KONAKION® MM

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using KONAKION® MM?

KONAKION® MM contains the active ingredient phytomenadione. KONAKION® MM is used to treat excessive bleeding problems. For more information, see Section 1. Why am I using KONAKION® MM? in the full CMI.

2. What should I know before I use KONAKION® MM?

Do not use if you have ever had an allergic reaction to KONAKION® MM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use KONAKION® MM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KONAKION® MM and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use KONAKION® MM?

- KONAKION® MM is given as an injection or as a liquid for you to swallow.
- 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.
- If you receive KONAKION® MM as an injection your doctor will usually prescribe a single injection or short course of injections.
- Your doctor will decide which is the best way for you to receive KONAKION® MM. KONAKION® MM should be used exactly as
 your doctor has prescribed.

More instructions can be found in Section 4. How do I use KONAKION® MM? in the full CMI.

5. What should I know while using KONAKION® MM?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using KONAKION® MM. Tell your doctor if you feel the injection is not helping your condition and be sure to keep all of your appointments.
Things you should not do	Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.
Driving or using machines	There is no information on use of KONAKION® MM with driving or operating machines.
Looking after your medicine	 KONAKION® MM will be stored in the pharmacy, or at the doctors surgery. Store KONAKION® MM in a cool dry place where the temperature stays below 25°C. KONAKION® MM should be protected from light.

For more information, see Section 5. What should I know while using KONAKION® MM? in the full CMI.

6. Are there any side effects?

KONAKION® MM can cause serious allergic reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

KONAKION® MM

Active ingredient(s): phytomenadione (also called Vitamin K1)

Consumer Medicine Information (CMI)

This leaflet provides important information about using KONAKION® MM. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KONAKION® MM.

Where to find information in this leaflet:

- 1. Why am I using KONAKION® MM?
- 2. What should I know before I use KONAKION® MM?
- 3. What if I am taking other medicines?
- 4. How do I use KONAKION® MM?
- 5. What should I know while using KONAKION® MM?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using KONAKION® MM?

KONAKION® MM contains the active ingredient phytomenadione. KONAKION® MM belongs to a group of medicines called Vitamin K.

KONAKION® MM is used to treat excessive bleeding problems.

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.

2. What should I know before I use KONAKION® MM?

Warnings

Do not use KONAKION® MM if:

 you are allergic to phytomenadione, or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction may include:

- o 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 skin
- You are pregnant or intend to become pregnant.

- The ampoule is damaged or shows signs of tampering.
- 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.
- The solution is cloudy or separated.
- If you are less than one year of age.
 KONAKION® MM Paediatric is recommended for use in children under one year of age.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as liver disease.
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives.
- are pregnant or intend to become pregnant, are breast feeding or intend to breast feed.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. <u>Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Such 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

Some medicines may interfere with KONAKION® MM and affect how 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KONAKION® MM.

4. How do I use KONAKION® MM?

How to take / use KONAKION® MM

- KONAKION® MM should be used exactly as your doctor has prescribed.
- Follow the instructions provided and use KONAKION®
 MM until your doctor tells you to stop.
- 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.
- 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.

When to take / use KONAKION® MM

- KONAKION® MM should be used exactly as prescribed.
- 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 use too much KONAKION® MM

If you think that you have used too much KONAKION® MM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using KONAKION® MM?

Things you should do

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.

Call your doctor straight away if you:

 Develop any of the serious side effects listed in <u>Section 6 Are there any side effects?</u> or if you do not feel well while you are receiving KONAKION® MM.

Remind any doctor, dentist or pharmacist you visit that you are using KONAKION® MM.

Things you should not do

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

Driving or using machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

Looking after your medicine

- 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Irritation, soreness or redness near the injection site Unusual taste, flushing or sweating 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reactions which may include: Rash Swelling Breathing difficulties	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KONAKION® MM contains

Active ingredient (main ingredient)	Phytomenadione (also called Vitamin K1)
, ,	Each 1 mL ampoule contains 10 mg of phytomenadione.
Other ingredients	Glycocholic acid
(inactive ingredients)	Lecithin (322)
	Sodium hydroxide
	Hydrochloric acid (507)
	Water for injection
Potential allergens	KONAKION® MM is lactose and gluten free.

Do not take this medicine if you are allergic to any of these ingredients.

What KONAKION® MM looks like

KONAKION® MM comes in one adult strength:

10 mg/1 mL. (AUST R 61654).

KONAKION® MM comes in packs of 5 ampoules.

KONAKION® MM is also available as a paediatric strength injection.

Who distributes KONAKION® MM?

Pharmaco (Australia) Ltd Level 13, 465 Victoria Avenue Chatswood NSW 2067 Australia

Phone: 1800 201 564

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