

A.H.F.S. Category 36:52

Mumps Skin Test Antigen USP

MSTA®


 Rx only

NOT FOR IMMUNIZATION, DIAGNOSIS, OR TREATMENT
NOT FOR DIAGNOSIS OF IMMUNITY TO MUMPS

Caution: Federal (USA) law prohibits dispensing without prescription.

DESCRIPTION

MSTA®, Mumps Skin Test Antigen, is a sterile suspension of killed mumps virus for intradermal use. It is prepared from the extraembryonic fluid of the virus-infected chicken embryo and is concentrated and purified by differential centrifugation. The virus is killed with formaldehyde solution, 1:1000, and is then diluted with isotonic sodium chloride solution. The resultant product contains approximately 0.012 molar glycine and less than 1:8,000 formaldehyde solution. Thimerosal (mercury derivative) 1:10,000 is added as a preservative. The skin test antigen is formulated to contain at least 40 complement fixing units (CFU) per mL, at the time of release, as determined by the Complement-Fixation Test. This product, after shaking, is slightly opalescent in color.

CLINICAL PHARMACOLOGY

Information is available concerning the pharmacologic mode of action of skin test antigens.¹ Skin testing is a widely employed and readily available method of clinically assessing the cellular immune response. A positive skin-test reaction indicates previous antigenic exposure, T-cell competence, an intact inflammatory response, and is an assessment of the cellular integrity of the immune response.

Skin testing with MSTa detects delayed-hypersensitivity.² Since most of the population (except for the very young) have had contact or infection with mumps virus,³ they usually demonstrate a delayed-hypersensitivity reaction to MSTa if an adequate cellular immune system exists.⁴

A single masked placebo-controlled study involving 90 cancer subjects was performed using MSTa, Tetanus Toxoid Fluid, Mixed Respiratory Vaccine, Dermatophyton O. staphage lysate and PPD (Tubersol®). The injection sites were read at 48 and 72 hours. The number of positive reactors to MSTa was greater than the number of positive subjects receiving the other antigens. None of the patients experienced any sloughing, necrosis, abscess formation, or painful lymphadenopathy as a result of the MSTa skin test. This study demonstrated that MSTa evoked a positive delayed-hypersensitivity (DH) reaction in immunocompetent individuals. The frequency of reactions in subjects with an impaired immune system was reduced. The sensitivity of MSTa has been demonstrated by the fact that: 1) in all instances when any of the other test antigens were positive, MSTa was also positive; and 2) several subjects showed a DH reaction to MSTa but did not show a DH reaction to the other antigens.²

INDICATIONS AND USAGE

MSTA, Mumps Skin Test Antigen, is indicated when detection of a delayed-hypersensitivity (DH) reaction is desired.

MSTA has not been tested in persons immunized with live mumps vaccine; therefore, its safety and efficacy in this population group has not been established.

MSTA is not indicated for the immunization, diagnosis, or treatment of mumps virus infection, or determination of immune status to mumps virus.

CONTRAINDICATIONS

MUMPS VIRUS FOR THE PREPARATION OF MUMPS SKIN TEST ANTIGEN IS PROPAGATED IN EGGS. THEREFORE, THIS PRODUCT SHOULD NOT BE ADMINISTERED TO ANYONE WITH A HISTORY OF HYPERSENSITIVITY (ALLERGY), ESPECIALLY ANAPHYLACTIC REACTIONS TO EGGS OR EGG PRODUCTS. IT IS ALSO A CONTRAINDICATION TO ADMINISTER MSTa TO INDIVIDUALS KNOWN TO BE SENSITIVE TO THIMEROSAL. IN ANY CASE, EPINEPHRINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE TO COMBAT UNEXPECTED ANAPHYLACTIC OR OTHER ALLERGIC REACTIONS.

WARNINGS

This product contains dry natural latex rubber as follows: The stopper to the vial contains dry natural latex rubber.

Neurologic complications, such as encephalopathies or peripheral-nervous systems disorders, or anaphylactic reactions have followed the administration of almost all biologics, although these have not been reported after the injection of MSTa.

PRECAUTIONS

GENERAL

Care is to be taken by the health-care provider for the safe and effective use of this product and to possible sensitivity to dry natural latex rubber.

EPINEPHRINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE TO COMBAT UNEXPECTED ANAPHYLACTIC OR OTHER ALLERGIC REACTIONS.

A separate, sterile syringe and needle or a sterile disposable unit should be used for each patient to prevent transmission of hepatitis or other infectious agents from person to person. Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

Special care should be taken to ensure the product is not injected into a blood vessel.

The antigen must be given intradermally. If it is injected subcutaneously, no reaction or an unreliable reaction may occur.

DRUG INTERACTIONS

MSTA has not been tested in persons immunized with live mumps vaccine; therefore, its safety and efficacy in this population has not been established.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

MSTA has not been evaluated for its carcinogenic, mutagenic potentials or impairment of fertility.

PREGNANCY

REPRODUCTIVE STUDIES – PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with Mumps Skin Test Antigen. It is not known whether Mumps Skin Test Antigen can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Mumps Skin Test Antigen should be given to a pregnant woman only if clearly needed. There are no carefully done studies available on the effect of the drug on later growth, development and functional maturation of the child.

USAGE IN NURSING MOTHERS

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Mumps Skin Test Antigen is administered to a nursing woman.

PEDIATRIC USE

SAFETY AND EFFECTIVENESS OF MST A IN CHILDREN HAVE NOT BEEN ESTABLISHED.

USAGE IN YOUNG ADULTS

SAFETY AND EFFECTIVENESS HAVE NOT BEEN ESTABLISHED IN YOUNG ADULTS WHO HAVE BEEN IMMUNIZED WITH MUMPS VACCINE.

ADVERSE REACTIONS

Local reactions may include tenderness, pruritus, vesiculation and rash. Sloughing, necrosis, abscess formation, and/or regional lymphadenopathy may be associated with unusually large DH reactions. Adverse reactions may include nausea, anorexia, headache, unsteadiness, drowsiness, sweating, sensation of warmth and lymphadenopathy. None of these reactions were noted in the clinical study.²

Epinephrine Injection (1:1000) must be immediately available to combat unexpected anaphylactic and other allergic reactions.

DOSAGE AND ADMINISTRATION

Parenteral drug products should be inspected visually for extraneous particulate matter and/or discoloration prior to administration. If these conditions exist, Mumps Skin Test Antigen should not be administered.

SHAKE VIAL WELL before withdrawing each dose.

A separate, sterile syringe and needle or a sterile disposable unit should be used for each patient to prevent transmission of hepatitis or other infectious agents from person to person. Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

An injection of 0.1 mL of the antigen is made on the inner surface of the forearm. Before injection, the skin over the site to be injected should be cleansed with a suitable germicide. Care should be taken to inject the test antigen intradermally.

Interpretation of Reactions – The reaction should be examined in 48 to 72 hours. A mean diameter (i.e., the longest width plus the longest length, divided by 2) of induration of 5 mm or more indicates a positive DH reaction to the antigen. A negative reaction, if the test dose has been given correctly, usually indicates either anergy or nonsensitivity. Pseudopositive reactions may develop in persons highly sensitive to egg protein.

HOW SUPPLIED

Vial, 1 mL (10 tests) – Product No. 49281-240-10

STORAGE

Store between 2° – 8°C (35° – 46°F). DO NOT FREEZE.

REFERENCES

1. Holborow EJ, et al. Immunology in Medicine. Second Edition, pp 19 and 121. Grune & Stratton, 1983
2. Unpublished data available from Aventis Pasteur Inc.
3. Petersdorf RG. Mumps. in Harrison's Principles of Internal Medicine, Ed. 7 (edited by M.M. Wintrobe, G.W. Thorn, R.D. Adams, E.Braunwald, K.J. Isselbacher, and R.G. Petersdorf) p 985. New York: McGraw-Hill Book Company, 1974
4. Dempster G. Mumps in Textbook of Virology, Ed. 5 (edited by A.J. Rhodes and C.E. Van Rooyen) p 461 Baltimore: The Williams & Wilkins Co., 1968

Product information
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Aventis Pasteur Inc.
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 **Aventis**

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