

## Vitamin K administration for newborns

The purpose of this leaflet is to provide information about the properties, importance, methods of administration, side effects and the risks of not administering vitamin K for newborns.

Vitamin K is a fat-soluble anti-bleeding compound that is essential for the body and is involved in the blood clotting process. Vitamin K has two forms: vitamer K<sub>1</sub> or phyloquinone and vitamer K<sub>2</sub> or menaquinone. The synthesis of clotting factors in the liver is initiated by phyloquinone.

The synthetic form of Vitamer K<sub>1</sub> is phytomenadione. Phytomenadione is a clear, yellow, viscous and almost odourless oil.

In Estonia, phytomenadione 2 mg/0.2 ml is used to prevent and treat bleeding in newborns and infants. It is used both as a solution for injection and orally. In addition to phytomenadione, the drug preparation contains the following excipients: glycocholic acid, lecithin, sodium hydroxide, hydrochloric acid and water.

**As of 2012, the World Health Organization recommends that all newborns should receive vitamin K<sub>1</sub> as an intramuscular injection within the first 6 hours of life.**

Phytomenadione is injected into the muscle once at a dose of 1 mg. With intramuscular administration, the bioavailability of phytomenadione is approximately 50% and the effect occurs within one to three hours. Phytomenadione is stored in the muscle and is gradually released over the course of a month. After breakdown, phytomenadione is excreted from the body through bile and urine.

With oral administration, the drug's entry into the bloodstream is individual and its effect occurs within 6–10 hours. When administered orally, phytomenadione is absorbed in the middle part of the small intestine. Absorption is possible only in the presence of bile and pancreatic secretion. Factors such as short bowel syndrome, small intestine conditions, absorption disorders, biliary atresia and pancreatic secretion problems can hinder absorption.

For oral administration, repeated doses of the drug are necessary:

- 2 mg in the first hours of life
- 2 mg on the 7th day of life
- 2 mg at one month of age
- 2 mg once a month until complementary feeding (usually until 6 months of age)

A repeat dose is required if the child spits out the medication or experiences vomiting/diarrhoea within 24 hours of administration.

Like other medications, phytomenadione may cause side effects. According to the drug information leaflet approved in January 2019, most infants have not experienced side effects. In very rare cases, rash may occur as a skin reaction. Rarely, an injection site reaction may occur, which can be severe and cause skin scarring. Anaphylactic reactions may occur extremely rarely. If any side effect becomes severe or if you notice any side effect not mentioned, please inform your doctor.

### **Haemorrhage caused by vitamin K deficiency**

Bleeding caused by a vitamin K deficiency or an immature coagulation system is called vitamin K deficiency bleeding (VKDB).

The amount of vitamin K crossing the placental barrier is insufficient to prevent haemorrhagic disease. Most vitamin K is absorbed from the intestines. Newborns have a sterile intestine, preventing the absorption of K<sub>1</sub>; therefore, newborns have a vitamin K deficiency. Breast milk contains a small amount of vitamin K and exclusive breastfeeding is not sufficient to provide the necessary amount of vitamin K.

- **Early VKDB** occurs in the first few days of life in infants who have not received vitamin K prophylaxis and whose mothers have used vitamin K metabolism-affecting medications (such as warfarin).
- **Classical VKDB** typically occurs in the first week of life in infants who are born in a disturbed condition or experience feeding difficulties.

**Risk factors** for early and classical VKDB include premature delivery, oxygen deprivation, delayed oral feeding, maternal use of blood thinners, antiepileptic drugs and antibiotics.

Due to VKDB, the child may experience gastrointestinal bleeding, less commonly cerebral haemorrhage.

- **Late VKDB** typically occurs between the fourth and eighth week of life. In particular, breastfed babies who have not received vitamin K prophylaxis are at risk.

**Risk factors** for late VKDB include impaired liver function in the child, jaundice due to bile duct obstruction, impaired bile absorption and prolonged use of antibiotics by the child.

VKDB can lead to cerebral haemorrhage (intracranial bleeding), preceded by bruises on the skin, gastrointestinal bleeding and impaired blood clotting.

### **Symptoms of VKDB include the following:**

- bleeding from the navel or nose
- skin turning white or bruising when the baby is touched lightly
- yellowing of the whites of the eyes after three weeks of life
- blood in stool or black stool
- restlessness or extreme lethargy, constant sleepiness

In Estonia, approximately 14,000 babies are born each year. Vitamin K administration in Estonia can prevent severe illness in up to three infants, including later severe disability or death. Therefore, according to paediatricians, it is considered crucial to carry out VKDB prevention in all infants.

Approved by the decision of the Care Quality Commission of East Tallinn Central Hospital on 10.01.2024 (protocol no. 1-24)