Package leaflet: Information for the patient

Konakion MM Paediatric ampoules 2 mg/0.2 ml

Oral solution or solution for injection

Phytomenadione (vitamin K_1)

Read all of this leaflet carefully before your baby or child is given this medicine, or before you start taking this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor, nurse or midwife.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you or your child get any side effects, talk to your doctor, nurse or midwife. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Konakion MM Paediatric is and what it is used for

Konakion MM Paediatric contains a medicine called phytomenadione. This is a man-made vitamin called vitamin K_1. Konakion MM Paediatric is most commonly used for the following:

- Babies who do not have enough vitamin K in their bodies. Giving Konakion MM Paediatric **prevents** and **treats** bleeding caused by a lack of vitamin K. This is called 'vitamin K deficiency bleeding' (VKDB). This is a serious, but rare condition. All newborn babies are given vitamin K_1 with their parent's permission.

Konakion MM Paediatric may also be used in adults and older children when small amounts of vitamin K are required, for the following:

- To prevent and treat bleeding after the use of certain medicines to thin the blood (called anticoagulants).
- To treat children aged 1 year and older normally after advice from a specialist haematologist (blood doctor).

Konakion MM Paediatric works by helping your body make blood clotting factors. These blood clotting factors help stop bleeding.

2. What you need to know before you or your child is given Konakion MM Paediatric

You or your child must not be given Konakion MM Paediatric if they are allergic (hypersensitive) to:

- Phytomenadione or any of the other ingredients of Konakion MM Paediatric (listed in Section 6: Further information).

If you are not sure if this applies to you or your child, talk to the doctor, nurse or midwife before being given Konakion MM Paediatric.

Warnings and precautions
Talk to your doctor, nurse or midwife before your child has Konakion if:
- They have a problem with the flow of bile in their body (cholestatic disease). Bile is important in helping the body to use some vitamins.

Talk to your doctor or nurse before having Konakion MM if:
- You have severe problems with your liver.
- You have an artificial heart valve.

Other medicines and Konakion MM Paediatric
Tell your doctor, nurse or midwife if you or your child is taking or has recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Konakion MM Paediatric can affect the way some medicines work. Also some other medicines may affect the way Konakion MM Paediatric works.
In particular, tell your doctor, nurse or midwife if you or your child are:

- Taking medicines to stop their blood clotting (anticoagulants).
- Pregnant or think you are pregnant and taking medicines for epilepsy (for example anticonvulsants like phenobarbital or phenytoin).

Pregnancy and breast-feeding
Talk to your doctor before having Konakion if you are pregnant, think you are pregnant, or breast-feeding. Your doctor will then decide if you should receive Konakion.

Driving and using machines
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 having Konakion.

Important information about some of the ingredients of Konakion MM Paediatric
Konakion MM Paediatric is essentially 'sodium free' as it contains less than 1 millimole sodium (2.64 mg in each millilitre).

3. How Konakion MM Paediatric is given

Prevention and treatment of vitamin K deficiency bleeding in babies

Konakion MM Paediatric can be given to your child by injection into a vein or muscle, or by mouth (orally). How it is given will depend upon what the medicine is being used for and whether your baby was born prematurely. The doctor will decide how much Konakion MM Paediatric your child needs.

Prevention of vitamin K deficiency bleeding

Healthy babies delivered at, or nearly at, full term
These babies will be given **either**:
- A single injection (1 mg) either at birth or soon after, **or**
- By mouth (oral) a first dose (2 mg) at birth or soon after. This is followed by a second 2 mg dose after 4 to 7 days and third 2 mg dose at 1 month. In exclusively formula-fed infants the third oral dose can be omitted.

Premature babies or full-term babies at special risk of bleeding
- These babies will be given Konakion MM Paediatric as an injection at birth or soon after.
- More injections may be given later if your baby is still at risk of bleeding.

Further doses:

- Babies who are given vitamin K by mouth and who are breast-fed (not given formula milk) may need more doses of vitamin K by mouth.
- Bottle-fed babies given the two doses of vitamin K by mouth may not need any more doses of vitamin K. This is because it is included in formula milk.

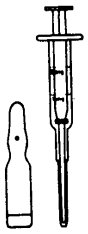
The instructions 'How to give your baby Konakion MM Paediatric by mouth' are given later in this section (section 3).

Treatment of vitamin K deficiency bleeding
- These babies will be given Konakion MM Paediatric as an injection (usually 1 mg).
- More injections may be given later if your baby is still at risk of bleeding. Some babies may also need a blood transfusion.

How to give your baby Konakion MM Paediatric by mouth
If your baby was given Konakion MM Paediatric by mouth at birth, you will be asked to give your baby another 2 mg dose. You will give them this by mouth 4 to 7 days after birth.
If your baby is having breast milk and no formula milk you may be asked to give your baby 2 mg doses once a month (by mouth).

The pictures in this leaflet show you how to give the doses to your baby by mouth, using the dispenser provided in the pack. If you are not sure, or have any worries about doing this, talk to your health visitor, midwife, doctor or pharmacist.

1. Ampoule and dispenser

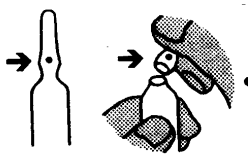


Picture 1

– Picture 1 shows the ampoule (the small glass container) and the dispenser. The part of the dispenser which can be moved in and out is called the plunger.

– Shake the ampoule until the liquid is in the bottom of the ampoule. Do not use it if it looks cloudy.

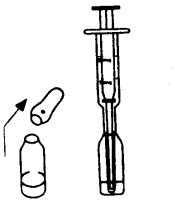
2. To open the ampoule



Picture 2

– 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 (see Picture 2).

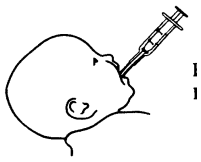
– Hold the top of the ampoule between the thumb and first finger of your other hand. Snap the top off by pushing **away** from the side with the spot (see Picture 2).



Picture 3

3. Put the dispenser into the ampoule. The tip of the dispenser should touch the bottom of the ampoule (see Picture 3). Pull the plunger up slowly to pull the medicine into the dispenser until it is level with the second mark (2 mg) on the side of the dispenser.

   The dispenser is designed to draw up the right dose from the ampoule. There may be some liquid left over in the ampoule even after the right dose has been removed. This is OK. Do not give your baby any extra liquid.



Picture 4

4. Put the dispenser into your baby's mouth as shown in Picture 4. Gently push the plunger in, to give your baby the medicine.

If your baby gets more Konakion MM Paediatric than they should
If your baby has had more Konakion MM Paediatric than they should, talk to a doctor, nurse or midwife. The following effects may happen to your baby; jaundice (signs of which are yellowing of the skin or the whites of the eyes), tummy ache, constipation, soft stools (poo), seeming unwell, being agitated (upset), a rash and changes to how well their liver works (shown up by blood tests).

If you forget to give your baby Konakion MM Paediatric
- If you forget to give your baby their dose of Konakion MM Paediatric by mouth, talk to your health visitor, midwife or doctor about when to give the next dose.
- Do not give your baby a double dose to make up for a forgotten dose.

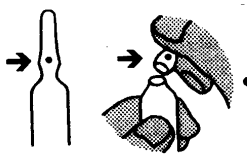
If someone else takes your baby's Konakion MM Paediatric by mistake, they should talk to a doctor.
If you have any further questions on the use of this medicine, ask your doctor, nurse or midwife.

Prevention and treatment of bleeding after the use of certain medicines to thin the blood (called anticoagulants) in adults and older children.

Konakion MM Paediatric 2 mg/0.2 ml will be used when small amounts of vitamin K are needed. It will be given to you either by injection into a vein or by mouth (orally). The solution is squirted into the mouth either using an oral dispenser or a syringe with the needle removed.

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

Elderly
Because elderly adults are sometimes more sensitive to Konakion MM Paediatric your doctor may decide to start you on a lower dose. This dose may be increased or repeated if necessary.

Children (aged 1 to 18 years)
Konakion MM Paediatric 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 or your child take more Konakion MM than they should
If you or your child has had more Konakion MM Paediatric than they should, talk to a doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Konakion MM Paediatric can cause side effects, although not everyone gets them.

The following side effects may happen with this medicine:

Allergic reactions
The signs may include:
- Swelling of your or your child's throat, face, lips and mouth. This may make it difficult for them to breathe or swallow.
- Sudden swelling of your or your child's hands, feet and ankles.

If you or your child has an allergic reaction, **tell a doctor straight away.**

A reaction where the injection was given
Rarely this may be severe. Signs include redness, swelling, pain and it may cause a scar.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Konakion MM Paediatric

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of the month.

- Konakion MM Paediatric ampoules should be stored in their original packaging to protect them from light
- Konakion MM Paediatric should be stored at a temperature below 25 °C (not frozen)
- Once opened use immediately
- Do not use this medicine if the liquid appears cloudy
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Konakion MM Paediatric contains
The active substance in Konakion MM Paediatric 2 mg/0.2 ml is vitamin K_1 (phytomenadione). Each 0.2 ml of liquid medicine contains 2 mg vitamin K_1.

Other ingredients are glycocholic acid, sodium hydroxide, lecithin, hydrochloric acid and water for injections.

What Konakion MM Paediatric looks like and contents of the pack
Konakion MM Paediatric is a slightly opalescent, pale yellow liquid ('oral solution or solution for injection').

Konakion MM Paediatric is supplied in amber-coloured glass ampoules in packs of 5 with plastic oral dispensers.

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CHEPLAPHARM Arzneimittel GmbH
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This leaflet was last revised in October 2020.
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The following information is intended for medical or healthcare professionals only:
The tear-off portion above is intended for the patient

INFORMATION FOR HEALTHCARE PROFESSIONALS

Konakion® MM Paediatric Ampoules 2 mg/0.2 ml
Oral solution or solution for injection
Phytomenadione (vitamin K_1)

Please refer to the Summary of Product Characteristics for full prescribing information.

Presentation
Amber glass ampoules containing 0.2 ml solution. The solution is clear to slightly opalescent and pale yellow in colour. Excipients are glycocholic acid, lecithin, sodium hydroxide, hydrochloric acid and water for injections. Konakion MM Paediatric 2 mg/0.2 ml is essentially 'sodium free' as it contains less than 1 mmol sodium (2.64 mg per 1 ml). Cartons of 5 ampoules.

PACKS CONTAIN PLASTIC ORAL DISPENSERS. NOT TO BE USED FOR INJECTIONS.

Prevention and treatment of vitamin K deficiency bleeding (VKDB) in neonates and infants

Posology and method of administration
Konakion MM Paediatric 2 mg/0.2 ml is for either injection (intravenous or intramuscular) or oral administration.

CAUTION: care is required when calculating and measuring the dose in relation to the baby's weight (10 times dosing errors are common).

Prophylaxis of vitamin K deficiency bleeding
Healthy neonates of 36 weeks gestation and older:
Either:

- 1 mg administered by intramuscular injection at birth or soon after birth

or

- 2 mg orally at birth or soon after birth. The oral dose should be followed by a further dose of 2 mg at 4-7 days of age. A further 2 mg oral dose should be given at 1 month after birth. In exclusively formula-fed infants the third oral dose can be omitted.

***Preterm neonates of less than 36 weeks gestation weighing 2.5 kg or greater, and term neonates at special risk (e.g. prematurity, birth asphyxia, obstructive jaundice, inability to swallow, maternal use of anticoagulants or antiepileptics)*:** 1 mg by intramuscular or intravenous injection at birth or soon after birth. The amount and frequency of further doses should be based on coagulation status.

Preterm neonates of less than 36 weeks gestation weighing less than 2.5 kg: 0.4 mg/kg (equivalent to 0.04 ml/kg) by intramuscular or intravenous injection at birth or soon after birth. This parenteral dose should not be exceeded. The amount and frequency of further doses should be based on coagulation status.

There is evidence that oral prophylaxis is insufficient in patients with underlying cholestatic liver disease and malabsorption.

CAUTION: care is required when calculating and measuring the dose in relation to the baby's weight (10 times dosing errors are common).

Dosing information for preterm babies at birth for the prophylaxis of Vitamin K deficiency bleeding

Weight of the baby	Dose of vitamin K at birth	Injection volume
1 kg	0.4 mg	0.04 ml
1.5 kg	0.6 mg	0.06 ml
2 kg	0.8 mg	0.08 ml
2.5 kg	1 mg	0.1 ml
Over 2.5 kg	1 mg	0.1 ml

Further oral doses in breast-fed infants have been advised, but safety or efficacy data for these additional doses is limited.

Therapy of early and/or late vitamin K deficiency bleeding
Initially 1 mg by intravenous injection and further doses as required, depending on clinical picture and coagulation status. Konakion therapy may need to be accompanied by a more immediate effective treatment, such as transfusion of blood or blood clotting factors to compensate for severe blood loss and delayed response to vitamin K_1.

Treatment of coumarin anticoagulant overdose in adults and older children (1 to 18 years)
Konakion MM Paediatric 2 mg/0.2 ml can be used when small quantities of vitamin K are required.

Adults
For full details of dose recommendations for vitamin K_1 therapy in patients with asymptomatic high International Normalized Ratio (INR) with or without mild haemorrhage please refer to the Summary of Product Characteristics.

Elderly
Elderly patients tend to be more sensitive to reversal of anticoagulation with Konakion MM; dosage in this group should be at the lower end of the ranges recommended. For elderly patients with asymptomatic high INR of 5.0 to 9.0 with or without mild haemorrhage, small doses of 0.5 to 1 mg intravenous or oral vitamin K_1 have been shown to effectively reduce the INR to < 5.0 within 24 hours.

Children
The optimal dose should be decided by the treating physician according to the indication, clinical situation and weight of the patient. However, based on clinical experience, the following recommendation is suggested:

Children with asymptomatic high INR with or without mild haemorrhage: intravenous vitamin K_1 in doses of 30 micrograms/kg have been reported to be effective in reversing asymptomatic high (> 8.0) INR in clinically well children.

Method of administration
Konakion MM Paediatric can be administered by intravenous injection or by oral administration depending on the indication. Administration by intramuscular injection is only suitable for the VKDB indication in babies.

At the time of use, the ampoule contents should be clear. Following incorrect storage, the contents may become turbid or present a phase-separation. In this case the ampoule must not be used.

***Parenteral use*:** A 1 ml syringe or smaller, preferably with 0.01 ml graduations, is recommended for the administration of injection volumes of 0.04 ml (0.4 mg) to 0.1 ml (1 mg), for example, 1 ml B-D Plastipak Syringes.

Konakion MM Paediatric should not be diluted or mixed with other parenteral medications, but may be injected into the lower part of an infusion set.

Oral use: For oral administration of 1 mg or 2 mg, **oral dispensers are provided in the pack**. After breaking the ampoule open, 0.2 ml of solution should be withdrawn into the oral dispenser until it reaches the mark on the dispenser (0.2 ml = 2 mg vitamin K). Drop the contents of the dispenser directly into the mouth by pressing the plunger.

Konakion MM Paediatric solution can also be given orally using a syringe (e.g. 1 ml syringe). The ampoule solution should not be diluted. The required amount should be withdrawn from the ampoule using a syringe with attached needle. The needle should then be removed from the syringe, the contents of the syringe directly administered into the patient's mouth and washed down with fluid.

Incompatibilities
Konakion MM Paediatric should not be diluted or mixed with other parenteral medications.

Shelf life
Unopened: 2 years.
Once opened use immediately.

Special precautions for storage
Store below 25 °C and protect from light.
Do not freeze.

Do not use if the solution is turbid.

Date of last revision of leaflet September 2023