

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KONAKION® MM 10 mg/1 mL Ampoule

Phytomenadione (Vitamin K₁)

Read all of this leaflet carefully before you receive KONAKION MM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- KONAKION MM has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. WHAT KONAKION MM CONTAINS

KONAKION MM ampoules: Each ampoule contains 10 mg phytomenadione in a mixed micelles vehicle of glycocholic acid and lecithin.

The other ingredients are glycocholic acid, sodium hydroxide, lecithin, hydrochloric acid, water for injections.

2. WHAT KONAKION MM IS USED FOR

KONAKION MM contains a synthetic Vitamin K. KONAKION MM works by helping your body make blood clotting factors. These blood clotting factors help stop bleeding.

KONAKION MM is used for the following:

To prevent and treat severe bleeding, caused by the over usage of certain medicines to thin the blood (called anticoagulants), or other causes of reduced vitamin K₁ (e.g. jaundice, liver and intestinal problems, prolonged use of certain antibiotics and other medicines).

3. BEFORE YOU ARE GIVEN KONAKION MM

You must not be given KONAKION MM

- If you are allergic (hypersensitive) to phytomenadione or any of the other ingredients of KONAKION MM (listed in Section 1 above).

If you are not sure if this applies to you, talk to your doctor or nurse before having KONAKION MM.

Take special care with KONAKION MM

Check with your doctor, nurse or pharmacist before having KONAKION MM if:

- You have problems with your liver.
- You have an artificial heart valve.
- You suffer from epilepsy (fits).
- You are taking medicines to stop your blood clotting (anticoagulants)

If any of the above apply to you, or if you are not sure, talk to your doctor, nurse or pharmacist before you are given KONAKION MM

Pregnancy and Breastfeeding

- Talk to your doctor, nurse or pharmacist before having KONAKION MM if you are pregnant, think you are pregnant, or breastfeeding. Your doctor will then decide if you should receive KONAKION MM.

If you are pregnant or breastfeeding your baby while taking KONAKION MM, please consult your doctor, pharmacist or other health care professional for advice.

Effects on the ability to drive and use machinery

KONAKION MM is not likely to affect you being able to drive or use any tools or machines.

Talk to your doctor if you notice any problems that might affect driving, using tools or machines while being given KONAKION MM.

Important information about some of the ingredients of KONAKION MM

KONAKION MM is essentially sodium (a type of salt) free' as it contains less than 1 mmol sodium (2,64 mg per 1 mL).

Using other medicines with KONAKION MM

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of KONAKION MM with these medicines may cause undesirable interactions. Please consult your, doctor, pharmacist or other health care professional for advice.

In particular tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- Medicines to stop your blood clotting (anticoagulants).
- Medicines used to treat epilepsy (fits).

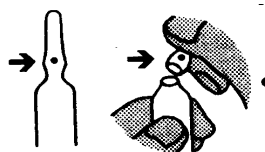
If any of the above apply to you, or if you are not sure, talk to your doctor, nurse or pharmacist before you are given KONAKION MM.

4. HOW KONAKION MM IS GIVEN

KONAKION MM will be given to you by a doctor or nurse. It will be given to you by injection into a vein. KONAKION MM can also be given by mouth. The solution is squirted into the mouth using a syringe as a dispenser.

To open the ampoule, 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. See picture below.



Adults

Injection

- For people who are bleeding after taking blood-thinning (anticoagulant) medicines, the usual dose is 5 to 10 mg by injection.
- For people who have severe bleeding the KONAKION MM dose (5 to 10 mg) is usually given with a blood transfusion.

Oral use

For people with mild bleeding or at risk of bleeding 1 to 5 mg KONAKION MM can be taken by mouth.

Elderly

Because elderly adults are sometimes more sensitive to KONAKION MM your doctor may decide to start you on a lower dose.

Children (aged 1 to 18 years)

KONAKION MM is normally used to treat children following advice from a specialist haematologist (blood doctor). The doctor will decide the dose your child should receive.

If you are given more KONAKION MM than you should

KONAKION MM is given by a doctor or nurse, therefore it is unlikely that you or your child will be given too much. However, if you are worried talk to your doctor or nurse.

If you have any further questions on the use of KONAKION MM, ask your doctor, nurse, pharmacist or healthcare professional.

If you use more KONAKION MM than you should or someone else accidentally uses your medicine, talk to a doctor or pharmacist or go to a hospital straight away. Take the medicine pack with you.

If you forget to use KONAKION MM

KONAKION MM is given by a doctor or nurse, therefore it is unlikely that you or your child will miss a dose. However, if you are worried talk to your doctor or nurse. If you have any further questions on the use of KONAKION MM, ask your doctor, nurse, pharmacist or healthcare professional.

Do not share medicines prescribed for you with another person.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre

5. POSSIBLE SIDE-EFFECTS

KONAKION MM can have side effects.

Contact your doctor immediately if you notice any of the following side effects:

Allergic reactions

The signs may include:

- Swelling of the throat, face, lips and mouth. This may make it difficult to breath or swallow.
- Sudden swelling of the hands, feet and ankles.

If you notice the above, tell your doctor straight away.

Effects where the injection was given

The signs may include swelling and redness along the vein where KONAKION MM was given, which is very tender or painful when touched or changes in the appearance of the skin.

If any of the above side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

Not all side-effects reported for KONAKION MM are included in this leaflet. Should your general health worsen while taking KONAKION MM, consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF KONAKION MM

- Your doctor or pharmacist is responsible for storing KONAKION MM. They are also responsible for disposing of any unused KONAKION MM correctly.
- Keep out of the reach and sight of children.
- Do not use KONAKION MM after the expiry date (EXP) printed on the pack.
- KONAKION MM ampoules should be stored at a temperature below 25 °C, but not frozen.
- KONAKION MM ampoules should be stored in their original package to protect from light.
- Do not throw away any left-over ampoules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

7. PRESENTATION OF KONAKION MM

KONAKION MM is supplied in amber coloured glass ampoules in packs of 10.

8. IDENTIFICATION OF KONAKION MM

KONAKION MM is a clear to slightly opalescent, pale yellow liquid.

9. REFERENCE NUMBER

KONAKION MM 10 mg/1 ml Ampoules: H2250 (Act 101/1965)

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,
South Tower, 1st Floor,
Sandton 2196,
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11. DATE OF PUBLICATION

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