**Konakion MM for children 2 mg/0.2 ml solution for injection and oral use**

**phytomenadione**

**What is Konakion MM for children and what is this medicine used for?**Konakion MM for children is a medication prescribed for the prevention and treatment of bleeding (hemorrhages) in (newborn) infants. The active ingredient in Konakion MM is a synthetic form of vitamin K1 (phytomenadione). Vitamin K1 is important for the blood clotting process.

**When should your child not use this medicine or when should you be extra careful?**

**When should your child not use this medicine?**Your child is allergic to any of the substances in this medicine. You can find these substances in section 6. If you are unsure, please contact the child's treating physician.

**When should you be extra careful with this medicine?**

* Your child suffers from other diseases.
* Your child exhibits allergies.
* Before starting treatment, make sure the treating physician is aware of these conditions.
* Cases of anaphylactic shock (a very serious allergic reaction) have been reported after intravenous administration of Konakion MM.
* Konakion MM contains sodium.
* This medicine contains less than 1 mmol of sodium (23 mg) per ampule, which means it is essentially "sodium-free."

**Is your child taking any other medications?**In addition to Konakion MM for children, is your child currently taking any other medications, has your child recently taken any, or is there a possibility that your child will take other medications in the near future? This includes medications that are available without a prescription. Please inform your doctor or pharmacist.

Konakion MM for children may reduce the effectiveness of certain anticoagulant medications (coumarin-type anticoagulants).

**How to use this medicine?**Always use this medicine exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, please contact your doctor or pharmacist.

The dosage depends on whether the infant being treated is a healthy newborn or a preterm infant and whether they are exclusively breastfed. Konakion MM can be given to your child orally or through injection into a vein (intravenous) or muscle (intramuscular). The method of administration depends on the purpose of the medication and whether your baby was born prematurely.

* Prevention of bleeding due to vitamin K1 deficiency
* Healthy babies born on or close to the due date

**These babies receive:**

1. A single injection (1 mg) at or shortly after birth, or
2. An initial oral dose (2 mg) at or shortly after birth, followed by a second dose of 2 mg after 4 to 7 days and a third dose of 2 mg after 1 month.
3. For infants receiving only formula feeding, the third oral dose may be omitted.
4. Preterm babies or full-term babies at high risk of bleeding
5. These babies receive Konakion MM as an injection at or shortly after birth.
6. Additional injections may be given later if your baby continues to be at risk of bleeding.

**Follow-up doses:**

Babies receiving breastfeeding (and not formula feeding) and oral vitamin K may require additional oral doses of vitamin K.

Babies receiving formula feeding and having received the 2 oral doses of vitamin K may not require additional doses of vitamin K because it is present in formula feeding.

Oral dispensers are available in the package for oral administration. After breaking the ampule, the dispenser should be placed vertically in the ampule, and 0.2 ml of solution should be drawn into the dispenser until it reaches the mark on the dispenser (0.2 ml = 2 mg vitamin K). Administer the contents of the dispenser directly into the baby's mouth by depressing the plunger.

At the time of administration, the ampule solution should be clear. Improper storage can cause the contents of the ampule to become cloudy or separate into different layers. If this is the case, the ampules should not be used.

**Has your child been administered too much of this medicine?**Jaundice (yellowing of the skin and/or eyes), abdominal pain, constipation, loose stools, a sense of discomfort in the child, restlessness, skin rash, and changes in liver function (observed in blood tests) have been reported in connection with overdosing of Konakion. The majority of side effects were not serious and resolved without treatment.

If you think your child has been given too much Konakion, please contact your doctor, midwife, or nurse.

**If your child stops using this medicine**The duration of treatment with Konakion MM for children depends on various factors, such as whether or not breastfeeding or premature birth is involved. It is advisable to follow the instructions of the doctor or midwife.

**Possible side effects**Like any medicine, this medicine can have side effects, although not everyone gets them.

• Hypersensitivity reactions can occur. If you notice any unusual effects, such as swelling in the face, skin rash, or difficulty breathing, please inform your doctor immediately.

• Irritation at the injection site may occur. Sometimes these reactions can be more severe, such as inflammation, tissue decrease, or tissue necrosis at the site.

**How to store this medicine?**

* Store below 25°C.
* Do not store in the freezer.
* Store in the original packaging to protect from light.
* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date stated on the label and box. The expiry date is stated as a month and a year. The last day of that month is the expiry date.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines you no longer need. They will be disposed of in a responsible manner and will not harm the environment.