

KONAKION[®] MM Paediatric

pronounced koe-nak-ee-on

contains the active ingredient phytomenadione (also called Vitamin K1)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KONAKION[®] MM Paediatric.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your baby receiving KONAKION MM Paediatric against the benefits they expect it will have for them.

If you have any concerns about your baby receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What KONAKION MM Paediatric is used for

KONAKION MM Paediatric contains the active ingredient phytomenadione.

KONAKION MM Paediatric is used to treat blood clotting problems.

KONAKION MM Paediatric belongs to a group of medicines called Vitamin K.

Vitamin K is used to prevent and treat Vitamin K Deficiency Bleeding (VKDB). This is when the newborn or older babies bleed excessively as the blood clotting system is not fully developed. Vitamin K works by

reversing some of the causes of excessive bleeding.

There are many different types of medicines used to treat bleeding disorders. KONAKION MM Paediatric belongs to one of these groups.

Your doctor, however, may have prescribed KONAKION MM Paediatric for another purpose.

Ask your doctor if you have any questions about why KONAKION MM Paediatric has been prescribed for your baby.

Before KONAKION MM Paediatric is given

When your baby must not have it

Do not use KONAKION MM Paediatric if:

- 1. Your baby has had an allergic reaction to KONAKION MM Paediatric, any other type of Vitamin K or any ingredients listed at the end of this leaflet.**
- 2. The ampoule is damaged or shows signs of tampering.**
- 3. The expiry date (EXP) printed on the pack has passed.**

If you use this medicine after the expiry date has passed it may not work as well.

- 4. The solution is cloudy or separated.**

If you are not sure if your baby should be receiving KONAKION MM Paediatric, talk to your doctor.

Before KONAKION MM Paediatric is given

Tell your doctor if:

- 1. Your baby has any other health problems including:**

- Liver disease or blockage of the bile ducts.
- Poor absorption of nutrients (called malabsorption).

- 2. Your baby is allergic to any other medicines, foods, dyes or preservatives.**

- 3. You have taken any of the following medicines during pregnancy:**

- Warfarin (Coumadin[®], Marevan[®]).
- Phenindione (Dindevan[®]).
- Antiepilepsy medicines.
- Tuberculosis medicines.
- Long-term antibiotics.

If you have not told your doctor about any of the above, tell them before your baby starts KONAKION MM Paediatric.

Taking other medicines

Tell your doctor if your baby is taking any other medicines including any that have been bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with KONAKION MM Paediatric. These medicines include:

- Long-term antibiotics.

These medicines may be affected by KONAKION MM Paediatric, or may affect how well it works. Your baby may need to use different amounts of medicine, or may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while your baby is receiving KONAKION MM Paediatric.

Ask your doctor or pharmacist if you are not sure about these medicines.

How Konakion MM Paediatric is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How it is used

KONAKION MM Paediatric can be used as an injection or as a liquid for the baby to swallow.

Usually, a doctor or nurse will give an injection into a muscle.

If it is given as a liquid into the baby's mouth, then the oral dispenser or another accurate measuring device should be used. After the liquid is placed in the baby's mouth, it is best to follow the dose with a feed, to ensure it is swallowed.

In the rare case that your baby already has a bleeding condition, then it may be given as an injection into a vein.

How long Konakion MM Paediatric is given for

Your doctor will usually prescribe one injection in the muscle or a number of doses given by mouth.

The length of therapy will vary according to whether your baby is breast-fed, on milk formula or if they are at particular risk of haemorrhagic disease.

If your baby is given KONAKION MM Paediatric orally, make sure they receive every dose as prescribed.

It is important that your baby receives every dose. If every dose is not given to your baby, KONAKION MM Paediatric may not work as well to prevent this disease.

In case of an overdose

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think your baby or anyone else may have taken too much KONAKION MM Paediatric. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While your baby is receiving KONAKION MM Paediatric

Things you must do

Tell your doctor or nurse if your baby vomits or has diarrhoea within 24 hours of receiving a dose of KONAKION MM Paediatric by mouth.

If your baby spits out or vomits an oral dose or if diarrhoea occurs within 24 hours, a repeat dose of

Konakion MM Paediatric may be needed.

Tell all doctors and pharmacists who are treating your baby that they are receiving KONAKION MM Paediatric.

Be sure to attend all of your baby's follow-up appointments so that all oral doses can be given.

It is important that your baby receives every dose. For KONAKION MM Paediatric to work properly all doses must be given to your baby.

Things you must not do

Do not miss any of your baby's follow-up oral doses of KONAKION MM Paediatric.

For KONAKION MM Paediatric to work properly all doses must be given to your baby.

Do not give KONAKION MM Paediatric to anyone else, other than your baby even if they have the same condition.

Do not use KONAKION MM Paediatric to treat other complaints that your baby has unless your doctor says to.

Do not give any other medicines to your baby whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you think your baby does not feel well while they are receiving KONAKION MM Paediatric.

KONAKION MM Paediatric helps prevent haemorrhagic disease (bleeding) in most babies but may have unwanted side effects in a few.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your baby may need medical treatment if they get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Irritation, soreness or redness near the injection site, rarely this may be severe.
- Unusual flushing or sweating.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- An allergic reaction (which may include rash, swelling or breathing difficulties).

This is a serious side effect. Your baby may need urgent medical attention. Serious side effects are rare.

Side effects usually occur within hours of the dose being administered.

This is not a complete list of all possible side effects. Others may occur in some babies and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making your baby unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. Your baby may not experience any of them.

After KONAKION MM Paediatric is given

Storage

KONAKION MM Paediatric will be stored in the pharmacy, at the doctors surgery, on the ward or at the baby health centre. It is kept in a cool dry place where the temperature stays below 25°C.

KONAKION MM Paediatric should be protected from light.

Product description

Availability

KONAKION MM Paediatric comes in one paediatric strength:

2 mg/0.2 mL.

KONAKION MM Paediatric comes in packs of 5 ampoules with 5 dispensers. The dispensers are for use if it is given by mouth.

KONAKION MM Paediatric is also available as an adult injection or tablet.

What KONAKION MM Paediatric looks like

KONAKION MM Paediatric is an amber glass ampoule containing a clear, yellow solution.

Ingredients

Active ingredient:

- Phytomenadione (also called Vitamin K1).
- Each 0.2 mL ampoule contains 2 mg of phytomenadione.

Inactive ingredients:

- Glycocholic acid
- Lecithin (322).
- Sodium hydroxide.
- Hydrochloric acid (507).
- Water for injection.

KONAKION MM Paediatric is lactose and gluten free.

Manufacturer

KONAKION MM Paediatric is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

4 - 10 Inman Road

Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number:

- AUST R 71758.

This leaflet was prepared on 9 July 2009.