KONAKION® MM

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.

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 you receiving KONAKION MM against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What KONAKION MM is used for

KONAKION MM contains the active ingredient phytomenadione.

KONAKION MM is used to treat excessive bleeding problems.

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

Vitamin K substances are used to treat excessive bleeding problems and work by reversing some of the causes of excessive bleeding. This risk of bleeding is usually caused by the use of too much medication to prevent blood clots (also known as anticoagulant medication).

There are many different types of medicines used to treat bleeding

disorders. KONAKION MM belongs to one of these groups.

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

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

Before you receive KONAKION MM

When you must not have it

Do not have KONAKION MM if:

1. You have had an allergic reaction to KONAKION MM, any other type of Vitamin K or any ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction may include:

- Shortness of breath
- · Wheezing or difficulty breathing
- Swelling of the face, lips, tongue, or other parts of the body
- Rash, itching or hives on the skinIf you use this medicine after the expiry date has passed it may not work as well
- 2. You are pregnant or plan to become pregnant.
- 3. The ampoule is damaged or shows signs of tampering.
- 4. 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.

5. The solution is cloudy or separated.

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

Do not give KONAKION MM to children less than one year of age.

KONAKION MM is for use in adults. KONAKION MM Paediatric is recommended for use in children under one year of age.

Before you receive KONAKION MM:

Tell your doctor if:

1. You are pregnant or plan to become pregnant.

It is not known whether KONAKION MM is harmful to an unborn baby when used by a pregnant woman. You must not use KONAKION MM if you are pregnant or plan to become pregnant.

2. You are breast-feeding or plan to breast-feed.

KONAKION MM may pass into breast milk. It is not known what effect KONAKION MM may have on your baby. Your doctor will discuss the risks and benefits of you receiving KONAKION MM while you are breast-feeding.

- 3. You have any other health problems including:
- · Liver disease.
- 4. You are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, tell them

before you start receiving KONAKION MM.

Taking other medicines

Tell your doctor if you 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 MM. These medicines include:

- Warfarin (Coumadin®, Marevan®), a medicine used to prevent blood clots
- Phenindione (Dindevan®), a medicine used to prevent and treat blood clots
- Some medicines used to treat epilepsy
- Aspirin and other salicylates
- Some cephalosporin antibiotics
- Some medicines used to treat tuberculosis

These medicines may be affected by KONAKION MM, or may affect how well it works. You may need to use different amounts of your medicine, or you 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 you are receiving KONAKION MM.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take KONAKION MM

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

They may differ from the information contained in this leaflet.

How much to take

KONAKION MM should be used exactly as your doctor has prescribed.

KONAKION MM is given as an injection or as a liquid for you to swallow. Your doctor will decide which is the best way for you to receive KONAKION MM.

If you receive KONAKION MM as an injection your doctor will usually prescribe a single injection or short course of injections. You may also receive it as a liquid to swallow.

How to use it

KONAKION MM is usually given as an injection into a vein by a doctor or nurse.

If you receive KONAKION MM as a liquid to swallow it will be administered with a suitable measuring device. It should be followed with a drink such as water.

How long to take it

Your dose or length of therapy may be adjusted according to your blood clotting response.

KONAKION MM may be given as a single injection or a short course of injections. You may then receive a course of oral Vitamin K depending on your response.

If you take too much (overdose)

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

You may need urgent medical attention.

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

Keep telephone numbers for these places handy.

While you are taking KONAKION MM

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking KONAKION MM.

Tell your doctor if you feel the injection is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

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

Things to be careful of

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving KONAKION MM.

KONAKION MM helps most people with bleeding problems but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you 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. • Unusual taste, 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. You may need urgent medical attention. Serious side effects are rare.

Side effects would 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 people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel 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. You may not experience any of them.

After KONAKION MM is given

Storage

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

KONAKION MM should be protected from light.

Product description

Availability

KONAKION MM comes in one adult strength: 10 mg/1 mL.

KONAKION MM comes in packs of 5 ampoules.

KONAKION MM is also available as a paediatric strength injection.

What KONAKION MM looks like

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

Ingredients

Active ingredient:

- phytomenadione (also called Vitamin K1).
- each 1mL ampoule contains 10 mg of phytomenadione.

Inactive ingredients:

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

KONAKION MM is lactose and gluten free.

Distributor

KONAKION MM is distributed by:

Pharmaco (Australia) Ltd Suite 1A, Level 2, 802 Pacific Highway, Gordon NSW 2072, Australia

Under license of CHEPLAPHARM Arzneimittel GmbH, Germany

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

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