SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Neokay 1mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin capsule contains 1mg phytomenadione.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft

The dark brown soft capsule contains a clear, odourless pale yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Neokay is indicated for the prevention of vitamin K deficiency bleeding in babies

4.2 Posology and method of administration

Oral prophylaxis in healthy neonates, including healthy preterm babies:
The contents of a single Neokay 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 carbemazepine, 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 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.

4.3 Contraindications

Do not give further doses of Neokay to any baby showing evidence of hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

Take expert advice before giving Neokay to any baby with protein C or protein S deficiency currently on treatment with warfarin.

4.5 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.

4.6 Pregnancy and lactation

Not relevant

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

No adverse effects have been associated with oral administration.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 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).

5.2 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 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.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 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

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

Do not freeze.

Store in the original packaging.

6.5 Nature and contents of container

Polypropylene plastic bottles with LDPE/HDPE blend caps. Containers contain soft gelatin capsules with pack sizes of 12 or 100.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 36116/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/02/2010

10 DATE OF REVISION OF THE TEXT

17/07/2025