

Package Leaflet: Information for the patient

Phytomenadione 10 mg/1 ml solution for injection

Phytomenadione (vitamin K₁)

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.

The name of this medicine is “Phytomenadione 10 mg/1 ml solution for injection” but will be referred to as “Phytomenadione 10 mg/1 ml” throughout this leaflet.

What is in this leaflet:

1. What Phytomenadione 10 mg/1 ml is and what it is used for
2. What you need to know before you are given Phytomenadione 10 mg/1 ml
3. How Phytomenadione 10 mg/1 ml is given
4. Possible side effects
5. How to store Phytomenadione 10 mg/1 ml
6. Contents of the pack and further information

1. What Phytomenadione 10 mg/1 ml is and what it is used for

Phytomenadione 10 mg/1 ml contains a medicine called phytomenadione. This is a man-made vitamin called vitamin K₁. Phytomenadione 10 mg/1 ml 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. It is normally used to treat these children after specialist advice from a haematologist (blood doctor).

This medicine 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 Phytomenadione 10 mg/1 ml

You must not be given Phytomenadione 10 mg/1 ml if you are allergic (hypersensitive) to phytomenadione or any of the other ingredients of this medicine (listed in Section 6: Further information). If you are not sure if this applies to you, talk to your doctor or nurse before having Phytomenadione 10 mg/1 ml.

Warnings and precautions

Check with your doctor or nurse before having Phytomenadione 10 mg/1 ml if:

- You have severe problems with your liver.
- You have an artificial heart valve.

Other medicines and Phytomenadione 10 mg/1 ml

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 10 mg/1 ml can affect the way some medicines work. Also, some other medicines may affect the way Phytomenadione 10 mg/1 ml 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 this medicine if you are pregnant, think you are pregnant, or breastfeeding. Your doctor will then decide if you should receive Phytomenadione 10 mg/1 ml.

Driving and using machines

Phytomenadione 10 mg/1 ml 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 this medicine.

Important information about some of the ingredients of Phytomenadione 10 mg/1 ml

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

3. How Phytomenadione 10 mg/1 ml is given

This medicine 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 phytomenadione 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 phytomenadione before surgery to reverse the effects of blood-thinning (anticoagulant) medicines.
- The maximum dose is usually no more than 40 mg phytomenadione in 24 hours.

Your doctor will usually check your blood for the levels of clotting factors, 3 hours after having phytomenadione and, if you need them give you more doses of Phytomenadione 10 mg/1 ml.

Elderly

Because elderly adults are sometimes more sensitive to this medicine 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 10 mg/1 ml 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 the medicine and, if necessary, give more doses of Phytomenadione 10 mg/1 ml.

If you are given more Phytomenadione 10 mg/1 ml than you should

Because this medicine 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 10 mg/1 ml 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Phytomenadione 10 mg/1 ml

- Your doctor or pharmacist is responsible for storing this medicine. They are also responsible for disposing of any unused medicine correctly.
- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date printed on the pack.
- Phytomenadione 10 mg/1 ml should be stored at a temperature below 25°C.

6. Contents of the pack and other information

What Phytomenadione 10 mg/1 ml contains

The active substance in Phytomenadione 10 mg/1 ml solution for injection is vitamin K₁ (phytomenadione). Each 1 ml of liquid medicine contains 10 mg vitamin K₁.

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

What Phytomenadione 10 mg/1 ml looks like and contents of the pack

This medicine is a slightly opalescent, pale yellow liquid ('solution for injection'). This liquid will be further diluted to make it weaker before it is given to you.

Phytomenadione 10 mg/1 ml solution for injection is supplied in amber coloured glass ampoules in packs of 10.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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**Phytomenadione 10 mg/1 ml
solution for injection**

Phytomenadione (vitamin K₁)

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

The name of this medicine is “Phytomenadione 10 mg/1 ml solution for injection” but will be abbreviated to “Phytomenadione 10 mg/1 ml” in some parts of this leaflet.

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. Phytomenadione 10 mg/1 ml solution for injection is essentially ‘sodium free’ as it contains less than 1 mmol sodium per ml (2.64 mg per 1 ml). Cartons of 10 ampoules.

Therapeutic indication

Phytomenadione 10 mg/1 ml solution for injection 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

Phytomenadione 10 mg/1 ml solution for injection 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 Phytomenadione 10 mg/1 ml 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 Phytomenadione 10 mg/1 ml 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 K₁ therapy in patients with major and life-threatening bleeding, please refer to the Summary of Product Characteristics.

Less severe haemorrhage: An intravenous injection of Phytomenadione 10 mg/1 ml given slowly at a dose of 0.5 – 1 mg. For full details of dose recommendations for vitamin K₁ 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 K₁ can be given. If surgery cannot be delayed, PCC can be given in addition to intravenous vitamin K₁ 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 K₁ may be required.

Elderly

Elderly patients tend to be more sensitive to reversal of anticoagulation with Phytomenadione 10 mg/1 ml; 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 Phytomenadione 10 mg/1 ml 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 Phytomenadione 10 mg/1 ml 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 K₁ intravenous 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: intravenous vitamin K₁ 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

Phytomenadione 2 mg/0.2 ml solution for injection 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.

This medicine is for intravenous injection and should be diluted with 55 ml of 5% glucose before slowly infusing the product. The solution should be freshly prepared and protected from light. Phytomenadione 10 mg/1 ml 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: 2 years.

Special precautions for storage

Store below 25°C and protect from light. Do not freeze.

Do not use if the solution is turbid.

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