

Patient Information Leaflet

Phytomenadione 2 mg/0.2 ml solution for injection

Phytomenadione (vitamin K₁)

Please read all of this leaflet carefully before your baby or child is given this medicine.

- 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 your child. Do not pass it on to others. It may harm them even if their symptoms are the same.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell the doctor, nurse or midwife.

The name of this medicine is “Phytomenadione 2 mg/0.2 ml solution for injection” but will be referred to as “Phytomenadione 2 mg/0.2 ml” throughout this leaflet.

In this leaflet:

1. What Phytomenadione 2 mg/0.2 ml is and what it is used for
2. Before your baby or child is given Phytomenadione 2 mg/0.2 ml
3. How Phytomenadione 2 mg/0.2 ml is given
4. Possible side effects
5. How Phytomenadione 2 mg/0.2 ml is stored
6. Further information

1. What Phytomenadione 2 mg/0.2 ml is and what it is used for

Phytomenadione 2 mg/0.2 ml contains a medicine called phytomenadione. This is a man-made vitamin called vitamin K₁. Phytomenadione 2 mg/0.2 ml is used for the following:

- Babies who do not have enough vitamin K in their bodies. Giving phytomenadione **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 K₁ with their parent’s permission.
- Babies and young children who may have had too much of certain medicines to thin their blood (called anticoagulants). Phytomenadione 2 mg/0.2 ml 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. Before your baby or child is given Phytomenadione 2 mg/0.2 ml

Your child must not be given Phytomenadione 2 mg/0.2 ml if they 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 your child, talk to the doctor, nurse or midwife before they are given Phytomenadione 2 mg/0.2 ml.

Take special care with Phytomenadione 2 mg/0.2 ml

Check with your doctor, nurse or midwife before your child has this medicine 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.

Taking other medicines

Please tell your doctor, nurse or midwife if 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 Phytomenadione 2 mg/0.2 ml can affect the way some medicines work. Also, some other medicines may affect the way Phytomenadione 2 mg/0.2 ml works.

In particular, tell your doctor, nurse or midwife if your baby or child is taking medicines to stop their blood clotting (anticoagulants).

Important information about some of the ingredients of Phytomenadione 2 mg/0.2 ml

This medicine is essentially 'sodium free' as it contains less than 1 millimole sodium per ml (2.64 mg in each millilitre).

3. How Phytomenadione 2 mg/0.2 ml is given

This medicine 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 medicine your child needs.

Prevention of vitamin K deficiency bleeding (VKDB)

Healthy babies delivered at or nearly 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 Phytomenadione 2 mg/0.2 ml 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 Phytomenadione 2 mg/0.2 ml by mouth' are given later in this section (section 3).

Treatment of vitamin K deficiency bleeding (VKDB)

- These babies will be given Phytomenadione 2 mg/0.2 ml 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.

Treatment of too much blood thinning medicine

Treatment of children who have had too much blood thinning medicine is usually decided by a haematologist (blood doctor).

- Phytomenadione 2 mg/0.2 ml will be given by injection into one of your child's veins (intravenous injection).
- The doctor will usually check your child's blood for the levels of clotting factors. This check will be made 2 to 6 hours after giving the medicine.

- If your child still does not have enough blood clotting factors, the doctor may give additional doses of Phytomenadione 2 mg/0.2 ml.

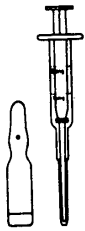
How to give your baby Phytomenadione 2 mg/0.2 ml by mouth

If your baby was given this medicine 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).

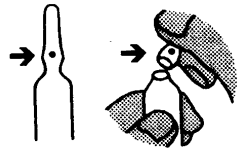
The pictures in this leaflet show you how to give the doses to your baby by mouth, using the dispenser provided in the pack. If you are not sure or have any worries about doing this talk to your health visitor, midwife, doctor or pharmacist.

1. Ampoule and dispenser



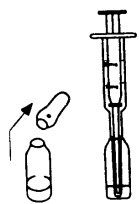
Picture 1

2. To open the ampoule



Picture 2

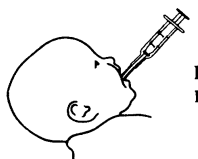
- Picture 1 shows the ampoule (the small glass container) and the dispenser. The part of the dispenser which can be moved in and out is called the plunger.
- Shake the ampoule until the liquid is in the bottom of the ampoule. Do not use it if it looks cloudy.
- Hold the bottom part of the ampoule between 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 Phytomenadione 2 mg/0.2 ml than they should

If your baby has had more of this medicine 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 Phytomenadione 2 mg/0.2 ml

- If you forget to give your baby their dose of this medicine 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 Phytomenadione 2 mg/0.2 ml 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.

4. Possible side effects

Like all medicines, Phytomenadione 2 mg/0.2 ml 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 baby's or child's throat, face, lips and mouth. This may make it difficult for them to breathe or swallow.
- Sudden swelling of your baby's or child's hands, feet and ankles.

If your baby or 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, 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 Phytomenadione 2 mg/0.2 ml is stored

- Phytomenadione 2 mg/0.2 ml ampoules should be stored in their original packaging to protect them from light.
- Phytomenadione 2 mg/0.2 ml should be stored at a temperature below 25°C.
- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date printed on the pack.
- Do not throw away any whole left over ampoules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

6. Further information

What Phytomenadione 2 mg/0.2 ml contains

The active substance in Phytomenadione 2 mg/0.2 ml is vitamin K₁ (phytomenadione). Each 0.2 ml of liquid medicine contains 2 mg vitamin K₁.

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

What Phytomenadione 2 mg/0.2 ml looks like and contents of the pack

This medicine is a slightly opalescent, pale yellow liquid ('solution for injection').

Phytomenadione 2 mg/0.2 ml solution for injection is supplied in amber coloured glass ampoules in packs of 5 with plastic oral dispensers.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Limited
8 The Chase, John Tate Road,
Hertford, SG13 7NN,
United Kingdom

Manufacturer

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 23-24
17489 Greifswald
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This information is intended for medical or healthcare professionals only:
The tear-off portion above is intended for the patient

INFORMATION FOR HEALTHCARE PROFESSIONALS

Phytomenadione 2 mg/0.2 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 2 mg/0.2 ml solution for injection" but has been abbreviated to "Phytomenadione 2 mg/0.2 ml" in some parts of this leaflet.

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. Phytomenadione 2 mg/0.2 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 5 ampoules.

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

Posology and method of administration

Phytomenadione 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 (VKDB)

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 intramuscular or intravenous 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) intramuscular or intravenous 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 (VKDB)

Initially 1 mg intravenous and further doses as required, depending on clinical picture and coagulation status. Phytomenadione 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 K₁.

Antidote therapy to anticoagulant drugs of the coumarin type

There have been no dose ranging studies performed to recommend a specific dose of Phytomenadione 2 mg/0.2 ml used as an antidote to anticoagulant drugs of the coumarin type in infants and children. Suggested doses are detailed below. Phytomenadione 2 mg/0.2 ml must be administered by intravenous injection in these patients. It is advisable that a haematologist is consulted about appropriate investigation and treatment in any infant or child in whom this medicine is being considered.

For patients on warfarin therapy, therapeutic intervention must consider the reason for the patient being on warfarin and whether or not anticoagulant therapy has to be continued (e.g. in a patient with mechanical heart valve or repeated thrombo-embolic complications) as vitamin K administration is likely to interfere with anticoagulation with warfarin for 2-3 weeks. For patients continuing to receive warfarin, the suggested dose for the partial reversal of anticoagulation is 30 micrograms/kg administered by intravenous injection. Phytomenadione 2 mg/0.2 ml is only suitable for the administration of doses of 30 micrograms/kg in children weighing over 13 kg.

The suggested dose of vitamin K for patients requiring a complete reversal of a warfarin overdose is 250-300 micrograms/kg administered by intravenous injection. It should be noted that the earliest effect seen with vitamin K treatment is at 4 to 6 hours and therefore, in patients with severe haemorrhage, replacement with coagulation factor concentrates may be indicated (discuss with haematologist). Phytomenadione 2 mg/0.2 ml is only suitable for the administration of doses of 250-300 micrograms/kg in children weighing over 1.6 kg. Prothrombin time should be measured 2 to 6 hours later and if the response has not been adequate, Phytomenadione 2 mg/0.2 ml administration may be repeated. Frequent monitoring of vitamin K dependent clotting factors is essential in these patients.

Method of administration

Phytomenadione 2 mg/0.2 ml can be administered by intramuscular or intravenous injection or by oral administration depending on the indication.

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: For the administration of injection volumes of 0.04 ml (0.4 mg) to 0.1 ml (1 mg), 0.5 ml syringes with 0.01 ml graduations are recommended. Undiluted Phytomenadione 2 mg/0.2 ml is compatible with 0.5 ml Omnican 50 syringes supplied by B.Braun.

Administration of Phytomenadione 2 mg/0.2 ml by intravenous infusion is not recommended because it must not be diluted or mixed with other parenteral medications. However, Phytomenadione 2 mg/0.2 ml may be administered by injecting the dose into the lower part of an infusion set containing 5% dextrose or 0.9% sodium chloride running at ≥ 0.7 ml/minute, see section, *Incompatibilities*.

Oral use: For oral administration, **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 baby's mouth by pressing the plunger.

Incompatibilities

Incompatibilities have been observed with diluted Phytomenadione solution and certain siliconised syringes, therefore, Phytomenadione 2 mg/0.2 ml must not be diluted before injection.

Do not dilute with sodium chloride containing solutions as precipitation may occur.

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.

This leaflet was last revised in October 2023