

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What PHYTOMENADIONE INJECTION is and what it is used for
2. Before you take PHYTOMENADIONE INJECTION
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1. WHAT PHYTOMENADIONE INJECTION IS AND WHAT IT IS USED FOR

PHYTOMENADIONE INJECTION contains a medicine called phytomenadione. This is a man-made vitamin called vitamin K1. PHYTOMENADIONE INJECTION 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. PHYTOMENADIONE INJECTION is normally used to treat these children after advice from a specialist haematologist (blood doctor). PHYTOMENADIONE INJECTION works by helping your body make blood clotting factors. These blood clotting factors help stop bleeding.

2. BEFORE YOU TAKE PHYTOMENADIONE INJECTION

You must not be given PHYTOMENADIONE INJECTION if you are allergic (hypersensitive) to phytomenadione or any of the other ingredients of PHYTOMENADIONE INJECTION (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 PHYTOMENADIONE INJECTION 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 PHYTOMENADIONE INJECTION can affect the way some medicines work. Also some other medicines may affect the way PHYTOMENADIONE INJECTION 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

PHYTOMENADIONE INJECTION 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 PHYTOMENADIONE INJECTION

PHYTOMENADIONE INJECTION is essentially 'sodium (a type of salt) free' as it contains less than 1 mmol sodium (2.64 mg per 1 ml).

3. HOW TO TAKE PHYTOMENADIONE INJECTION

PHYTOMENADIONE INJECTION 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 PHYTOMENADIONE INJECTION and, if you need them give you more doses of Konakion MM.

Elderly

Because elderly adults are sometimes more sensitive to PHYTOMENADIONE INJECTION 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)

PHYTOMENADIONE INJECTION 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 PHYTOMENADIONE INJECTION and, if necessary, give more doses of Konakion MM.

If you are given more PHYTOMENADIONE INJECTION than you should

Because PHYTOMENADIONE INJECTION 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 PHYTOMENADIONE INJECTION 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

5. How to store

- Your doctor or pharmacist is responsible for storing Konakion MM. They are also responsible for disposing of any unused PHYTOMENADIONE INJECTION correctly.
- Keep out of the sight and reach of children.
- Do not use PHYTOMENADIONE INJECTION after the expiry date printed on the pack.
- PHYTOMENADIONE INJECTION ampoules should be stored at a temperature below 30°C.

6. Further information

What PHYTOMENADIONE INJECTION contains

The active substances is Phytomenadione

- The other ingredients are:

Benzyl Alcohol, Disodium EDTA, Tween 80, Propylene Glycol, Water for injection

What PHYTOMENADIONE INJECTION look like and contents of the pack

A clear Yellowish solution.

10 x 1 ml Ampoule pack in a mono carton with Insert

Marketing Authorisation Holder

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Plot No 2104/2/A,

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