

Package leaflet: Information for the user

Neokay 1mg Capsules

Phytomenadione

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or healthcare professional.
- If you notice any side effects not listed in this leaflet, please tell your doctor or healthcare professional.

In this leaflet:

1. What Neokay is and what it is used for
2. Before you use Neokay
3. How to use Neokay
4. Possible side effects
5. How to store Neokay
6. Further information

1. WHAT NEOKAY IS AND WHAT IT IS USED FOR

Neokay contains phytomenadione, a synthetic Vitamin K, which is essential in the body for blood to clot. Newborn babies can have too little Vitamin K and so may develop a serious, but rare condition that causes bleeding. Neokay is used to prevent your baby from developing a tendency to bleed due to a deficiency in vitamin K.

2. BEFORE YOU USE NEOKAY

Do not use Neokay:

- if your baby is showing any signs of an allergic reaction to Neokay or any of its ingredients (listed in section 6).
- if your baby is not well enough to be fed within a few hours of birth
- if the baby's mother is taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin.

Take special care with Neokay:

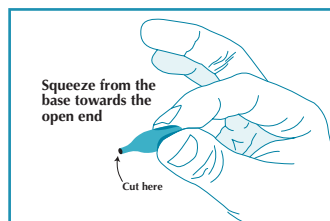
- if your baby has protein C or protein S deficiency and/or is currently taking warfarin. Do not give Neokay to your baby unless specifically advised to do so by their consultant.
- If your baby has a bleed (eg from the cord stump) or shows signs of bruising consult your doctor immediately.

3. HOW TO USE NEOKAY

Always use Neokay exactly as your doctor has told you. You should check with your doctor or healthcare professional if you are not sure.

Healthy newborn babies, including healthy premature babies:

The contents of a single Neokay capsule should be given. Cut the narrow tip off the capsule and squeezing the liquid into the baby's mouth, as shown in the picture. 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.



Breast-fed babies:

Breast milk contains relatively little vitamin K. The contents of a single Neokay capsule should be given at birth. This protects healthy babies from the risk of bleeding due to vitamin K deficiency in the first week of life. For babies who are only being breast-fed, the contents of a single capsule should be given once weekly for 12 weeks. This offers the best protection against late vitamin K deficiency bleeding. Each dose should be given as described above.

If you forget to give a dose, give one as soon as you remember and continue to give the remainder of the doses as directed.

If you have any further questions on the use of this product, ask your doctor or healthcare professional.

4. POSSIBLE SIDE EFFECTS

There are no known side effects from taking Neokay. If you do notice any side effects, please tell your doctor or healthcare professional.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NEOKAY

Do not store above 25°C. Do not freeze. Store in the original package.

Keep out of the sight and reach of children.

Do not use Neokay after the expiry date which is stated on the bottle (EXP). The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your healthcare professional how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION**What Neokay contains**

- Each capsule contains 1mg of the active substance phytomenadione
- The other ingredient is fractionated coconut oil

What Neokay looks like and contents of the pack

Neokay comes as a dark brown soft capsule containing a clear, odourless pale yellow liquid. It is packed in polypropylene plastic bottles with caps made from a blend of low and high density polyethylene. It is available in pack sizes of 12 or 100 soft gelatin capsules.

Marketing Authorisation Holder

Neoceuticals Limited, The Innovation Centre, Innovation way, Heslington, York, YO10 5DG

Manufacturer

Central Pharma (Contract Packing) Ltd, Caxton Road, Bedford, MK41 0XZ

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