

# KONAKION<sup>®</sup> MM Paediatric (phonetic pronunciation – koe-nak-ee-on)

## 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<sup>®</sup> MM Paediatric?

KONAKION<sup>®</sup> MM Paediatric contains the active ingredient phytomenadione. KONAKION<sup>®</sup> MM Paediatric is used to prevent and treat Vitamin K Deficiency Bleeding (blood clotting problems).

For more information, see Section [1. Why am I using KONAKION<sup>®</sup> MM Paediatric?](#) in the full CMI.

### 2. What should I know before I use KONAKION<sup>®</sup> MM Paediatric?

Do not use if your baby has ever had an allergic reaction to KONAKION<sup>®</sup> MM Paediatric or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if your baby has any other medical conditions or take any other medicines or if you have taken any medicines during pregnancy.**

For more information, see Section [2. What should I know before I use KONAKION<sup>®</sup> MM Paediatric?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with KONAKION<sup>®</sup> MM Paediatric 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<sup>®</sup> MM Paediatric?

- 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<sup>®</sup> MM Paediatric orally, they must receive every dose as prescribed for effective disease prevention.

More instructions can be found in Section [4. How do I use KONAKION<sup>®</sup> MM Paediatric?](#) in the full CMI.

### 5. What should I know while using KONAKION<sup>®</sup> MM Paediatric?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist visit that your baby is using KONAKION<sup>®</sup> MM Paediatric.</li><li>• Tell your doctor or nurse if your baby vomits or has diarrhoea within 24 hours of receiving a dose of KONAKION<sup>®</sup> MM Paediatric by mouth. A repeat dose may be required.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not miss your baby's doctor follow-up appointments to ensure all oral doses are received.</li><li>• 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.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• There is no information on use of KONAKION<sup>®</sup> MM Paediatric with driving or operating machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Not expected to be applicable.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• KONAKION<sup>®</sup> MM Paediatric will be stored in the pharmacy, at the doctors surgery, on the ward or at the baby health centre.</li><li>• It is kept in a cool dry place where the temperature stays below 25°C.</li><li>• KONAKION<sup>®</sup> MM Paediatric should be protected from light.</li></ul>

For more information, see Section [5. What should I know while using KONAKION<sup>®</sup> MM Paediatric?](#) in the full CMI.

### 6. Are there any side effects?

Side effects usually occur within hours of the dose being administered and may include 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<sup>®</sup> MM Paediatric (phonetic pronunciation – koe-nak-ee-on)

Active ingredient(s): phytomenadione

## Consumer Medicine Information (CMI)

This leaflet provides important information about using KONAKION<sup>®</sup> MM Paediatric. **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<sup>®</sup> MM Paediatric.**

**Where to find information in this leaflet:**

- [1. Why am I using KONAKION<sup>®</sup> MM Paediatric?](#)
- [2. What should I know before I use KONAKION<sup>®</sup> MM Paediatric?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use KONAKION<sup>®</sup> MM Paediatric?](#)
- [5. What should I know while using KONAKION<sup>®</sup> MM Paediatric?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using KONAKION<sup>®</sup> MM Paediatric?

KONAKION<sup>®</sup> MM Paediatric contains the active ingredient **phytomenadione**. KONAKION<sup>®</sup> MM Paediatric belongs to a group of medicines called Vitamin K.

**KONAKION<sup>®</sup> MM Paediatric is used to treat blood clotting problems.**

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<sup>®</sup> MM Paediatric belongs to one of these groups.

Your doctor, however, may have prescribed KONAKION<sup>®</sup> MM Paediatric for another purpose.

Ask your doctor if you have any questions about why KONAKION<sup>®</sup> MM Paediatric has been prescribed for your baby.

## 2. What should I know before I use KONAKION<sup>®</sup> MM Paediatric?

### Warnings

**Do not use KONAKION<sup>®</sup> MM Paediatric if:**

- Your baby is allergic to phytomenadione, or any other type of Vitamin K or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure your baby can use this medicine.
- The ampoule is damaged or shows signs of tampering.
- The expiry date (EXP) printed on the pack has passed.

- The solution is cloudy or separated.

**Check with your doctor if your baby:**

- Has any other medical conditions including:
  - Liver disease or blockage of the bile ducts.
  - Poor absorption of nutrients (called malabsorption).
  - Is allergic to any other medicines, foods, dyes or preservatives.
  - Takes any medicines for any other condition.

**Check with your doctor if you:**

- Have taken any of the following medicines during pregnancy:
  - Warfarin (Coumadin<sup>®</sup>, Marevan<sup>®</sup>).
  - Phenindione (Dindevan<sup>®</sup>).
  - 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<sup>®</sup> MM Paediatric.

During treatment, your baby 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 [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

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

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with KONAKION<sup>®</sup> MM Paediatric and affect how it works.**

These medicines include:

- Long-term antibiotics.

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<sup>®</sup> MM Paediatric.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your**

baby is taking and if these affect KONAKION® MM Paediatric.

## 4. How do I use KONAKION® MM Paediatric?

### How it is used

- KONAKION® MM Paediatric must be given to your baby exactly as prescribed by the doctor.
- 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.
- 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.

### How long is KONAKION® MM Paediatric 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 you suspect that your baby misses a dose of KONAKION® MM Paediatric

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.

### If you give your baby too much KONAKION® MM Paediatric

If you think that you have given your baby too much KONAKION® MM Paediatric, your baby 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 Paediatric?

### Things you should do

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

### Call your doctor straight away if you:

- Notice your baby vomiting or having diarrhoea within 24 hours from receiving a dose of KONAKION® MM Paediatric by mouth.

Remind any doctor, dentist or pharmacist you visit that your baby is using KONAKION® MM Paediatric.

### Things you should not do

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

### Driving or using machines

There is no information on use of KONAKION® MM Paediatric with driving or operating machines.

### Drinking alcohol

**Although not expected to be applicable, tell your doctor if you drink alcohol and your baby is breast-fed.**

### Looking after your medicine

- 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.

## 6. Are there any side effects?

All medicines can have side effects. If your baby does 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.

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

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>Unusual flushing or sweating</li><li>Irritation, soreness or redness near the injection site, in rare cases this can be severe</li></ul>	<b>Speak to your doctor if your baby has any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Allergic reactions may include:</b> <ul style="list-style-type: none"><li>Rash</li><li>Swelling</li><li>Breathing difficulties</li></ul> <b>Other rare side effects that could be severe:</b> <ul style="list-style-type: none"><li>Inflammation and tissue injury of the injection site</li></ul>	<b>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.</b>

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

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

## Reporting side effects

After you have received medical advice for any side effects your baby experiences, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://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 giving your baby any of their medicines.**

## 7. Product details

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

### What KONAKION® MM Paediatric contains

<b>Active ingredient (main ingredient)</b>	Phytomenadione (also called Vitamin K1) Each 0.2 mL ampoule contains 2 mg of phytomenadione
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>Glycocholic acid</li><li>Lecithin (322)</li><li>Sodium hydroxide</li><li>Hydrochloric acid (507)</li><li>Water for injection</li></ul>

<b>Potential allergens</b>	KONAKION® MM Paediatric is lactose and gluten free
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**Do not take this medicine if your baby is allergic to any of these ingredients.**

### What KONAKION® MM Paediatric looks like

KONAKION® MM Paediatric is an amber glass ampoule containing a clear, yellow solution. (AUST R 71758).

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.

### Who distributes KONAKION® MM Paediatric?

Pharmaco (Australia) Ltd  
Level 13, 465 Victoria Avenue  
Chatswood NSW 2067  
Australia  
Phone: 1800 201 564

Under license of CHEPLAPHARM Arzneimittel GmbH, Germany

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