K-one® MM

Phytomenadione

Active Ingredient
Phytomenadione.

Indication
• Prophylaxis & treatment of haemorrhagic disease in the newborn.
• Haemorrhage or risk of haemorrhage as a result of severe hypoprothrombinemia" (i.e. deficiency of clotting factors II, VII, IX & X) of various etiologies, including over dosage of courmarin-type anticoagulants, their combination with phenylbutazone, & other forms of hypovitaminosis K (e.g. in obstructive jaundice as well as liver & intestinal disorders, & after prolonged treatment with antibiotics, sulphonamides or salicylates).
• Prevention & treatment of bleeding due to vitamin K deficiency.

Dosage & Administration
Prophylaxis: Mild Hemorrhage or hemorrhagic tendency: The usual dose for neonates is 2 mg orally at or just after birth. Then 2 mg on 4th - 5th day & another 2 mg on 28th - 30th day orally. If the oral route is unsuitable then 2 mg of drug can be administered by IM or IV route. Children over 1 year of age are could be given 5-10 mg orally. A single 1 mg (0.1ml) dose IM is recommended in children who are not assured of receiving a second oral dose or, in the case of breast-fed children, who are not assured of receiving a third oral dose.
To ensure a total protection of the newborns, 3 prophylactic doses of Vitamin K should be administered orally following the dosing schedule mentioned above.

Therapy: Initially, 1 mg by intravenous injection, with further doses as required, based on the clinical picture & coagulation status.
Neonates with special risk factors (Pre-maturity, birth asphyxia (inadequate intake of oxygen by the baby during birth process), obstructive jaundice, inability to swallow, maternal use of anticoagulants or anti-epileptics]: 1 mg intramuscularly or intravenously at birth or shortly after birth if the oral route is unsuitable.

Intramuscular & intravenous doses should not exceed 0.4 mg/kg in premature infants weighing less than 2.5 kg. The size & frequency of further doses should be based on coagulation status.

Side Effect
There are isolated unconfirmed reports on the possible occurrence of anaphylactoid reactions & venous irritation or phlebitis after parenteral use of Phytomenadione injections.

Precaution & Contraindication
Careful monitoring of the coagulation parameters is necessary for patients with severely impaired liver function after administration of Phytomenadione. It is contraindicated in patients with known hypersensitivity to any of its constituents.

Use in Pregnancy & Lactation
Though Vitamin K1 does not readily cross the placental barrier & only a small fraction of administered Vitamin K1 enters into the breast milk, it is not recommended for Phytomenadione to be given to expectant mothers as prophylaxis of hemorrhagic disease in the newborn. Vitamin K1 should be given to pregnant women only if the benefit to the mother outweighs the risk to the fetus.

Preparation
Phytomenadione 2 mg / 0.2 ml Oral / IM / IV

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH