

# *There is no friendlier way to give Vitamin K.*

*Introducing the only fully approved  
Vitamin K oral preparation in the UK  
available in an easy to use gel capsule.*



**NeoKay<sup>®</sup>**

- **Clinically proven to prevent Vitamin K deficiency bleeding<sup>1</sup>**
- **Easy to use gel capsule - simply clip off the top and squeeze the contents of the capsule into the baby's mouth**
- **Waste friendly delivery system - no sharps for easy, efficient disposal**
- **Convenient once a week dose<sup>2</sup>**

For further information please visit [www.neo-ceuticals.co.uk](http://www.neo-ceuticals.co.uk)



NEOCEUTICALS



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# NeoKay<sup>®</sup>

#### References:

1. Wariyar U, et al. Six years' experience of prophylactic oral vitamin K. *Arch Dis Child Fetal Neonatal Ed* 2000; 82: F64-F68.
2. Recommended for first three months.

**NeoKay<sup>®</sup> Summary of Product Characteristics. Name of the Medicinal Product:** NeoKay<sup>®</sup> 1mg capsules. **Qualitative and Quantitative Composition:** Each soft gelatin capsule contains 1mg phytomenadione. For a full list of excipients, see below. **Pharmaceutical Form:** Capsule, soft. The dark brown soft capsule contains a clear, odourless pale yellow liquid. **Clinical Particulars. Therapeutic Indications:** NeoKay<sup>®</sup> is indicated for the prevention of vitamin K deficiency bleeding in babies. **Posology and Method of Administration:** *Oral prophylaxis in healthy neonates, including healthy preterm babies:* The contents of a single NeoKay<sup>®</sup> capsule should be administered by cutting the narrow tubular tip off the capsule and squeezing the liquid into the baby's mouth. Another dose should be given if the first dose is spat out or the baby is sick within three hours of the dose being given. *Unwell babies and babies of mothers taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin at the time of delivery:* Babies who are not well enough to be fed within a few hours of birth and babies whose mothers are taking any of the above drugs should be treated with an intramuscular formulation of vitamin K at birth. *Exclusively breast-fed babies:* The administration of 1mg NeoKay<sup>®</sup> by mouth at birth protects healthy term babies from the risk of bleeding due to vitamin K deficiency in the first week of life. Evidence to date suggests that for babies who are being exclusively breast-fed, a dose of 1mg once weekly for 12 weeks offers the best protection against late vitamin K deficiency bleeding. **Contraindications:** Do not give further doses of NeoKay<sup>®</sup> to any baby showing evidence of hypersensitivity to any of the constituents. **Special Warnings and Precautions for Use:** Take expert advice before giving NeoKay<sup>®</sup> to any baby with protein C or protein S deficiency currently on treatment with warfarin. **Interaction with Other Medicinal Products and Other Forms of Interaction:** Vitamin K acts as an antidote to the anticoagulant drugs of the coumarin type therefore concomitant use is not recommended except in the treatment of warfarin overdosage. It is not an antidote to heparin. **Pregnancy and Lactation:** Not relevant. **Effects on Ability to Drive and Use Machines:** Not relevant. **Undesirable Effects:** No adverse effects have been associated with oral administration. **Overdose:** No case of overdose has been reported. **Pharmacological Properties: Pharmacodynamic Properties:** Pharmacotherapeutic group: Vitamin K, ATC code: B02 BA01 Vitamin K is an essential co-factor in the hepatic synthesis of prothrombin (factor II) and of several other blood clotting factors (factor VII, IX, X and the coagulation inhibitors protein C and protein S). Low levels at birth may lead to the development of a generalised bleeding tendency (haemorrhagic disease of the new born). **Pharmacokinetic Properties:** Phytomenadione is a fat soluble vitamin which does not cross the placenta readily. There is relatively little in human milk. Cow's milk contains more, and infant formula milks are artificially fortified. The half life in plasma is 2-3 hours. Vitamin K is absorbed from the small intestine and taken up by the liver but is only stored in the body for relatively short periods of time. Intra-muscular administration of phytomenadione in an emulsion may aid retention by setting up a "depot" muscle store. Bile salts aid absorption. The mixture of short and medium chain triglycerides contained in the NeoKay<sup>®</sup> formulation is readily absorbed, even in the absence of biliary and pancreatic secretions. The drug is metabolised to more polar metabolites and excreted in the urine and bile as glucuronide and sulphate conjugates. **Preclinical Safety Data:** Not applicable. **Pharmaceutical Particulars: List of Excipients:** Fractionated coconut oil (containing at least 95 percent of saturated 8 and 10 carbon atom fatty acids). The soft capsule shell consists of gelatin, glycerol, iron oxide red (E172), iron oxide black (E172) and purified water. **Incompatibilities:** None known. **Shelf Life:** 2 years. **Special Precautions for Storage:** Do not store above 25°C. Do not freeze. Store in the original packaging. **Nature and Contents of Container:** Polypropylene plastic bottles with LDP/HDP blend caps. Containers contain soft gelatin capsules with pack sizes of 12 or 100. **Special Precautions for Disposal:** No special requirements. **Marketing Authorisation Holder:** Neoceuticals Limited, 3 The Grange, Flaxby, Knaresborough, HG5 0RJ. **Marketing Authorisation Number(s):** PL 36116/0001. **Date of First Authorisation/Renewal of the Authorisation:** June 2010. **Date of Revision of the Text:** June 2010. **Adverse Events Should be Reported. Reporting Forms and Information can be Found at** [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) **Adverse Events Should Also be Reported to Neoceuticals Ltd. Tel: +44 (0)1748 828865.** NeoKay<sup>®</sup> is distributed for Neoceuticals by M&A Pharmachem Ltd, Wigan Rd, Westhoughton BL5 2AL. Tel: +44 (0)1942 816184. ©2010 Neoceuticals Ltd. All rights reserved.