developed Bell's palsy on the left side of her face, and added that the "patient's face is uncontrolled." The nurse confirmed that the patient visited the ER, but the date and details were not provided at the time of this report. Bell's palsy was considered to be disabling by the reporter. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1526

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276540-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	16-Mar-2007	27-Mar-2007	11	17-Apr-2007	19-Apr-2007	CO		25-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0244U	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Abasia, Diarrhoea, Flushing, Hypokinesia, Hypotension, Hypotension, Inflammation, Intensive care, Myalgia, Nausea, Pharyngolaryngeal pain, Pyrexia, Rash

**Symptom Text:** Severe myalgias starting 3/27/07 to the point of being unable to sit up or walk. Fever stated 4/4/07 PM. With in 1 hr of onset of fever, pt became hypotensive and had a flushing rash. She was admitted to the PICU and supported with pressors. As of 4/6/07, she is improving. No source had been identified. CK <7, BCXs neg. 04/19/07-records received from facility-DOS 4/4-4/10/07-DC DX: Hypotension. Rash. Presented with 2 week history not feeling well with significant myalgias. C/O sore throat, throat culture negative. Nausea, diarrhea. Developed progressive muscle pain. RX with dopamine. Source of infection may have been area of inflammation on back of earlobe at earring hole site.

**Other Meds:** Prevacid

**Lab Data:** BCx x 2 Neg, Ck <7, Strep (-), ASO (-), CXR (-), Pelvic (-), UCx x 2 neg, CRP = 8.3, ESR = 36 Records received 4/19/07-CXR normal. EKG WNL. Elevated WBC. CK WNL. Blood and urine cultures negative.

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276541-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	29-Mar-2007	29-Mar-2007	0	17-Apr-2007	19-Apr-2007	LA		19-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2061AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** patient collapsed 15 to 20 minutes after receiving MCV4 and Gardasil vaccines.

**Other Meds:** None

**Lab Data:** CBC with diff, LMP, BHCG, EKG, Echocardiogram, head CT scan, Chest X-ray, EEG

**History:** Hx headaches / depression / systolic murmur

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276554-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	06-Apr-2007	06-Apr-2007	0	17-Apr-2007	26-Apr-2007	AZ		26-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	03194		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Cold sweat, Dizziness, Pallor

**Symptom Text:** Dizziness following HPV injection, clammy, pale blood pressure went from 110/68 decreased to 80/52

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1529

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276557-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Mar-2004	25-Mar-2007	1098	17-Apr-2007	26-Apr-2007	WI		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1853BB	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1426F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pityriasis rosea, Urticaria

**Symptom Text:** Received vaccines 3/22/07, developed hives on stomach and back 3/25/07. On 4-3-07 saw a dermatologist and was diagnosed with pityriasis rosea.

**Other Meds:** Ortho

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1530

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276564-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	23-Mar-2007	Unknown		17-Apr-2007	27-Apr-2007	FL		27-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0011U	0	Left arm	Intramuscular	HEPA MNQ	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysfunctional uterine bleeding

**Symptom Text:** Dysfunctional uterine bleeding, without prior history of said WT = 100 lb.

**Other Meds:** None

**Lab Data:** Pending

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276602-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	03-Apr-2007	03-Apr-2007	0	17-Apr-2007	27-Apr-2007	PA		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526014AA	0	Left arm	Intramuscular	
	HEPA	SMITHKLINE BEECHAM	AHAVB14BAA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0263U	0	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1968AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Gaze palsy, Loss of consciousness, Muscle rigidity, Pallor, Staring

**Symptom Text:** 5 minutes after HPV vaccine was given patient became pale, her eyes rolled back in her head, and she became rigid, she lost conscious 30 seconds. When she came to she had postical s/s of a blank stare for about 5-10 seconds. She did become A x O x S. BP 116/ 78 P 64, Pulse O2 97%. Before vaccine BP 115/65

**Other Meds:**

**Lab Data:**

**History:** Allergic rhinitis, exercise induced asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1532

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276621-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	10-Apr-2007	11-Apr-2007	1	17-Apr-2007	18-Apr-2007	WY		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U1875AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1208F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abasia, Asthenia, Back pain, Chills, Delirium, Dizziness, Dizziness, Fatigue, Headache, Injection site inflammation, Malaise, Neck pain, Pain, Pallor, Pyrexia, Sleep disorder, Speech disorder

**Symptom Text:** Laurie (mother) reports: Emily started feeling sick the morning after the shot. She started out with a mild headache, neck, and back pain. She originally attributed it to being tired. By 9:00 pm on 4-11-07 she was running a high fever, hurting everywhere, had back pain, and a severe headache. She left work early because she was so ill. She did not sleep well that night. Her fever was high enough that you could feel the heat rising from her from a foot away. She was delirious, saying strange things throughout the night. I gave her tylenol and kept cold rags on her head. During her high fever time she had chills and severe headache. The shot sight was approximately four inches in diameter. Emily was unable to walk without assistance because she was dizzy and lightheaded. She was in bed with someone watching her for two days. She was still very week on the third day and slept most of the time. The shot was given on 4-10-07. Emily missed school Thursday (4-12) and Friday (4-13). She returned today 4-16-07. She still has a headache and neck pain. She is taking tylenol every four hours so that she can function. Emily has asthma and is allergic to septra and ceclor. She also had seizures from the pertussis in DPT shots and was never able to finish the series. Emily is still tired and has no color in her face but continues to do what she has to because she needs to be at school due to graduation being only 24 days away. If Emily had been the only one to get sick we would have said she must have had something else but we know of three other students to have reactions, that is why we were concerned. If you have any questions feel free to call or e-mail. Thank you for your time, Laurie Cunningham 307-248-1262 johnlaur@silverstar.com lcunningham@lcsd2.org

**Other Meds:**

**Lab Data:** None -

**History:** Septra and Ceclor. Reaction as a child to DTP.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276624-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	06-Mar-2007	06-Mar-2007	0	17-Apr-2007	18-Apr-2007	CA		18-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1085F	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B007AA	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2082AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0962F	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Malaise, Nausea, Pain in extremity

**Symptom Text:** Pain and numbness in arm for 2 days after vaccine administered. Malaise and intermittent nausea since day of vaccination.

**Other Meds:** ZOPENEX

**Lab Data:** N/A

**History:** Asthma

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276629-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	17-Jan-2007	12-Feb-2007	26	17-Apr-2007	19-Apr-2007	ME		25-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0954F	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Anaemia haemolytic autoimmune, Fatigue, Pallor

**Symptom Text:** Acute onset Autoimmune hemolytic anemia requiring IV steroids and hospitalization. Records received 4/24/07-from facility for DOS 02/13-02/15/07- DC DX: warm agglutinin autoimmune hemolytic anemia. Found at routine visit to be anemic by PCP. RX with high dose steroids. Two week HX of fatigue pallor, nauseated. 4-6 weeks prior had URI .

**Other Meds:** None

**Lab Data:** Available Records received 4/24/07-hemoglobin 5.4 and hematocrit 17. WBC 3.6. Platelets 211,000. LDH 493. Total Bilirubin 3.8. DAT Coombs found to have IgG anti-e antibody. Retic count elevated.

**History:** Migraine Records received 4/24/07-PMH: meconium aspiration ventilated for 10 days, full term. Several episodes of dehydration as a toddler required ER visits and IV hydration.

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276631-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	12-Feb-2007	08-Mar-2007	24	18-Apr-2007	27-Apr-2007	WA		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01860	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Gardasil #1 12/12/06, Gardasil #2 2/12/07 New onset seizures on 3/8/07 and 3/9/07 (non-hypoglycemic)

**Other Meds:** Insulin, Synthroid

**Lab Data:** CT/MRI normal, EEG normal

**History:** IDDM, Hypothyroidism x 8yrs

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276633-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	10-Feb-2007	Unknown		17-Apr-2007	27-Apr-2007	DE		27-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0187U	0	Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** C/O pain in her L arm where she got the Gardasil injection (02/10/07). Pain starts when she rotates arm inward or lift it shoulder level or above.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276634-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	06-Apr-2007	07-Apr-2007	1	17-Apr-2007	27-Apr-2007	OR		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2689AA	4	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	1030F	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1425F		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Chills, Dizziness, Dyspnoea, Hyperhidrosis, Oedema peripheral, Palpitations, Pyrexia, Tachycardia, Urticaria

**Symptom Text:** High fever, difficulty breathing, hives, diaphoresis, chills, weakness with difficult ambulation, tachycardia, arm swollen twice it's normal size per patient report, racing heard and severe dizziness (no syncope). Dizziness persists.

**Other Meds:** None

**Lab Data:** Complete neurologic evaluation

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1538

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276640-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	09-Mar-2007	16-Mar-2007	7	17-Apr-2007	19-Apr-2007	--		25-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0961F	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Choroidal naevus, Corneal deposits, Macular oedema, Uveitis, Uveitis

**Symptom Text:** B Uveitis (par planitis) treatment with steroids on-going 04/25/07-records received from PCP-eye exam by ophth on 4/5/07-3 week history of blurred vision in left eye. Ocular exam slowed acuities of 20/20 OD and 20/30 OS. Right eye had a few keratic precipitates, trace vitreous cells and a nevus along the superior arcade. Left eye had keratic precipitates, 10 AC cell/hpf, much more vitreous cell, pars plana exudation and mild macular edema. DX:acute bilateral uveitis most like pars planitis. PMH: anxiety.

**Other Meds:**

**Lab Data:** Evaluation for Sarcoid neg, evaluation for arthritis pending Records received 4/25/07- Labs: HLA-B27 positive. Rheumatoid factor negative. Angiotensin Converting Enzyme (ACE) 42.

**History:** Anxiety

**Prex Illness:** Mild Pharyngitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1539

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276699-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	22-Jan-2007	24-Jan-2007	2	18-Apr-2007	18-Apr-2007	FR	WAES0704HUN00005	18-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Thrombocytopenia

**Symptom Text:** Information has been received from a physician concerning a 15 year old female with a history of upper respiratory tract infection (1 week prior vaccination) who on 22-Jan-2007 was vaccinated with human papillomavirus vaccine for prophylaxis. On 24-JAN-2007 the patient experienced immuno-thrombocytopenia and was hospitalized. Subsequently, the patient recovered from thrombocytopenia due to steroid treatment. The reporter felt that thrombocytopenia was not related to therapy with Gardasil. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** platelet count 24an07 24 G/l, platelet count 29Jan07 147 G/l

**History:** Upper respiratory tract infection

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276755-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	16-Apr-2007	17-Apr-2007	1	18-Apr-2007	27-Apr-2007	FL		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Heart rate increased, Nausea

**Symptom Text:** Dizzy, Nausea, Rapid Heartbeat

**Other Meds:** Concerta, Lexapro, Valtrex, Kariva

**Lab Data:**

**History:** Herpes simplex virus Type 1

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276756-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	28-Feb-2007	28-Feb-2007	0	18-Apr-2007	27-Apr-2007	CA		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	024EU	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Urticaria on lower arm after HPV immunization

**Other Meds:**

**Lab Data:**

**History:** Penicillin Allergy

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1542

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276758-1      **Related reports:** 276758-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	09-Apr-2007	10-Apr-2007	1	18-Apr-2007	27-Apr-2007	TX		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1501F	1	Right arm	Unknown	
	MNQ	AVENTIS PASTEUR	U2155UA	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	1213F	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1424F	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Guttate psoriasis, Rash macular, Streptococcal identification test positive

**Symptom Text:** Patient returned to clinic within 24 hours of vaccination for macular rash on trunk. Macules approx 1-2 cm, annular. Pt did test (+) for strep and was diagnosed with gutate psoriasis vs vaccine rxn.

**Other Meds:**

**Lab Data:** 4/10/07 (+) Strep

**History:** Acne

**Prex Illness:** none

**Prex Vax Illns:** fever~Vaccine not specified~~0~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276758-2      **Related reports:** 276758-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	09-Apr-2007	11-Apr-2007	2	24-Apr-2007	03-May-2007	TX		08-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1501F	1	Left arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	1213F	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1424F	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2155CA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous

**Symptom Text:** Pt presented with rash discrete erythematous lesion on trunk, Afebrile no lesion prior to immunization.

**Other Meds:**

**Lab Data:**

**History:** Acne

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1544

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276760-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	16-Apr-2007	Unknown		18-Apr-2007	27-Apr-2007	TX		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U	1	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache, Nausea, Pyrexia

**Symptom Text:** Patient c/o nausea, fever, HA, fatigue 3 days, cont. sxs.

**Other Meds:**

**Lab Data:**

**History:** Sulfur

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1545

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276797-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Mar-2007	11-Mar-2007	4	18-Apr-2007	23-Apr-2007	CA		02-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Blister, Chapped lips, Dehydration, Fluid replacement, Injection site erythema, Injection site pain, Injection site swelling, Lip swelling, Stomatitis

**Symptom Text:** pt. received TDAP,HPV,VZV and MENING on 3/7/07. Within a week, one of the injections sites swelled,became painful and red. The doctor's office was notified of this reaction. Within two weeks of injections, both lips swelled for one day. Within 4 weeks of injection, lips cracked and by the fith week after injection pt was hospitalized for severe stomatitis. Please note, the pt has never suffered these symptoms before, nor has she seeked care for this problem prior to this outbreak. Pt became dehydrated and needed i.v. care. Pt had blister type lesions that started on the outside of the lips and continued to spread to the back of the throat. Pt has improved greatly and should have a full recovery.

**Other Meds:** none

**Lab Data:** lip culture and blood cultures.

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1546

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276813-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	15-Mar-2007	15-Mar-2007	0	13-Apr-2007	23-Apr-2007	--	WAES0703USA03619	07-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Injection site irritation, Throat irritation

**Symptom Text:** Information has been received from a nurse concerning a 27 year old female (inappropriate age) who on 15-MAR-2007 was vaccinated with HPV. On 15-MAR-2007, the patient experienced burning in her arm near the injection site as well as burning in her throat after receiving HPV. The patient sought unspecified medical attention. On 15-MAR-2007, the patient recovered from burning in her arm near the injection site and burning in her throat. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276968-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
37.0	F	11-Oct-2006	12-Oct-2006	1	19-Apr-2007	27-Apr-2007	MD		07-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Diarrhoea, Influenza like illness, Insomnia, Myalgia, Nausea, Pyrexia, Vaccine positive rechallenge, Vomiting

**Symptom Text:** Noticed both after 1st and 2nd dose, within 1st 4-5 days. Flu-like symptoms. Sleeplessness, fever (100.0), nausea, vomiting, myalgia, arthralgia, diarrhea. No treatment.

**Other Meds:** Flonase

**Lab Data:** None

**History:** Neosporin

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 276976-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.1	F	13-Apr-2007	16-Apr-2007	3	19-Apr-2007	27-Apr-2007	NC		30-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B065CA	0	Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1282F	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1947AA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration, Injection site pain

**Symptom Text:** Lg, tender, erythematous area of approx 8x 11 cm with area of induration 6 x 7 cm, around site of Menactra vaccine. Tender area of eryth. and induration 3 x 6 cm of TDaP vaccine. Both vacc. given 3 days ago. Given Zyrtec 10 mg qd

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1549

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277000-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	22-Jan-2007	22-Jan-2007	0	19-Apr-2007	20-Apr-2007	AZ		20-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral

**Symptom Text:** within on half hour of administration hand, feet were red and swollen lasted several hours School nurse cooroborated, patient not seen in office by about 6 hours symptoms were gone

**Other Meds:** advair/albuteral inhaler

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277005-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	11-Apr-2007	12-Apr-2007	1	19-Apr-2007	30-Apr-2007	CO		30-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1311F	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0243U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site bruising, Injection site erythema, Injection site pruritus, Injection site warmth

**Symptom Text:** 4/12/07 AT 2:15 pm noted area at injection site slight itching - looked bruised - now red and hot to touch. 50mm X 35mm. No difficulty breathing, swelling, itching on other areas. Advised Benadryl PRN.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277102-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	19-Apr-2007	19-Apr-2007	0	20-Apr-2007	23-Apr-2007	MI		23-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Balance disorder, Convulsion, Dizziness, Headache

**Symptom Text:** Had HPV4 immunization at approx. 6:00pm and at 9:00pm Erin had a seizure. she was taken to the Emergency department and kept overnight. This Am she is still experiencing severe dizziness with loss of balance and headache.

**Other Meds:**

**Lab Data:**

**History:** High functioning Down's Syndrome

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277106-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	20-Apr-2007	20-Apr-2007	0	20-Apr-2007	23-Apr-2007	NY		23-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00110	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia facial, Paraesthesia

**Symptom Text:** A few minutes after the vaccine was administered, the patient stated that the left side of her face felt numb and was tingly. We let her rest for 15 minutes and the feeling did not subside. I contacted her primary health provider and I gave her 50mg benadryl IM, and she had total relief of her symptoms within five minutes. She left for home with her mother in stable condition, with instructions to call us if she had any other problems.

**Other Meds:** None

**Lab Data:**

**History:** Allergy to milk and peanuts. Reports heart palpitations when under stress.

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1553

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277112-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	05-Jan-2007	05-Jan-2007	0	20-Apr-2007	23-Apr-2007	NY	WAES0704USA01525	23-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	1	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Immediate post-injection reaction, Injection site swelling, Rash pruritic, Scab, Skin exfoliation, Skin exfoliation, Skin exfoliation, Swelling

**Symptom Text:** Information has been received from a registered nurse at a dermatology office, concerning a 17 year old female patient who on 20-SEP-2006 was vaccinated with the first dose of Gardasil (Lot #653736/0868F), and on 05-JAN-2007, with the second dose of Gardasil (Lot #655165/1425F) at an OB-GYN office. The nurse reported that on 05-JAN-2007, following the second vaccination, the patient, immediately got a bump on the right arm, "by approximately 19-JAN-2007 ("within 2 weeks of the vaccination"), the patient's "arm was itchy, scaly and bigger, than spread to whole body and face;" the patient developed a severe rash with itching. Prior to the first visit at the dermatology office, the nurse confirmed that the patient reported she had received treatment (date not specified) from a clinic, involving 2 courses of methylprednisone and cephalexin. On 27-JAN-2007, when the patient initially visited the dermatology office, the nurse indicated that the rash "looked like a sunburn that had peeled, was swollen, flaked and scabbed." Treatment on 27-JAN-2007 included an injection of DEPO-MEDROL), MOISTEREL cream (OTC). At the time of this report, it was unknown if the patient had recovered; the patient had a follow up visit scheduled at the dermatology office for 17-APR-2007. The reporter considered the severe rash with itching, peeling, swelling, flaking and scabbing to be disabling as the patient had missed school, and also an other medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** None

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1554

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277113-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	12-Feb-2007	12-Feb-2007	0	20-Apr-2007	23-Apr-2007	FR	WAES0704USA02616	23-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Immediate post-injection reaction, Pain in extremity, Paraesthesia, Syncope, Tonic convulsion

**Symptom Text:** Information has been received from a health authority concerning a 16 year old female with reportedly no other relevant medical history, who on 12-FEB-2007w as vaccinated intramuscularly, into the left, upper, arm with Gardasil, (Lot # NE45050). On 12-FEB-2007, immediately post vaccination (P.V.), the patient complained of pain and paraesthesia in the left arm. Ten minutes p.v. the patient experienced syncope with tonic convulsion for one minute. She was hospitalized. No information regarding treatment and duration of hospitalization was given, but the time until complete recovery was reported as "6 hours". The case is closed. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277114-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		20-Apr-2007	23-Apr-2007	--	WAES0704USA03052	23-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular			

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Abasia, Asthenia, Sensory loss, Syncope

**Symptom Text:** Information has been received from physician's assistant concerning a 16 year old female who was vaccinated intramuscularly with a 0.5 ml dose of Gardasil. it was reported that the patient was seen in the emergency room and the patient "collapsed, experienced weakness, sensory loss in extremities and the patient could not walk" after receiving Gardasil. The patient was hospitalized and the length of hospitalization was unknown. At the time of the report, it was unknown, if the patient recovered. The reporter considered collapsed, experienced weakness, sensory loss in extremities and could not walk to be disabling. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1556

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277115-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	16-Oct-2006	15-Nov-2006	30	20-Apr-2007	23-Apr-2007	PA	WAES0704USA02501	10-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0800F	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, LIFE THREATENING, SERIOUS

**MedDRA PT** Breast cancer, Breast mass, Cervical dysplasia, Cervical dysplasia, Cervical dysplasia, Condition aggravated, Human papilloma virus test positive, Mammogram abnormal, Mastectomy, Pregnancy test negative, Surgery

**Symptom Text:** Information has been received from a registered nurse, concerning a 26 year old female patient with a low grade squamous intraepithelial lesion, cervical dysplasia and cervical intraepithelial neoplasia-1 (18-AUG-2006), who on 16-OCT-2006 was vaccinated with the first dose, 0.5ml, IM in the left arm, of Gardasil (Lot #654540/0800F). There was no concomitant medication. On 15-DEC-2006, at an office visit scheduled to determine if she was pregnant, the patient reported that she felt a small lump in her left breast that had been there since approximately 15-NOV-2006 ("approximately one month"). The nurse added that the patient was sent to the hospital for a pregnancy test, which was negative. On 09-JAN-2007, the patient had a mammogram of the left breast which recommended that she undergo a biopsy, and on 17-Jan-2007, an ultrasound guided core biopsy of the left breast was performed; on 19-Jan-2007, the biopsy result showed "invasive and intraductal breast carcinoma." On 20-Jan-2007 the patient was vaccinated with the second dose, 0.5 ml, IM in the left arm, of Gardasil (Lot #654540/0800F). On 21-MAR-2007, a repeat Pap smear result was positive for human papilloma virus, and the nurse added that the usual treatment to remove the abnormal cells with the loop electrosurgical excision procedure (LEEP), was not performed due to the patient's breast cancer diagnosis. The nurse stated that the patient was scheduled to be seen by 2 surgeons for consideration and opinions of a bilateral mastectomy, and indicated that the patient would undergo chemotherapy following the surgery. The reporter considered the patient's invasive and intraductal breast carcinoma and/or positive human papilloma virus results to be immediately life-threatening and an other significant medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Breast biopsy 01/19/07 - invasive and intraductal breast carcinoma, Cervical smear 08/18/06 - ASC low grade squamous cell intraepithelial lesion encompassing HPV, mild dysplasia, CIN 1, cervical smear 03/21/07 - ASCUS, positive for HPV viru

**History:**

**Prex Illness:** Low grade squamous intraepithelial lesion, Cervical dysplasia, cervical intraepithelial neoplasia I

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1557

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277122-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	10-Apr-2007	10-Apr-2007	0	20-Apr-2007	26-Apr-2007	NJ		26-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	4214AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0250U	0	Right arm	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Cold sweat, Dizziness, Fall, Headache, Nausea, Somnolence, Vomiting

**Symptom Text:** 940 AM found patient on floor with fists lasted approx. 3-5 seconds after patient responsive but c/o headache, dizziness, nausea - BP 122/82 - skin cool and clammy - MD in to check patient c/o of same symptoms but with onset of vomiting - responsive at all times but drowsy - transported to hospital 1030 AM. (when patient fell she hit her head on a cabinet).

**Other Meds:**

**Lab Data:** CT scan - small subdural hematoma (when patient fell she hit her head on a cabinet).

**History:** None

**Prex Illness:** Migraines

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277126-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.5	F	02-Mar-2007	02-Mar-2007	0	20-Apr-2007	01-May-2007	WA		01-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0263U		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site urticaria, Reaction to previous exposure to any vaccine

**Symptom Text:** Immediately after 3rd HPV shot she developed an approx 4 inch red/warm wheal at the injection site. This same reaction occurred years earlier with the 2nd MMR.

**Other Meds:** SERTRALINE

**Lab Data:**

**History:** Anorexia

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1559

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277130-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	03-Apr-2007	10-Apr-2007	7	20-Apr-2007	01-May-2007	MI		01-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site pain, Myalgia

**Symptom Text:** 2/20/2007 received 1st injection of HPV vaccine only noticed pain at site of injection the first day. 2nd HPV vaccine received 4/3/2007--no pain until 4/10 began to notice and has progressed to today 'muscle hurting all the way around' pain level "10" on scale 1 to 10.

**Other Meds:** Thylerol

**Lab Data:** None known

**History:** Thyroid condition

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1560

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277139-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	11-Apr-2007	12-Apr-2007	1	20-Apr-2007	02-May-2007	OH		02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	1	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cellulitis, Oedema peripheral, Pain in extremity

**Symptom Text:** Pt stated had reaction to 1s injection determined not related to Gardasil . C/O cellulitis to L finger/hand inj given in L delt. 2nd injection to R delt, pt c/o same reaction - swelling, pain to L finger/hand again - saw PCP tx for cellulitis. Atzo given.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277140-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	02-Apr-2007	09-Apr-2007	7	20-Apr-2007	02-May-2007	TX		02-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	00914	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oedema peripheral, Pain in extremity

**Symptom Text:** swelling, painful arm (L)

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1562

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277142-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	09-Mar-2007	19-Apr-2007	41	20-Apr-2007	07-May-2007	NJ		07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01870	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Hypotonia, Lip swelling, Neurological examination normal, Oedema peripheral, Paraesthesia

**Symptom Text:** Received Gardasil on 03/09/2007. Patient reported numbness / tingling feeling in left fingers, arm and left swollen lip, then hands felt floppy / numb. Negative for shortness of breath, chest pain, fever, injury. Physical exam grossly normal, normal neurological exam.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1563

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277166-1 (S)    **Related reports:** 277166-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	27-Mar-2007	27-Mar-2007	0	23-Apr-2007	24-Apr-2007	--	WAES0704USA02270	25-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy, Pregnancy test positive, Uterine dilation and curettage, Vaginal haemorrhage, Vaginal haemorrhage, Vaginitis bacterial

**Symptom Text:** Information has been received from a physician for the Pregnancy registry for GARDASIL, concerning a 26 year old female patient with a history of first trimester miscarriage in 2006 who on 25-JAN-2007 was vaccinated IM with a first dose of HPV. The physician reported that on 27-MAR-2007 the patient was vaccinated with second dose of HPV and had a positive pregnancy test the next day. The patient presented to the physician's office on 09-APR-2007 with vaginal bleeding and a pelvic ultrasound determined that she was suffering a spontaneous abortion. She was at 6 weeks gestation. The patient was admitted to the hospital on the night of 09-APR-2007 with severe vaginal hemorrhaging and underwent an emergency dilation and curettage procedure. The patient was recovering without complication. The physician added that, on 27-MAR-2007, the patient was diagnosed with bacterial vaginosis but she did not take the prescribed treatment. The physician considered spontaneous abortion to be significantly disabling and life threatening. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** pelvic ultrasound 04/09/07 spontaneous abortion; complete blood cell Result not reported; total serum human 03/28/07 positive

**History:** Miscarriage

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1564

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277166-2 (S)    **Related reports:** 277166-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	27-Mar-2007	05-Apr-2007	9	24-Apr-2007	26-Apr-2007	--		26-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage, Uterine dilation and curettage

**Symptom Text:** Patient was apparently pregnant at time of administration of second vaccine dose. Apparently got pregnant right at or after 1st dose given. Experienced 1st trimester spontaneous abortion requiring emergency D & C hemorrhage.

**Other Meds:**

**Lab Data:** + pregnancy test

**History:** Previous 1st trimester miscarriage

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277167-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Apr-2007	01-Apr-2007	0	23-Apr-2007	24-Apr-2007	PA	WAES0704USA02668	25-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Gaze palsy

**Symptom Text:** Information has been received from a physician concerning a 12-15 year old (exact age unknown) female patient who in April 2007, was vaccinated with a dose of Gardasil. The patient started to convulse in front of the physician and her eyes rolled back after receiving the Gardasil. The patient received medical attention. The physician's office followed up with the patient the next day and she was doing fine. Upon internal review, convulsion was considered to be an other important medical event. The physician reported that another patient in the same age group convulsed after receiving the Gardasil. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277168-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		23-Apr-2007	24-Apr-2007	PA	WAES0704USA03302	25-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Condition aggravated, Convulsion

**Symptom Text:** Information has been received from a physician concerning a 12-15 year old (exact age unknown) patient with a history of seizure disorder (date not known), was vaccinated with a dose of Gardasil. The physician reported that the patient convulsed almost immediately after receiving the Gardasil, but he did not witness the patient's experience. The physician's office followed up with the patient next day and the patient was doing fine. Upon internal review, convulsion was considered to be an other important medical events. The physician reported that another patient in the same age group convulsed after receiving Gardasil. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Convulsion disorder

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1567

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277187-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	28-Mar-2007	28-Mar-2007	0	23-Apr-2007	02-May-2007	TX	TX07026	03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Deafness, Fall, Head injury, Syncope, Visual disturbance

**Symptom Text:** Patient was administered the HPV (Gardasil) #1 vaccine at 12:30 pm. Patient was sitting when the vaccine was administered, she got up from the exam table, standing besides the table. Patient fainted, falling on the floor, hitting her head to left side, pt. said she stopped hearing and saw everything white. She was helped from the floor and placed on exam table on a laying position. She was resting for 1 hour. Pt after 1 hour felt better and left the office walking.

**Other Meds:** NONE

**Lab Data:**

**History:** NKDA

**Prex Illness:** Ingrown toenail

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277188-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	30-Mar-2007	30-Mar-2007	0	23-Apr-2007	02-May-2007	TX	TX07027	03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache

**Symptom Text:** 3/30/07 10:00 AM HPV vaccine was administered on her left upper arm sitting on an exam table. 2-3 minutes after administering vaccine, pt. c/o a headache and dizziness. Pt. was placed on exam table in a laying position.

**Other Meds:** Fluoride

**Lab Data:** No test performed at the office on 3-30-07.

**History:** No known drug allergies, just diagnosed with Type II Diabetes

**Prex Illness:** Type II Diabetes

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277195-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	17-Apr-2007	17-Apr-2007	0	23-Apr-2007	03-May-2007	AK		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1427F	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Patient developed hives on her arm and then on trunk approximately 3 hours after administration of 2nd HPV vaccine.

**Other Meds:** Paroxetine, Nasonex

**Lab Data:**

**History:** Allergic Rhinitis, Anxiety NOS, ADHD

**Prex Illness:** Allergic Rhinitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1570

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277199-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	13-Apr-2007	13-Apr-2007	0	23-Apr-2007	02-May-2007	CA		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2002AC	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0263U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration, Injection site pruritus, Reaction to previous exposure to any vaccine

**Symptom Text:** 12 cm x 9 cm, red , hard, itchy area, around inj site on left arm-Old imm site (from Age 3-given in Foreign country) swelled up and go "bubbly".

**Other Meds:** PPD

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1571

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277202-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	09-Apr-2007	10-Apr-2007	1	23-Apr-2007	02-May-2007	KS		02-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2610AA	5	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Injection site erythema, Injection site pain, Injection site warmth, Neck pain, Pain

**Symptom Text:** Of reports sore, red, hot left upper arm, also pain on the left side of her neck, fatigue and body aches.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277211-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	01-Feb-2007	01-Feb-2007	0	23-Apr-2007	02-May-2007	TX		02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0013U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Pain at injection site lasting greater than 2 months.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1573

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277226-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	12-Mar-2007	13-Apr-2007	32	23-Apr-2007	24-Apr-2007	NC		24-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0314U	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash maculo-papular

**Symptom Text:** AFTER RECEIVING 2ND SHOT OF GARDASIL 4/12/07 SHE DEVELOPED A RASH ON THE INSIDE OF HER ARM(SAME AREN BUT OPPOSITE THE SITE OF THE INJECTION)- SHE HAD NO OTHER SIGNS SYMPTOMS- THE RASH WAS MACULOPAPULAR AND THE AREA INVOLVED WAS 4 CM IN DIAMETER

**Other Meds:** orthotricyclenlo tablets

**Lab Data:** NORMAL TEMPRATURE AND BLOOD PRESSURE

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1574

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277235-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
52.0	F	22-Nov-2006	22-Dec-2006	30	23-Apr-2007	24-Apr-2007	CA		24-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	?	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Joint swelling, Rheumatoid arthritis

**Symptom Text:** Second injection of Gardasil given on November 11,2006. On December 22,2007 needed to go to the emergency room at Hospital with swollen joints in hands and extreme pain, have been diagnosed with Rheumatoid Arthritis.

**Other Meds:** none

**Lab Data:** Have been diagnosed with Rheumatoid arthritis

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277241-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	28-Mar-2007	28-Mar-2007	0	23-Apr-2007	03-May-2007	CA		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1874U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Depressed mood, Fatigue

**Symptom Text:** Depressed mood and fatigue started evening of vaccine lasted 4 days.

**Other Meds:**

**Lab Data:**

**History:** Biaxin

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1576

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277262-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		24-Apr-2007	25-Apr-2007	TX	WAES0704USA02388	30-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Adverse event, Incorrect route of drug administration, Unevaluable event

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date, the patient was vaccinated with second dose of Gardasil (lot # not reported) SQ. Subsequently, the patient experienced an unspecified adverse event after the second dose of Gardasil was given. The patient sought medical attention and was hospitalized. The reporting physician did not administer the vaccine and was requesting follow-up from a medical team member. No further information was available at the time of reporting. Additional information has been requested. 4/26/07 CDC spoke with a nurse at the reporters office (the reporter for 277262). "While rounding in the hospital he was asked for advice about a patient (not his patient) who received her second HPV vaccine SQ instead of IM. They wanted to know if they should repeat the dose or not. He contacted Merck who responded with a letter saying they had not looked at this in the trials, etc. The patient did not have any problems.....the vaccine was administered incorrectly. " 4/27/07 Per email from CDC, "the report says the patient was hospitalized. According to your note, the pt. was NOT hospitalized. Correct? If so, we will have this corrected in VAERS." 4/27/07 Per email from CDC, "according to the nurse the patient was NOT hospitalized" 4/27/07 Per email from CDC, "Please change this in the VAERS database." Database change completed.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1577

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277273-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	10-Apr-2007	13-Apr-2007	3	24-Apr-2007	03-May-2007	TX		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Burning sensation, Haematoma, Injection site swelling, Skin reaction

**Symptom Text:** Skin reaction w/cresent shaped burn like reaction one week after 2nd dose of Gardasil. Swollen below injection site, probable hematoma.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277280-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	21-Feb-2007	23-Feb-2007	2	24-Apr-2007	03-May-2007	DE		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives - no treatment

**Other Meds:** Loestrin

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277281-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
27.0	F	11-Apr-2007	18-Apr-2007	7	24-Apr-2007	02-May-2007	NC		03-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01880	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Rash papular, Skin burning sensation

**Symptom Text:** redness, with pimple like sore and burning x 1 week 1 day (only reported today 4-19-07) per patient, temp 98.4

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277305-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	12-Apr-2007	12-Apr-2007	0	24-Apr-2007	03-May-2007	OR		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Affect lability, Agitation, Crying

**Symptom Text:** Emotional agitation, sobbing for unknown reasons - very emotions for 2-3 hours.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277309-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	11-Apr-2007	11-Apr-2007	0	24-Apr-2007	03-May-2007	PA		03-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1148F	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	
	HEPA	SMITHKLINE BEECHAM	AHAVB148AA	1	Right arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U1908AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Hypotonia, Loss of consciousness, Muscle rigidity, Pallor, Postictal state, Staring

**Symptom Text:** After vaccine was given pt stated "she felt like she was going to pass out" she turned pale and rigid and lost conscious for about 1 min and when she came to she had post ictal s/s of a blank stare for about 5-10 sec and no response. Pt did walk back to a room without much time, when she got back to the room she became "limp" and needed to be lifted onto a tablet. Went home A+o x '53

**Other Meds:** None

**Lab Data:** O2 Sat 98%, BP 102/78

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1582

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277319-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	13-Apr-2007	13-Apr-2007	0	24-Apr-2007	25-Apr-2007	NM	A0647898A	07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0187U		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB148AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness, Syncope

**Symptom Text:** This case was reported by a physician and described the occurrence of unconscious in a 12-year-old female subject who was vaccinated with Havrix, Gardasil for prophylaxis. The subject was reported to be "otherwise healthy". The subject experienced on adverse events following previous vaccinations. There were no concurrent medications. On 13 April 2007 at 11:00, the subject received the 1st dose of Havrix (.5 ml, unknown, left arm). On 13 April 2007 at an unspecified time, the subject received the 1st dose of Gardasil. On 13 April 2007, 2 minutes after vaccination with Havrix and an unspecified time after vaccination with Gardasil, the subject experienced two episodes of dizziness and fainting within five minutes of dosing. The subject was unconscious for a minute or less with each episode. This case was assessed as medically serious by manufacturer. On 13 April 2007, the events were resolved.

**Other Meds:** No concurrent medication

**Lab Data:** UNK

**History:** The subject was reported to be "otherwise healthy". The subject experienced no adverse events following previous vaccinations.

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1583

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277326-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	20-Apr-2007	20-Apr-2007	0	24-Apr-2007	25-Apr-2007	MI		25-Apr-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Dizziness, Nausea, Syncope

**Symptom Text:** Seizure of approx. 1 min. occured 3 hrs. following immunization, fainting twice immediately following seizure lasting approx. 30 sec. each episode, seizure of approx. 15 seconds 15 hours after immunization, severe dizziness following initial seizure lasting approx. 40 hrs. accompanied by nausea; treated in Emergency Room within 15 min. post-seizure; phenobarbital administered via IV following diagnostic tests and discharged home.

**Other Meds:** Aspirin, Levothyroxine

**Lab Data:** Blood tests and urinalysis results normal; CT scan indicated no change from previous scan.

**History:** NO HISTORY OF SEIZURES PRIOR TO THIS INCIDENT; Down Syndrome, Obstructive Sleep Apnea, Moya Moya Disease, Hypothyroidism, Wolff-Parkinson-White Syndrome, Arthritis secondary to hip dysplasia

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277330-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	23-Apr-2007	23-Apr-2007	0	24-Apr-2007	26-Apr-2007	MO		26-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F	1	Right arm	Intramuscular	HPV

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, No adverse effect

**Symptom Text:** Patient given second dose of HPV vaccine 2 weeks after receiving the first dose. No adverse reaction. No treatment needed.

**Other Meds:** none

**Lab Data:** None

**History:** Unknown

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277339-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	19-Apr-2007	20-Apr-2007	1	24-Apr-2007	25-Apr-2007	OH		25-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	U2106AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0187U	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Activities of daily living impaired, Dizziness

**Symptom Text:** Persistent dizziness for several days, prevented her from working for 1-2 days

**Other Meds:** Septra

**Lab Data:**

**History:** Acne

**Prex Illness:** None

**Prex Vax Illns:** uncertain~DTaP (unknown mfr)~1~0~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1586

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277351-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	10-Apr-2007	10-Apr-2007	0	25-Apr-2007	26-Apr-2007	FR	WAES0704USA03084	26-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NE12410	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Oedema peripheral, Skin warm

**Symptom Text:** Information has been received from a physician concerning a 13 year old female with no relevant past medical history, and no history of allergies, who on 10-APR-2007 was vaccinated intramuscularly into the left upper arm with the first dose of Gardasil (Batch # NE12410). On 10-Apr-2007, a few hours post vaccination, the patient experienced swelling of the entire left arm including the fingers with redness and warmth. The patient was treated with cortisone and antiallergic agents. At the time of this report, the patient had not recovered. The reporting physician felt that the events were important for other medical events. Additional information has been requested. Other business partner numbers include E2007-02275.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1587

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277352-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
50.0	F	21-Feb-2007	21-Feb-2007	0	25-Apr-2007	26-Apr-2007	MI	WAES0704USA03897	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	0243U	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

**MedDRA PT** Condition aggravated, Facial palsy, Guillain-Barre syndrome, Inappropriate schedule of drug administration

**Symptom Text:** Information has been received from a registered nurse, concerning a 50 year old female with hearing loss (16-AUG-2007), a facial nerve disorder, Lyme disease with arthritis, pruritus, multiple allergic reactions to antibiotics including tetracycline, CECLOR and KEFLEX, and multiple drug hypersensitivities including morphine, and propoxyphene and DARVO CET, who on 21-FEB-2007 was vaccinated with the first dose, 0.5 ml, IM in the left deltoid, of Gardasil (lot #656372/0243U). Concomitant therapy included INDERAL, MINOCIN, TRILISATE TABLETS/LIQUID), DIAMOX and MIDRIN. On 05-APR-2007 the patient was hospitalized after she developed facial palsy. The nurse reported that on 09-APR-2007, the patient called the office to report her condition. The patient remained hospitalized until 16-APR-2007, and on that day she called the office, and stated that she "had a possible diagnosis of Guillian Barre syndrome." The patient reported she believed that Gardasil caused her condition, and had requested a human papilloma virus antibody test. The reporter considered the event of facial palsy and possible Guillian Barre syndrome to be an other significant medical event. Additional information has been requested.

**Other Meds:** MIDRIN, DIAMOX, TRILISATE TABLETS/LIQUIS, MINOCIN, INDERAL

**Lab Data:** Unknown

**History:**

**Prex Illness:** Hearing loss; Facial nerve disorder; Lyme disease; Pruritus; Arthritis; Allergic reaction to antibiotics; Drug hypersensitivity

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1588

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277359-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Feb-2007	22-Feb-2007	0	25-Apr-2007	03-May-2007	NY		03-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1208F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Nausea

**Symptom Text:** Vaccia given 2:45 - on 2/22/07 - for remainder of day. Patient felt increase fatigue, lightheaded, nauseated. Spent day in nurse office sleeping.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277375-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	18-Apr-2007	21-Apr-2007	3	25-Apr-2007	26-Apr-2007	MI		26-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0244U	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives, was treated with relief with Benedryl and prednisone

**Other Meds:**

**Lab Data:**

**History:** NOne reported

**Prex Illness:** None reported

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277385-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	20-Mar-2007	06-Apr-2007	17	25-Apr-2007	26-Apr-2007	CA		26-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	42159AA	0	Right arm	Intramuscular	
	HEPA	SMITHKLINE BEECHAM	AHAVB129AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00114	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Henoch-Schonlein purpura

**Symptom Text:** Developed Henoch-Schonlein-Purpura 4/6/07. Received Hepatitis A vaccine, HPV, & MVC-4 vaccine on 3/20/07.

**Other Meds:**

**Lab Data:** Had mild hematuria which has now resolved

**History:** none

**Prex Illness:** none

**Prex Vax Illns:** n/a~~NULL~~In Patient

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277390-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Jan-2007	09-Jan-2007	1	25-Apr-2007	07-May-2007	NC		07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B005CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1209F	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	121974AB	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Eye swelling, Headache, Rash, Throat tightness, Wheezing

**Symptom Text:** 1 hr after visit eyes swollen, rash on both wrists, wheezing (Hx of Asthma), HA, took 2 ASA for HA and Benadryl. Also tightness in throat. Better with in 15 minutes of Benadryl. Pt was on no allergy meds at this time.

**Other Meds:** Hx of Asthma-been on Flonase, Claritin, Albuterol in past

**Lab Data:** Allergy testing by Allergist (+) Skin test to Menactra

**History:** Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277393-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	23-Apr-2007	24-Apr-2007	1	25-Apr-2007	03-May-2007	PA		03-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Injection site pruritus, Urticaria

**Symptom Text:** Pt's school nurse called pt c/o SOB at school. Also c/o itching and Welt at site of 2nd Gardasil injection site. Advised to send pt to closest ER for evaluation.

**Other Meds:** None

**Lab Data:** None

**History:** Seasonal allergies

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1593

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277402-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	10-Apr-2007	10-Apr-2007	0	26-Apr-2007	27-Apr-2007	AL	WAES0704USA03424	27-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Dry mouth, Dysphagia, Dyspnoea, Headache, Throat tightness

**Symptom Text:** Information has been received from a physician concerning a 21 year old female who on approximately 10-APR-2007 was vaccinated with a first dose of Gardasil. On approximately 10-APR-2007 the patient experienced dry mouth, tightness in her throat, difficulty swallowing, shortness of breath, diarrhea and headache. The patient was treated with dexamethasone injection and Benadryl injection. Subsequently, the patient recovered. There were no laboratory or diagnostic tests performed. The reporting physician considered dry mouth, tightness in her throat, difficulty swallowing, shortness of breath, diarrhea and headache to be other important medical events. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** None

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277403-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	Unknown	Unknown		26-Apr-2007	27-Apr-2007	NC	WAES0704USA04051	27-Apr-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Renal failure

**Symptom Text:** Information has been received from a physician concerning a 12 year old female patient with a history of "kidney failure" who was vaccinated with a dose of Gardasil. The patient had a complete kidney failure a few days after getting the Gardasil. Unspecified medical attention was sought by the patient. The outcome of the patient was unknown at the time of this report. Upon internal review, kidney failure was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Renal failure

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277413-1

<b>Age</b>	<b>Gender</b>	<b>Vaccine Date</b>	<b>Onset Date</b>	<b>Days</b>	<b>Received Date</b>	<b>Status Date</b>	<b>State</b>	<b>Mfr Report Id</b>	<b>Last Edit Date</b>
Unknown	U	Unknown	Unknown		26-Apr-2007	03-May-2007	MO		04-May-2007

<b>VAX Detail:</b>	<b>Type</b>	<b>Manufacturer</b>	<b>Lot</b>	<b>Prev Doses</b>	<b>Site</b>	<b>Route</b>	<b>Other Vaccine</b>
	VARCEL	MERCK & CO. INC.	1250F	1	Left arm	Subcutaneously	
	MNQ	AVENTIS PASTEUR	U2208AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0014U	0	Left arm	Intramuscular	
	TDAP	AVENTIS PASTEUR	C26900AA	5	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anaphylactic reaction, Dyspnoea, Rash, Wheezing

**Symptom Text:** Anaphylaxis, rash, wheezing, mild difficulty breathing. Recovered completely with steroids, Benadryl, etc. Has since had second Gardasil, no problems.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277420-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	Unknown	Unknown		26-Apr-2007	03-May-2007	--		04-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0960F	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure decreased, Heart rate decreased, Syncope vasovagal

**Symptom Text:** Increase vagal response after HPV shot, decrease BP, decrease HR, 98/60 ---> 88/56, 74---> 40

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1597

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277430-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	08-Mar-2007	10-Mar-2007	2	26-Apr-2007	27-Apr-2007	NY		27-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Myalgia, Pain

**Symptom Text:** PATIENT DESCRIBED MUSCLE ACHES AND JOINT PAIN ABOUT 2 DAYS AFTER RECEIVING INITIAL DOSE OF GARDASIL ON 3/8/07. PATIENT CONTINUED WITH BODY ACHES AND JOINT PAIN UP UNTIL APRIL 6TH PATIENT REPORT THIS ON DATE 2ND INJECTION WAS TO BE GIVEN ON 4/20/2007. PATIENT HAD CONTACTED HER PCP WHO ADVISED HER NOT TO CONTINUE THE SERIES.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1598

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277453-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	26-Apr-2007	Unknown		26-Apr-2007	03-May-2007	NH	NH0719	04-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Medication error, Unevaluable event

**Symptom Text:** Sisters in same exam room; both due to receive HPV vaccine and Menactra. 12 y/o patient received 1 dose of HPV vaccine in each arm, I'm simultaneously, instead of 1 dose HPV and 1 dose Menactra.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277457-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	07-Mar-2007	07-Mar-2007	0	26-Apr-2007	03-May-2007	MO		04-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2690AA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0014U	0	Left arm	Intramuscular	
	MNQ	AVENTIS PASTEUR	U2208AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaphylactic reaction, Dyspnoea, Rash, Wheezing

**Symptom Text:** Anaphylaxis, rash, wheezing, mild difficulty breathing. Recovered completely with steroids, Benadryl etc.

**Other Meds:** Concerta 18 mg

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277458-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	24-Apr-2007	25-Apr-2007	1	26-Apr-2007	03-May-2007	MO		04-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	AVENTIS PASTEUR	C2632AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Hypersensitivity, Nausea, Pruritus, Rash

**Symptom Text:** Patient developed itching and rash on her chest which is a typical location for her when she has an allergic reaction. Also had dizziness, fatigue and nausea.

**Other Meds:** Orthotricyclen, Allegra D, Differin gel

**Lab Data:** none

**History:** Sulfa drugs

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277498-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	27-Apr-2007	27-Apr-2007	0	27-Apr-2007	04-May-2007	DE		04-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0389U		Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Head injury, Loss of consciousness

**Symptom Text:** Pt passed out after injection - Head injury obtained.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1602

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277508-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	06-Apr-2007	10-Apr-2007	4	27-Apr-2007	30-Apr-2007	TX		30-Apr-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	2	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Insomnia, Nausea

**Symptom Text:** Light-headedness and nausea, mostly with position changes or walking, lasting up to 2 hrs, relieved with lying down, for 3 days, beginning 4 days after receiving 3rd Gardasil vaccine. Had 2 episodes 1st day, then 4 episodes next day. Came in for eval 3rd day, had brief episode that morning, and for 2 min. while standing in office. Menses started 2nd day. Also some difficulty falling asleep 1st and 2nd days. Symptoms all resolved by 4th day, was reportedly back to normal. No treatment given except recommendation to increase fluids, get up slowly.

**Other Meds:** none

**Lab Data:** Fasting complete metabolic profile and CBC were WNL.

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277537-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	11-Apr-2007	Unknown		27-Apr-2007	04-May-2007	VA		04-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy

**Symptom Text:** Patient received Gardasil vaccine on 4-11-07. On 4-25-07, patient had + pregnancy test.

**Other Meds:** Xanax, Lexapro, Lamictal, Prilosec, Depo shots

**Lab Data:** Beta HCG = 135, 364 on 4-25-07

**History:**

**Prex Illness:** Sinusitis, no fever

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1604

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277575-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	07-Mar-2007	07-Mar-2007	0	30-Apr-2007	01-May-2007	--	WAES0704USA03910	02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, LIFE THREATENING, SERIOUS

**MedDRA PT** Convulsion, Gaze palsy, Loss of consciousness, Muscle twitching, Oxygen supplementation, Stomach discomfort, Unresponsive to stimuli

**Symptom Text:** Information has been received from a licensed practical nurse (LPN) concerning a 13 year old female patient who on 07-MAR-2007 was vaccinated IM in the right deltoid with the first dose, 0.5ml, of Gardasil (Lot #657006/0188U). There was no concomitant medication. The nurse reported that on 07-MAR-2007, 10 minutes after the vaccine was administered, the patient complained of an upset stomach, and then passed out. The nurse reported that the patient's breathing was normal, but she did not regain conscious or respond to verbal stimulation; "the patient's eyes then "rolled back in her head and she began twitching with seizure like activity." The patient's pulse oximetry results were between 80# to 100%, and oxygen was administered. The nurse stated that 911 was called, and an intravenous line was started with Valium, 10 mg, administered prior to the ambulance arrival. The patient was taken to the ER, but was not admitted, and her symptoms "lasted at least 20 minutes." The nurse confirmed that the patient had recovered on the same day, 07-MAR-2007, and added that on 12-APR-2007, when the patient returned to the office, her exam revealed no symptoms. The nurse considered the events to be life threatening, and an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** pulse oximetry 03/07/07 80%; pulse oximetry 03/07/07 100%

**History:** None

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1605

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277584-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	06-Apr-2007	06-Apr-2007	0	30-Apr-2007	10-May-2007	SD		10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscle spasms, Muscular weakness, Musculoskeletal discomfort, Musculoskeletal pain, Neck pain, Pain in extremity, Pain in extremity

**Symptom Text:** Pt is in with left arm pain. She said she used to get some cramps or charley horse occasionally somewhere in her hand between the third and fourth digits kind of "like toe cramps". Subsequently she got more cramps the day of the shot and then started developing an allusive pain in the anterior shoulder across the pectoral region and anterior deltoid and then down the arm into the radial forearm and into the hand. The pain migrates a little bit worse with use. It dose not keep her from sleeping at night. She notes that her hand is somewhat weaker and it has been progressively getting worse for the last 2 weeks. She has not had any neck pain. Denies any loss of sensation. No color change. No temperature change or coldness or circulatory symptoms. She received the Gardasil on 04-06-07 left deltoid. 2 months ago she was Indian wrestling and somewhat wrenched her neck a little bit and had some minor discomfort and when she extends her head she has a little bit of pain or discomfort at the base of her neck. No history of neck pain. No history of cervical disk problems, any other injury, or trauma to the left upper extremity. No other neurologic symptoms. No fevers. No URI symptoms, respiratory complaints, no cough, wheezy, dyspnea, no cardiac complaints. No abdominal pain, diarrhea or vomiting. No urinary frequency, dysuria or change, No gross weight change or any constitutional symptoms. No swelling of the extremities. No skin rashes or unusual markings.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277590-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	10-Apr-2007	10-Apr-2007	0	30-Apr-2007	10-May-2007	OH		10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain

**Symptom Text:** Pain at injection site

**Other Meds:** Orthocycline low

**Lab Data:**

**History:** Asthma-Albuterol

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1607

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277591-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
1.0	M	11-Apr-2007	20-Apr-2007	9	30-Apr-2007	10-May-2007	WV		10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1118F	0	Left leg	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB093BA	0	Right leg	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Skin lesion, Varicella

**Symptom Text:** 9 days after vaccination-temp of 102 and multiple chickenpox lesions on face and trunk-multiple lesions

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1608

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277597-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
11.0	F	07-Feb-2007	07-Feb-2007	0	30-Apr-2007	10-May-2007	CA		10-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fatigue, Syncope

**Symptom Text:** patient fainted in office approx 10 min. after injection. Patient rested a few minutes then went home. About 3:30pm mother reported child was feeling fatigued and was sleeping. Pt had ER visit later. 2-21-07 pt had a followup appt

**Other Meds:** none

**Lab Data:** CT negative, blood work 24 hr pending. On 2-21-07 doctor treated with Amoxicillin for sinusitis

**History:** Hx hypoglycemia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277622-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Apr-2007	08-Apr-2007	1	30-Apr-2007	10-May-2007	IN		10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	1	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Influenza like illness

**Symptom Text:** Flu like symptoms after 2nd Gardasil injection

**Other Meds:** Synthroid, Estra Step

**Lab Data:** None

**History:** Hypothyroid

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277623-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	27-Apr-2007	28-Apr-2007	1	30-Apr-2007	10-May-2007	WI		10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	03884	2	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Dizziness, Headache, Influenza like illness, Injection site pain, Vaccine positive rechallenge

**Symptom Text:** In addition to mild tenderness at injection site, flu like symptoms; headache, light headed, chills. No SOB. Miler symptoms with prior Gardasil (Both symptomatic treatment and reassurance.

**Other Meds:**

**Lab Data:** None

**History:** NKDA

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277657-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	27-Feb-2007	27-Feb-2007	0	30-Apr-2007	10-May-2007	MO		10-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	01870	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysphagia, Dysphonia, Dysphonia, Dyspnoea

**Symptom Text:** Gardasil - 1st inj 2/27/07 10-11 AM -03:00 pm could not breath, swallow - voice deep- hoarse. Did not go to ER - Fri AM took Benadryl, Baby ASA, throat spray. Lasted 2-3 days office today for 2nd inj told reaction after 1st inj.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1612

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277664-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	30-Oct-2006	31-Oct-2006	1	01-May-2007	02-May-2007	OH	WAES0704USA05875	02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0689F	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Arthralgia, Joint swelling

**Symptom Text:** Information has been received from a physician concerning his daughter, a 23 year old female with no drug reactions or allergies with acne who on 31-AUG-2006 was vaccinated intramuscularly with the first 0.5 ml dose of Gardasil (Lot # 653736/0689F). Concomitant therapy included hormonal contraceptives (unspecified) and doxycycline. On 30-OCT-2006, the patient was vaccinated, intramuscularly with the second 0.5 ml dose of Gardasil. On approximately 31-OCT-2006, "two months after the first dose", the patient experienced arthralgia, with progressive pain in her knees, and wrists, and left wrist swelling. On 26-FEB-2007, the patient was vaccinated, intramuscularly with the third 0.5 ml dose of Gardasil. The patient sought unspecified medical attention. Laboratory evaluation revealed elevated sedimentation rate (sed rate), elevated C-reactive protein, negative rheumatoid factor, and antinuclear antibodies (ANA) pending. The physician reported that he believed the pain was causing the patient significant disability as she could not participate in former activities. The patient was treated with ADVIL. At the time of the report, the patient had not recovered. The physician considered the patient's arthralgia with progressive pain in her knees and wrists and left wrist swelling to be disabling. Additional information has been requested.

**Other Meds:** Doxycycline, Hormonal contraceptives

**Lab Data:** erythrocyte - elevated, serum C-reactive - elevated, serum ANA - pending, serum rheumatoid factor - negative

**History:**

**Prex Illness:** Acne

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277665-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	23-Apr-2007	23-Apr-2007	0	01-May-2007	02-May-2007	NY	WAES0704USA05616	02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0014U	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Convulsion, Hypotension, Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a 16 year old female with no pertinent medical history who on 23-APR-2007 was vaccinated, intramuscularly, with a 0.5 ml first dose Gardasil (lot #653736/0014U). There were no concomitant medication. On 23-APR-2007, while attempting to leave the physician's office, the patient "appeared to have a seizure" and lost consciousness. It was reported that the incident lasted only a few seconds. When the patient regained consciousness it was discovered that her blood pressure was low. On 23-APR-2007, the patient recovered and was able to leave the physician's office with her mother. Upon internal review, "appeared to have a seizure" was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Unknown

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1614

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277666-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	Unknown	Unknown		01-May-2007	02-May-2007	--	WAES0704USA05597	02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion, Drug exposure during pregnancy

**Symptom Text:** Information has been received via the Merck pregnancy registry, from a licensed practical nurse, concerning a 19 year old female patient who was vaccinated with a first and second dose of Gardasil (dates unspecified), and during the vaccination series discovered she was pregnant (date of the LMP and estimated date of delivery were unspecified). The nurse reported that the patient elected to undergo an abortion for personal reasons, and clarified that this decision was "totally unrelated to receiving Gardasil." Upon internal review, elected to undergo an abortion was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:**

**Prex Illness:** Pregnancy NOS (LMP = unknown)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1615

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277667-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	20-Apr-2007	20-Apr-2007	0	01-May-2007	02-May-2007	IL	WAES0704USA05029	02-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		NULL	1	Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy, Facial palsy, Hypoaesthesia facial

**Symptom Text:** Information has been received from a consumer concerning her 18 year old female, daughter with chronic sinusitis and herpes simplex (cold sores in her mouth) and a history of ear infections who in February 2007 was vaccinated by injection with the first dose of Gardasil. Concomitant therapy included VALTREX. On 20-APR-2007, the patient was vaccinated by injection with the second dose of Gardasil. Within a few hours, after receiving the second dose of approximately, 20-APR-2007, the patient felt something strange on the right side of her face. Initially, she felt some numbness. Subsequently, the numbness was accompanied by some paralysis on the right side of her face. She went to her physician and she was diagnosed with a mild case of bells palsy. At the time of the report, the patient had not recovered. Upon internal review, it was determined that Bell's palsy was considered on other important medical event. Additional information has been requested.

**Other Meds:** VALTREX

**Lab Data:** Unknown

**History:** Ear infection

**Prex Illness:** Herpes simplex; chronic sinusitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277668-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	09-Feb-2007	09-Feb-2007	0	01-May-2007	02-May-2007	IN	WAES0704USA04977	02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Benign hydatidiform mole, Blighted ovum, Drug exposure during pregnancy

**Symptom Text:** Information has been received via the pregnancy registry, from a consumer concerning her 16 year old daughter, who was pregnant with an estimated date of conception on 05-JAN-2007, and on 09-FEB-2007 was vaccinated with the first dose of Gardasil. There was no concomitant medication. On 29-MAR-2007, the mother reported that her daughter, who was then "12 weeks pregnant," experienced a miscarriage; the mother added that the pregnancy was considered to be a blighted ovum, which she also referred to as a "mole pregnancy." The mother added that in April 2007, her daughter received the second dose of Gardasil. At the time of this report, it was unknown if the patient had recovered from the events. Upon internal review, blighted ovum, "mole pregnancy" and miscarriage were determined to be an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** Unknown

**History:**

**Prex Illness:** Pregnancy NOS (LMP = 1/5/2007)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1617

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277669-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	18-Apr-2007	18-Apr-2007	0	01-May-2007	02-May-2007	CA	WAES0704USA04219	02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dizziness, Fatigue, Feeling hot, Pallor, Paraesthesia, Sensation of heaviness, Syncope, Thirst

**Symptom Text:** Information has been received from a physician concerning a 17 year old female patient with past episodes of fainting with vaccinations who on 18-APR-2007 was vaccinated IM in the left arm with her first dose of Gardasil, lot #657617/0384U. After receiving the injection the patient fainted, which lasted a few seconds. The patient was completely white in the face and she complained that entire body felt like she was burning up. She was not warm to touch and did not have a fever. The patient kept asking for water. She regained color to her face 15 minutes later. She felt tingling for one hour or so both legs and arms and was very dizzy. Her eyes were closed for approximately 1 hour and she felt exhausted. The patient was given smelling salts and when asked if she was aware of what was being done to her, she "smelled violets". She had a fan on her for 30 minutes and she started to feel better. Her blood pressure was taken 2 or 3 times for approximately one hour and her pulse was also monitored. "Blood pressure reading (90/60 normal for patient). Pulse (60 normal for patient) for first 15 to 30 minutes after reaction was very faint." She was very alert one hour later (eyes open and talking) but complained of her legs feeling heavy. The patient had to be wheeled out to her car. The physician did not believe the patient hyperventilated to bring these reactions on herself. The physician believed giving the patient smelling salts, monitoring the blood pressure, pulse and putting the patient in front of a fan to cool her down was another medical event and the patient's experience was disabling because she went to bed and not able to do anything for rest of the day. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Blood pressure 04/19/06 90/60, total heartbeat count 04/19/06 60

**History:** Syncope; Immunisation

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277677-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	30-Apr-2007	01-May-2007	1	01-May-2007	10-May-2007	MO		10-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Swelling face

**Symptom Text:** 5/1/07 3:30 pm PC from client. States she woke up at noon today with a swollen, red face and "red spots all over both legs. Had received HPV immun on 4/30/07 in the afternoon went to express care at 1:00 pm and was seen by Dr states she was given Benadryl pills and steroid cream.

**Other Meds:** None

**Lab Data:** Unknown

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277744-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	26-Dec-2006	15-Jan-2007	20	01-May-2007	02-May-2007	CA		02-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Arthralgia, Arthralgia, Fatigue, Influenza like illness

**Symptom Text:** arthralgias of hands and wrists, flu-like symptoms, fatigue, knee and ankle pain starting 2-3 weeks after gardasil vaccine

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277751-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
25.0	F	24-Apr-2007	25-Apr-2007	1	01-May-2007	02-May-2007	MA		02-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** persistent vomiting for several hours resulting in emergency room visit. Treated with Zofran, Ativan and IV fluids. CT Scan needed to rule out intestinal obstruction as patient has Crohn's colitis.

**Other Meds:** Pentasa, Prilosec, Seasonal, Calcium+D supplement

**Lab Data:** Blood work for electrolytes - pre and post treatment. CT scan to rule out intestinal obstruction - patient has Crohn's colitis

**History:** Crohn's colitis

**Prex Illness:** None

**Prex Vax Illns:** none~~NULL~~In Patient|none~~NULL~~In Sibling1



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277776-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	24-Apr-2007	29-Apr-2007	5	02-May-2007	03-May-2007	MA		03-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain, Injection site pain

**Symptom Text:** Chest pain for 4 days which started 5 days after gardasil administration. Also has injection site pain.

**Other Meds:** none

**Lab Data:** Negative chest Xray and normal EKG.

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1622

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277788-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	06-Apr-2007	09-Apr-2007	3	02-May-2007	07-May-2007	NJ	NJ200705	07-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1425F	1	Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Grand mal convulsion, Joint contracture, Partial seizures

**Symptom Text:** 16 year old s/p receiving HPV #2 on 4/6/07. Presented 4/9/07 with possible focal seizure (contracture right hand) sent to ER then admitted with Grand Mal seizure episode that evening. Patient placed on Dilantin discharged home on Dilantin PO. No FMH of seizure episodes.

**Other Meds:** Not Known

**Lab Data:** C-scan of brain (neg), MRI of Brain Negative

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1623

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277813-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	05-Feb-2007	05-Feb-2007	0	03-May-2007	04-May-2007	FR	WAES0704CZE00002	04-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NE43130		Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Back pain, Cardiac murmur, Chest pain, Cough, Dyspnoea, Dyspnoea, Hyperhidrosis, Nausea, Vertigo, Viral infection

**Symptom Text:** Information has been received from a physician concerning a 16 year old virgin female who on 05-FEB-2007 was vaccinated (first dose) with Gardasil. There was no concomitant medication, no medical history information. On 05-FEB-2007 the patient experienced vertigo, back pain, chest pain, difficulties in breathing, cough, nausea and sweating and was hospitalized. Subsequently, the patient recovered and was on 08-FEB-2007 discharged from the hospital. The final diagnosis made by hospital physicians was virosis. According to the hospital chart these adverse experiences were not taken as related to vaccination. Based on the re-evaluation of the situation by the physician, administering vaccine, vertigo, back pain, chest pain, difficulties in breathing and cough, nausea and sweating could be possibly related to therapy with Gardasil. Administering physician received the information about patient's hospitalization on 11-APR-2007 when patient was visiting the site in order to obtain second dose of Gardasil vaccine. Vaccination was not performed, physician requested detailed information about hospitalization. - Based on the hospital chart, patient was vaccinated around 3p.m. on 05-FEB-2007. Although patient was informed that she should eliminate any physical activity for 48 hours after vaccination patient went to her temporary job at 6p.m. Patient reported that there was close weather and she experienced vertigo. On 7p.m. patient went to a dancing class and smoked a cigarette, nevertheless she didn't practice because of back pain, vertigo and cough. At 8p.m. patient went together with her friends to a restaurant, smoked cigarettes and experienced nausea, vertigo and sweating. On the way home patient climbed the stairs (4, floor) and experienced difficulty in breathing. Consequently, ambulance was called and patient was admitted to hospital. Cardiological examination excluded cardiac reason of chest pain (accidental murmur present). Total bilirubin was slightly increased (25.8), BP 115/60, temperature 37.7 deg C. Additiona

**Other Meds:** None

**Lab Data:** blood pressure 05Feb07 115/60 mmHg, body temp 05Feb07 37.7 deg C, total serum bilirubin 05Feb07 25.8 micromol/L slightly increased

**History:** None

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1624

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277814-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	16-Apr-2007	17-Apr-2007	1	03-May-2007	04-May-2007	AZ	WAES0704USA05024	04-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Guillain-Barre syndrome, Hypoaesthesia, Muscular weakness

**Symptom Text:** Information has been received from a physician concerning a 16 year old female (also reported as 18 year old ) who on 16-APR-2007 was vaccinated with a dose of Gardasil. Since 1 day post-injection, the patient had progressive bilateral leg numbness and weakness and motor weakness. The physician inquired about the possibility of Guillian Barre Syndrome. At the time of this report, the outcome was unknown. Upon internal review, progressive bilateral leg numbness and weakness and motor weakness were considered to be other important medical events. No further information is available.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1625

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277815-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	29-Jan-2007	29-Jan-2007	0	03-May-2007	04-May-2007	MA	WAES0704USA05652	04-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNC	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1447F	0	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Muscular weakness, Paraesthesia, Paraesthesia

**Symptom Text:** Information has been received from a physician concerning an 18 year old female patient who on 29-JAN-2007 was vaccinated in her left arm with her first dose of Gardasil, lot #655617/1447F. Concomitant therapy included meningococcal vaccine (unspecified). On 29-JAN-2007 after receiving the injection the patient experienced weakness and tingling in her left arm which spread over the entire length of her arm and also to her jaw. She experienced so much discomfort in her jaw that she had difficulty chewing. An examination of the patient ruled out Guillain-Barre Syndrome. The above reaction eventually resolved in two weeks and on approximately 12-FEB-2007, the patient recovered. The physician considered the events to be disabling. Additional information has been requested.

**Other Meds:**

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1626

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277816-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
35.0	F	04-Apr-2007	04-Apr-2007	0	03-May-2007	04-May-2007	GA	WAES0704USA06106	04-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0011U	2	Left arm	Intramuscular	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, Injected limb mobility decreased, Insomnia, Musculoskeletal pain

**Symptom Text:** Information has been received from a registered nurse concerning a 35 year old female with a history of papilloma viral infection who on unspecified dated, was vaccinated with the first and second dose of Gardasil. 04-APR-2007, the patient was vaccinated with a third dose of Gardasil (lot # 654702/0011U) 0.5 ml IM into the left deltoid. Concomitant therapy included ORTHO TRI-CYCLEN, and ALLEGRA-D. On 05-APR-2007, the patient sought medical attention by contacting the physician's office. The patient reported that on 04-APR-2007, immediately after being vaccinated with the third dose of vaccine, she noticed symptoms. She had severe shoulder pain. The patient could not lift her arm laterally and could not sleep due to the pain. The patient was ordered MEDROL DOSE PACK, heat, and LORCET PLUS. The patient had also been seen at an orthopedics office. She was given 2 steroid injections and she is being set up for physical therapy. The patient did not have any symptoms with the first two doses of vaccine. At the time of reporting, the patient had not recovered. No further information was available at the time of reporting. The reporter felt that the events were disabling. Additional information has been requested.

**Other Meds:** ORTHO TRI-CYCLEN, ALLEGRA-D

**Lab Data:** None

**History:** Papilloma viral infection

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1627

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277817-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	Unknown		03-May-2007	04-May-2007	LA	WAES0704USA06507	04-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with the first dose of Gardasil, injection. Concomitant therapy included MENACTRA. Subsequently on an unspecified date, the patient "passed out" 15 minutes after receiving Gardasil. The patient was sent to the hospital but the length of stay was unknown. Subsequently on an unspecified date, the patient recovered from the event. Additional information has been requested.

**Other Meds:**

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1628

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277857-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	30-Apr-2007	30-Apr-2007	0	03-May-2007	07-May-2007	MD		07-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	AVENTIS PASTEUR	42183AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00124	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1280F	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site irritation, Injection site pruritus

**Symptom Text:** Pt noted pruritis at the injection site on the afternoon after administration followed by erythema and a burning sensation also localized to the injections site. She was seen 4 days later when the erythema measured 13 x 7.5 cm. There were no other sx, constitutional or otherwise.

**Other Meds:** Flonase, Zaditor

**Lab Data:**

**History:** None.

**Prex Illness:** Trichomonis vaginosa and allergic rhinitis

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1629

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277902-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	19-Apr-2007	20-Apr-2007	1	04-May-2007	07-May-2007	AZ	WAES0704USA05125	08-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0384U	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dyspnoea, Ear pain, Injection site erythema, Injection site swelling, Malaise, Nasal congestion, Pharyngeal oedema, Pharyngolaryngeal pain, Tinnitus

**Symptom Text:** Information has been received from a health Medical Assistant (N.A.) concerning a 22 year old female patient who is currently sexually active and had a history of thyroid cancer in OCT-2006. On 19-APR-2007 patient was vaccinated IM in left deltoid with a first dose of Gardasil, lot #657617/0384U. Concomitant therapy included LOESTRIN and LEVOXYL. The medical assistant reported that one or two days post injection the patient's injection site was little red, swollen and puffy. On 23-APR-2007 patient called the office saying she had not felt good since getting the injections. The injection site was no longer red or swollen and she had no fever but her throat was swollen and she was having trouble breathing (unknown time period injections site reaction resolved and new symptoms occurred). The patient was complaining of a stuffy nose, sore throat, ears ache and ringing of the ears. She wanted to "pull her hair out" because of the ringing of the ears. The patient was instructed to go to the Emergency room (ER) or walk in clinic for treatment. The outcome of trouble breathing, ear pain, feeling unwell, nasal congestion, throat was swollen, sore throat and ringing of the ears was not recovered. The reporter considered the event "difficulty breathing" to be life threatening. The reporter felt the events to be disabling because the patient was not able to go to work or school. Additional information has been requested.

**Other Meds:** LOESTRIN, LEVOXYL

**Lab Data:** Unknown

**History:** Thyroid cancer

**Prex Illness:** Sexually active

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1630

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277994-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	09-Mar-2007	16-Mar-2007	7	07-May-2007	08-May-2007	CT	WAES0704USA05584	08-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0961F		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Uveitis

**Symptom Text:** Information has been received from a physician concerning a 17 year old female with anxiety who on 09-MAR-2007 was vaccinated intramuscularly with Gardasil (Lot#654389/0961F). Concomitant therapy included Celexa. At the time of vaccination the patient had mild pharyngitis. On 16-MAR-2007 the patient developed bilateral uveitis. The patient was treated with unspecified oral steroids and a periocular kenolg injection. The physician reported that the patient was evaluated for sarcoid which was negative. The patient was also evaluated for arthritis, at the time of this report the results were pending. The uveitis was considered an other medical event. Additional information has been requested.

**Other Meds:** CELEXA

**Lab Data:**

**History:** Anxiety, Pharyngitis

**Prex Illness:** Pharyngitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 277995-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	Unknown	Unknown		07-May-2007	08-May-2007	--	WAES0704USA06669	08-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Syncope

**Symptom Text:** Information has been received from a school nurse concerning an approximately 16 year old female who on an unspecified date was vaccinated with a dose of Gardasil. Approximately 5 minutes after receiving the dose, the patient experienced a fainting spell and a seizure. Unspecified medical attention was sought. Subsequently, the patient recovered. Upon internal review, the patient's seizure was considered an other important medical event. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 278066-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	03-May-2007	04-May-2007	1	07-May-2007	08-May-2007	NY		10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus generalised

**Symptom Text:** Pt states she started itching friday on the buttocks and itching has now spread to abdomen and thighs. Pt took Benadryl and was instructed to continue with Benadryl today and call me tomorrow unless it becomes worse and was then told to seek medical attention after discussing this with Dr

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 278067-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	02-Apr-2007	Unknown		07-May-2007	08-May-2007	VA	VA07-007	08-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		1208F	1	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy

**Symptom Text:** positive pregnancy test on 4/24/07; HPV4 #2 given 04/02/07

**Other Meds:**

**Lab Data:** positive urine HCG on 4/24/07

**History:** none reported

**Prex Illness:** none reported

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 278130-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	29-Nov-2006	29-Nov-2006	0	08-May-2007	09-May-2007	--	WAES0705USA00039	09-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	HPV4	MERCK & CO. INC.		0955F	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abortion, Drug exposure during pregnancy

**Symptom Text:** Information has been received from a registered nurse concerning a 17 year old female who was 18 weeks pregnant and was vaccinated with her first dose of Gardasil (lot 653978/0955F) on 29-Nov-2006. There was no concomitant medication. In March 2007, the patient experienced an abortion. The nurse believes that the patient terminated the pregnancy for reasons other than the vaccine. The first dose of the vaccine was given at her pediatrician's office. Subsequently the patient experienced an inappropriate schedule of the vaccine when she received the 2nd dose on 24-Apr-2007. Upon internal review, abortion was considered to be an other important medical event. Additional information has been requested.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:** Pregnancy NOS (LMP = Unknown) Pregnancy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1635

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 278266-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	28-Mar-2007	02-Apr-2007	5	09-May-2007	10-May-2007	--	WAES0705MYS00002	10-May-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown			

**Seriousness:** PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Erythema, Hypersensitivity, Hypoaesthesia, Hypoaesthesia, Pain, Pain in extremity, Pain in extremity, Pruritus generalised, Rash generalised

**Symptom Text:** Information has been received from a physician concerning a female who on approximately 15-JAN-2007 was vaccinated with Gardasil. On 28-MAR-2007, the patient was vaccinated with a second dose of Gardasil. On 02-APR-2007 the patient experienced itchiness and red spots on whole body. After seven days of itchiness, the patient received an injection to reduce the allergic response on the whole body. On approximately 28-APR-2007 the patient still experienced itchy palms and feet. Additionally the patient experienced aching and numbness in both hands and feet. She complained that it was hard to complete the housework due to aching and numbness. On approximately 01-MAY-2007 the patient experienced red spots and itchiness on face. Subsequently, the patient recovered from itchiness and red spots on whole body. However, the patient's itchy palms and feet as well as aching and numbness persisted. The red spots and itchiness on face also persisted. The reporter felt that itchiness and red spots on whole body, itchy palms and feet, aching, numbness, red spots and itchiness on face were related to therapy with Gardasil. Aching and numbness were considered to be disabling. No further information is available.

**Other Meds:** Unknown

**Lab Data:**

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 278267-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	24-Apr-2007	24-Apr-2007	0	09-May-2007	10-May-2007	MA	WAES0705USA00095	10-May-2007

  

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Anorexia, Asthenia, Dizziness, Immediate post-injection reaction, Mobility decreased, Muscular weakness, Nausea, Pain in extremity, Pain in extremity

**Symptom Text:** Information has been received from a health professional concerning a 26 year old female with sulfonamide allergy who on 22-FEB-2007 was vaccinated, in the left arm, with a first dose of Gardasil (lot # 655849/0263U). There was no concomitant medication. There were no adverse symptoms reported after the first dose. On 24-APR-2007 the patient was vaccinated with Gardasil a second dose. Immediately after the vaccination, the patient experienced left arm pain, nausea, dizziness and loss of appetite. On 25-APR-2007 the patient experienced a lot of pain in her left arm that radiated down to her hand. Her fingers were weak and she was unable to use her hand. Also on that same day the pain radiated to the patient's left leg for a half an hour. Patient was treated with ice and ibuprofen. On 26-APR-2007 the patient recovered. The reporting registered nurse considered unable to use her hand, nausea, loss of appetite, dizziness, fingers were weak, pain in left arm that radiated down her hand, and left leg pain to be disabling.

**Other Meds:** None

**Lab Data:** None

**History:**

**Prex Illness:** Sulfonamide allergy

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 11 MAY 2007 03:14

Page 1637

Vax Name: HPV (GARDASIL) All comb. w/AND

**Vaers Id:** 278268-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	24-Apr-2007	25-Apr-2007	1	09-May-2007	10-May-2007	TX	WAES0705USA00797	10-May-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HIBV	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

**MedDRA PT** Groin pain, Headache, Herpes zoster, Meningitis viral, Rash

**Symptom Text:** Information has been received from a physician, via a company representative, concerning a 12 year old female patient who on 24-APR-2007 was vaccinated with the first dose of Gardasil. Concomitant therapy included hepatitis A virus vaccine (manufacturer unspecified), PedvaxHib and Menactra. On 25-APR-2007, the day following the vaccinations, the patient returned to the office with complaints of groin pain; blood work (unspecified) testing was performed, and was negative. On 30-APR-2007 the patient experienced a headache and a rash on her leg, and again returned to the physician's office; the patient was diagnosed with zoster, and was given Tylenol and codeine for treatment of the symptoms. On 03-MAY-2007, the patient presented that the patient may have viral meningitis. At the time of this report, the physician reported that the patient may have viral meningitis. At the time of this report, the patient had not recovered from the events. Additional information has been requested.

**Other Meds:**

**Lab Data:** diagnostic laboratory 04/25/07 - negative

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

**Total Non Serious** 1498 92%

**Total Serious Non Fatal** 136 8%

**Total Death:** 3 0%

**Total All Reports:** 1637