Consumer Medicine Information

KONAKION® MM and KONAKION® MM Paediatric

Phytomenadione (Vitamin K_1)

10mg in 1mL mixed micelle (MM) solution for injection or oral use
2mg in 0.2mL mixed micelle (MM) paediatric solution for injection or oral use

What is in this leaflet

This leaflet answers some common questions about KONAKION.

It does not contain all the available information.

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

All medicines have risks and benefits. You, your doctor, midwife or pharmacist must weigh the risks of you or your baby receiving KONAKION against the benefits expected for you or your baby.

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

Keep this leaflet with the medicine.

You may need to read it again.

What KONAKION is used for

KONAKION contains the active ingredient phytomenadione, which is also called vitamin K_1.

KONAKION belongs to a group of medicines called haemostatic agents, meaning they assist with blood clotting problems.

KONAKION is used to prevent or treat blood clotting problems and works by reversing some of the causes of excessive bleeding.

In adults, this risk of bleeding is usually caused by too much medication which prevents blood clotting (known as anticoagulants) such as warfarin (Coumadin®, Marevan®). The risk of bleeding can also be caused by diseases that cause low levels of vitamin K such as jaundice, liver or intestinal disorders, or prolonged use of some antibiotics or salicylates (such as aspirin).

In newborn babies, KONAKION MM Paediatric is used to prevent and treat bleeding due to low levels of Vitamin K.

Ask your doctor, midwife or pharmacist if you have any questions why you or your baby should or should not use KONAKION.

Before you or your baby takes KONAKION

When you must not take it

Do not take KONAKION if:

1. **you or your baby has had an allergic reaction to KONAKION, phytomenadione or any other type of Vitamin K, or any ingredients listed at the end of this leaflet.**
   Some symptoms of an allergic reaction include shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, and rash, itching or hives on the skin.

2. **the pack is torn or shows signs of tampering.**

3. **the expiry date 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 you or your baby should be receiving KONAKION talk to your doctor, midwife or pharmacist.

Before you or your baby takes KONAKION

Before you or your baby start to take KONAKION, you should discuss any of the following with your doctor, midwife or pharmacist:

1. **you or your baby have any other health problems including:**

   - liver disease

2. **your baby weighs less than 2.5kg**

3. **you or your baby are allergic to any other medicines, foods, dyes or preservatives.**

4. **you are pregnant or plan to become pregnant**
   KONAKION is not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby. Your doctor, midwife or pharmacist can discuss these risks and benefits with you.

5. **you are breastfeeding or plan to breastfeed**
   In nursing mothers, taking KONAKION does not pose a risk to the nursing baby. KONAKION is not recommended for nursing mothers as a way of preventing haemorrhagic disease in the newborn.

6. **you intend to take anticoagulant therapy in the near future eg: warfarin (Coumadin®, Marevan®).**
   In this case large doses of KONAKION should be avoided.

In cases of severe haemorrhage caused by anticoagulants, KONAKION is not an immediately effective treatment and other treatments should also be used

Taking other medicines

Tell your doctor, midwife or pharmacist if you or your baby are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with KONAKION. These medicines include:

- warfarin (Coumadin®, Marevan®), a medicine used to prevent blood clots
- some medicines used to treat epilepsy

Your doctor, midwife or pharmacist may have more information on medicines to be careful with or avoid while you or your baby are taking KONAKION.

How to take KONAKION

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

They may differ from the information contained in this leaflet.

How much to take

Adults

The dose of KONAKION depends on your condition. The usual dose of KONAKION MM for injection is 5 mg to 10 mg. If given by mouth the usual dose of KONAKION MM is 1 mg to 5 mg. Your doctor will decide on how you should receive KONAKION and which dose is best for you.

For elderly patients, the dosage should be at the lower end of the dose range given above.

Children 1 year and over

Children of this age should only be treated on the recommendation of a physician. Your doctor will decide the dose your child should receive.

Children under one year

For children under one year of age, KONAKION MM Paediatric 2 mg in 0.2 mL should be used.

Prevention of excessive bleeding
The usual dose is 2 mg (1 ampoule of KONAKION MM Paediatric 2 mg in 0.2 mL) by mouth at birth or shortly after birth, followed by a further 2 mg four to seven days later.

In babies who are solely breastfed, a third oral dose of 2 mg is usually given four to six weeks after birth.

A single 1 mg intramuscular (into muscle) injection (0.1 mL of KONAKION MM Paediatric 2 mg in 0.2 mL) may be given by a doctor or midwife instead of the oral doses.

Treatment of excessive bleeding
The dose for the treatment of haemorrhage in newborns may vary and a health professional should monitor your baby and give the dose required.

How to use it

KONAKION MM ampoules 10 mg in 1 mL should be administered by a health professional. It is given as a slow intravenous (into vein) injection, or occasionally, by an infusion. KONAKION MM can also be given by mouth. The solution is squirted into the mouth using a syringe as a dispenser.

KONAKION MM Paediatric ampoules 2 mg in 0.2 mL may be given as an injection into a vein or muscle by a doctor or midwife. If a baby is being **treated** for bleeding then it is likely that KONAKION MM Paediatric 2 mg in 0.2 mL will be given by injection directly into the vein.

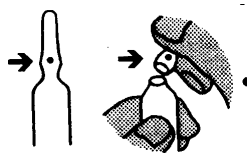
KONAKION MM Paediatric can also be given by mouth. At birth this is usually given by a doctor or midwife. Any subsequent doses may be administered by the doctor, midwife or parents depending on your circumstances.

The solution is squirted in the baby's mouth using one of the dispensers provided. Each pack of 5 ampoules contains 5 re-usable dispensers for oral administration only. The dispensers should be washed under hot water before and after use.

A needle and syringe for injection is <u>not</u> provided in the pack. The dispensers provided are for oral use only.

Opening the ampoule (refer to the picture below)

- Hold the bottom part of the ampoule between the thumb and first finger of one hand
- Make sure the spot is facing **towards** your thumb
- Hold the top of the ampoule between the thumb and first finger of your other hand
- Snap the top off by pushing away from the side with the spot



Using the dispenser

- After breaking the ampoule open, place a dispenser vertically into the ampoule
- Withdraw the solution from the ampoule into the dispenser until the solution reaches the marking on the dispenser
- Administer the contents of the dispenser directly into the newborn's mouth

How long to take KONAKION

KONAKION is usually only used over short periods.

In case of an overdose

Immediately telephone your doctor, midwife or pharmacist, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to your nearest Accident and Emergency Centre, if you think you or anyone else may have taken too much KONAKION. Do this even if there are no signs of discomfort or poisoning.

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

While you or your baby are taking KONAKION

Things you must do

Tell all doctors, dentists, midwives and pharmacists who are treating you (or your baby) that you (or your baby) are taking KONAKION.

Tell your doctor if you become pregnant while taking KONAKION.

Things you must not do

If you take anti-coagulant medicines and are likely to continue doing so, large doses of KONAKION should be avoided.

Do not use KONAKION to treat other complaints to those mentioned in this leaflet unless your health professional tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how KONAKION affects you.

However, KONAKION is not expected to affect your ability to drive a car or operate machinery.

Side effects

Tell your doctor, midwife or pharmacist as soon as possible if you or your baby is not well while taking KONAKION.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You or your baby may need medical treatment for some of the side effects.

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

Tell your doctor, midwife or pharmacist if you notice the following and it worries you:

- irritation, soreness or redness near the injection site

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

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

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

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

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

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

After taking KONAKION

Storage

Keep your KONAKION ampoules in the pack until it is time to take them.

If you take KONAKION out of the pack it may not keep well.

Keep KONAKION in a cool dry place where the temperature stays below 25^{o}C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep KONAKION where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If you stop taking KONAKION or the expiry date printed on the packaging has passed, ask your pharmacist what to do with any product that is left over.

Product description

Availability

KONAKION MM 10 mg in 1 mL solution comes in packs of 5 ampoules.

KONAKION MM Paediatric 2 mg in 0.2 mL solution comes in packs of 5 ampoules.

What KONAKION looks like

KONAKION MM (mixed micelle) solution is clear to slightly pale yellow in colour.

Ingredients

Active ingredient

phytomenadione (also called Vitamin K_1)

KONAKION MM ampoule contains 10mg phytomenadione in 1mL solution

KONAKION MM Paediatric ampoule contains 2mg phytomenadione in 0.2mL solution

Inactive ingredients

Glycocholic acid, sodium hydroxide, lecithin, hydrochloric acid, water for injection.

Distributor

KONAKION is distributed by:

Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060

Telephone: 0800 804 079

This leaflet was prepared on 09 January 2019.