Package Leaflet: Information for the patient

Konakion® MM Ampoules 10mg/ml **Roche**
solution for injection
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.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

What is in this leaflet:

1. What Konakion MM is and what it is used for
2. What you need to know before you are given Konakion MM
3. How Konakion MM is given
4. Possible side effects
5. How to store Konakion MM
6. Contents of the pack and further information

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 bleeding after the use of certain medicines to thin the blood (called anti-coagulants).
- To treat children (aged 1 year and older) who have liver disease or low levels of vitamin K in their body because of illness. Konakion MM is normally used to treat these children 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
Check with 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
Please 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).

Pregnancy and breast-feeding

Talk to your doctor before having Konakion if you are pregnant, think you are pregnant, or breastfeeding. 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 (2.64mg per 1ml).

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 or through a small tube into one of your veins (intravenous infusion).

Adults
- For people who are bleeding after taking blood-thinning (anticoagulant) medicines, the usual dose is 5 to 10 mg.
- For people who have severe bleeding the Konakion dose (5 to 10 mg) is usually given with a blood transfusion.
- For people with mild bleeding or at risk of bleeding, the usual dose is 0.5 to 1 mg.
- If you need to have emergency surgery you may be given 5 mg Konakion before surgery to reverse the effects of blood-thinning (anticoagulant) medicines.
- 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.

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 dose is usually no more than 5 mg.
- Some children may also need a blood transfusion.

The doctor will usually check the child's blood for the levels of clotting factors, 2 to 6 hours after they have Konakion MM and, if necessary, give more doses of Konakion MM.

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 may 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.**

A reaction 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5. How to store Konakion MM

- Your doctor or pharmacist is responsible for storing Konakion MM. They are also responsible for disposing of any unused Konakion MM correctly.
- Keep out of the sight and reach of children.
- Do not use Konakion MM after the expiry date printed on the pack.
- Konakion MM ampoules should be stored at a temperature below 25°C.

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 infusion’). This liquid will be further diluted to make it weaker before it is given to you.

Konakion MM is supplied in amber coloured glass ampoules in packs of 10.

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This leaflet was last revised in August 2016

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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 Ampoules 10 mg/ ml

solution for injection
Phytomenadione (vitamin K_1)

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

Presentation
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 as an antidote to anticoagulant drugs of the coumarin type in the treatment of haemorrhage or threatened haemorrhage, associated with a low blood level of prothrombin or factor VII.

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

Adults
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 (over at least 30 seconds) at a dose of 5 - 10 mg together with prothrombin complex concentrate (PCC). Fresh frozen plasma (FFP) may be used if PCC is not available. The patient's INR 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. Coagulation profiles must be monitored on a daily basis until these have returned to acceptable levels; in severe cases more frequent monitoring is necessary.

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: An intravenous injection of Konakion MM given slowly at a dose of 0.5 – 1 mg. For full details of dose recommendations for vitamin K_1 therapy in patients with asymptomatic high International Normalised Ratio (INR) with or without mild haemorrhage, please refer to the Summary of Product Characteristics.

Reversal of anticoagulation prior to surgery: For emergency surgery that can be delayed for 6-12 hours, 5 mg intravenous vitamin K_1 can be given. If surgery cannot be delayed, PCC can be given in addition to intravenous vitamin K_1 and the INR checked before surgery.

Use with anticoagulants other than warfarin: The dosing recommendations above apply to patients taking warfarin. There are limited data regarding reversal of the effects of other anticoagulants, such as acenocoumarol or phenprocoumon. The half lives of these anticoagulants are different to warfarin and different doses of vitamin K_1 may be required.

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.

Children aged 1 to 18 years
It is advisable that a haematologist is consulted about appropriate investigation and treatment in any child in whom Konakion MM is being considered.

For patients on warfarin therapy, therapeutic intervention must take into consideration the reason for the child being on warfarin and whether or not anticoagulant therapy has to be continued (e.g. in a child with mechanical heart valve or repeated thromboembolic complications) as vitamin K administration is likely to interfere with anticoagulation with warfarin for 2 – 3 weeks.

It should be noted that the earliest effect seen with vitamin K treatment is at 4 – 6 hours and therefore in patients with severe haemorrhage replacement with coagulation factors may be indicated (discuss with haematologist).

Dose of vitamin K
There are few data available regarding use of Konakion MM in children over 1 year. There have been no dose ranging studies in children with haemorrhage. The optimal dose should therefore be decided by the treating physician according to the indication, clinical situation and weight of the patient. Suggested dosages based on clinical experience are as follows:

Children with major and life-threatening bleeding: a dose of 5 mg vitamin K_1 i.v. is suggested (together with PCC if appropriate, or FFP if PCC is not available).

Children with asymptomatic high International Normalised Ratio (INR) with or without mild haemorrhage: i.v. vitamin K_1 at doses of 30 micrograms/kg have been reported to be effective in reversing asymptomatic high (>8) INR in clinically well children.

INR should be measured 2 to 6 hours later and if the response has not been adequate, the dose may be repeated. Frequent monitoring of vitamin K dependent clotting factors is essential in these patients.

Neonates and babies
Konakion MM Paediatric 2 mg/0.2 ml should be used in these patients.

Method of administration - Instructions for infusion in adults
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.

Konakion MM Ampoules are for intravenous injection and should be diluted with 55ml of 5% glucose before slowly infusing the product. The solution should be freshly prepared and protected from light. Konakion MM Ampoule solution should not be diluted or mixed with other injectables, but may be injected into the lower part of an infusion apparatus.

Shelf life
Unopened: 3 years.

Special precautions for storage
Store below 25°C and protect from light. Do not freeze.
Do not use if the solution is turbid.

This leaflet was last revised in August 2016