Package leaflet: Information for the patient

Konakion MM Ampoules 10 mg/ml
solution for injection and oral solution
Phytomenadione (vitamin K_1)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you 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 get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Konakion MM contains a medicine called phytomenadione. This is a man-made vitamin called vitamin K_1.
Konakion MM is used for the following:
- To prevent and treat severe 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 works by helping your body make blood clotting factors. These blood clotting factors help stop bleeding.

2. What you need to know 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 6: Further information).
If you are not sure if this applies to you, talk to your doctor or nurse before having Konakion.

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

- Taking medicines to stop your 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.

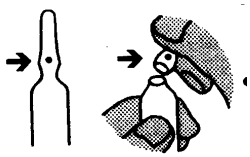
Important information about some of the ingredients of Konakion MM
Konakion MM is essentially 'sodium (a type of salt) free' as it contains less than 1 mmol sodium (2.64 mg per 1 ml).

3. 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
- 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 dose (5 to 10 mg) is usually given with a blood transfusion.
- The maximum dose is usually no more than 40 mg Konakion in 24 hours.

Your doctor will usually check your blood for the levels of clotting factors 3 hours after having Konakion MM and, if you need them, give you more doses of Konakion MM.

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. This dose may be increased or repeated if necessary.

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
Because Konakion MM is given by a doctor or nurse, it is unlikely that you or your child will be given too much or 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 this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Konakion MM can cause side effects, although not everyone will get them.

The following side effects may happen with this medicine:

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

If you have an allergic reaction, **tell a doctor straight away.**

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

Other possible side effects
If Konakion MM is given too quickly into a vein the following effects may happen:
- Flushing of the face, sweating
- Blue colour to the skin, seen most on the lips
- A feeling of tightness in the chest
- Problems with blood circulation

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

- 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 that month
- Konakion MM ampoules should be stored at a temperature below 25 °C, but not frozen
- Konakion MM ampoules should be stored in their original packaging to protect them from light
- 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 contains
The active substance in Konakion MM Ampoules 10 mg/ml is vitamin K_1 (phytomenadione). Each 1 ml of liquid medicine contains 10 mg vitamin K_1.

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

What Konakion MM looks like and contents of the pack
Konakion MM is a slightly opalescent, pale yellow liquid (‘solution for injection or oral solution’).
Konakion MM is supplied in amber-coloured glass ampoules in packs of 10.

Marketing Authorisation Holder
CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489 Greifswald
Germany

Manufacturer
CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 23-24
17489 Greifswald
Germany

This leaflet was last revised October 2020.

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The following information is intended for medical or healthcare professionals only:
The tear-off portion to the left is intended for the patient

INFORMATION FOR HEALTHCARE PROFESSIONALS

Konakion® MM Ampoules 10 mg/ml
solution for injection and oral solution
Phytomenadione (vitamin K_1)

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

Amber glass ampoules containing 1 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 Ampoules 10 mg/ml are essentially 'sodium free' as they contain less than 1 mmol sodium (2.64 mg per 1 ml). Cartons of 10 ampoules.

Therapeutic indication
Konakion MM is indicated in the treatment of haemorrhage or threatened haemorrhage, associated with a low blood level of prothrombin or factor VII. The main indication is:
As an antidote to anticoagulant drugs of the coumarin type.

Posology and method of administration
Konakion MM Ampoules 10 mg/ml is for intravenous injection or oral administration.

Adults: As an antidote to anticoagulant drugs
Severe or life-threatening haemorrhage, e.g. during anticoagulant therapy: The coumarin anticoagulant should be withdrawn and an intravenous injection of Konakion MM given slowly in a dose of 5 mg - 10 mg together with fresh frozen plasma (FFP), or prothrombin complex concentrate (PCC). The prothrombin level should be estimated three hours later and, if the response has been inadequate, the dose should be repeated. Not more than 40 mg of Konakion MM should be given intravenously in 24 hours.

For full details of dose recommendations for vitamin K_1 therapy in patients with major and life-threatening bleeding please refer to the Summary of Product Characteristics.

Less severe haemorrhage: Konakion MM can be given orally or by slow intravenous injection in a dose of 1 mg – 5 mg. 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 of 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 International Normalized Ratio (INR) of 5.0 – 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 recommendations are suggested:

Children with major and life-threatening bleeding: a dose of 5 mg vitamin K_1 by intravenous injection is suggested (together with FPP or PCC if appropriate).

Children with asymptomatic high International Normalized Ratio (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.

Infants and Neonates
Konakion MM Paediatric (2 mg/0.2 ml) should be used.

Instructions for use
Konakion MM ampoule solution should not be diluted.
Do not use if the solution is turbid.
For single use only

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

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

Date of last revision of leaflet
September 2023