Inj. K MM™

Phytomenadione

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Presentation

Inj. K MM™ : Each ampoule contains 10 mg of Phytomenadione BP in 1 ml of clear solution.

Inj. K MM™ Pediatric: Each ampoule contains 2 mg of Phytomenadione BP in 0.2 ml of clear solution.

Description

Vitamin K_1 (Phytomenadione) is a procoagulant factor. As a component of a hepatic carboxylase system, Vitamin K_1 is involved in the post-translational carboxylation of clotting factors II (Prothrombin), VII, IX and X and the clotting inhibitors protein C and protein S. Coumarins inhibit the reduction of Vitamin K_1 (quinone form) to Vitamin K_1 (hydroquinone) and also prevent the Vitamin K_1 epoxide arising after carboxylation from being reduced to the quinone form.

Vitamin K_1 is an antagonist of coumarin-type anticoagulants, e.g. Phenprocoumon. It does not, however, neutralise the activity of Heparin; Protamine is the antagonist of Heparin.

Vitamin K_1 is ineffective in hereditary hypoprothrombinemia or hypoprothrombinemia induced by severe hepatic failure.

Lack of Vitamin K_1 leads to an increased tendency to haemorrhagic disease in the newborn. Vitamin K_1 administration, which promotes synthesis of the above-mentioned coagulation factors by the liver, can reverse an abnormal coagulation status and bleeding due to vitamin K_1 deficiency.

Indications and uses

Haemorrhage or risk of haemorrhage as a result of severe 'hypoprothrombinemia' (i.e. deficiency of clotting factors II, VII, IX and X) of various etiologies, including overdosage of courmarin-type anticoagulants, their combination with Phenylbutazone, and other forms of hypovitaminosis K (e.g. in obstructive jaundice as well as liver and intestinal disorders, and after prolonged treatment with antibiotics, sulphonamides or salicylates).

Prophylaxis and treatment of haemorrhagic disease in the newborn.

Dosage and Administration

Adults

Standard dosage

Severe haemorrhage e.g: during anticoagulant therapy.

The anticoagulant should be withdrawn and an IV injection of Inj K MM given slowly (in at least 30 seconds) in a dose of 10-20 mg (1-2, 10 mg ampoules). The Prothrombin level should be estimated three hours later and if the response has been inadequate, the dose should be repeated. Not more than 50 mg of Inj K MM should be given IV in 24 hours. Inj. K MM therapy should be accompanied, when necessary i.e. in life-threatening situations, by a more immediately effective treatment such as transfusions of whole blood or blood-clotting factors.

Neonates with special risk factors (e.g. prematurity, birth asphyxia, obstructive jaundice, inability to swallow, maternal use of anticoagulants or antiepileptics):

- 1 mg intramuscularly or intravenously at birth or shortly after birth if the oral route is unsuitable.
- Intramuscular and intravenous doses should not exceed 0.4 mg/kg (equivalent to 0.04 ml/kg) in premature infants weighing less than 2.5 kg (see Precautions).

The size and frequency of further doses should be based on coagulation status.

Side-effects

There are isolated unconfirmed reports on the possible occurrence of anaphylactoid reactions after parenteral use of Phytomenadione mixed-micelle solutions.

Very rarely, venous irritation or phlebitis has been reported in association with parenteral administration of Phytomenadione.

Precautions

At the time of use, the mixed micelle ampoule solutions must be clear. Following incorrect storage, the solution may become turbid or a phase separation may occur. In such cases, the ampoule must not be used.

When patients with severely impaired liver function are treated, the formation of prothrombin may be impaired. Therefore, careful monitoring of the coagulation parameters is necessary after administration of Inj. K MM.

In potentially fatal and severe haemorrhage due to overdosage of coumarin anticoagulants, IV injections of Inj. K MM should be accompanied by a more immediately effective treatment, such as transfusions of whole blood or blood-clotting factors. When patients with prosthetic heart valves are given transfusions for the treatment of severe or potentially fatal haemorrhages, fresh frozen plasma should be used.

Large doses of Inj. K should be avoided if it is intended to continue with anticoagulant therapy.

Parenteral administration may be associated with an increased risk of kernicterus in premature infants weighing less than 2.5 kg.

Use in Pregnancy and Lactation

Pregnancy: No controlled studies of Phytomenadione have been performed in animals or pregnant women. On the basis of many years' clinical experience, however, it is safe to assume that neither Vitamin K_1 nor the excipients contained in the Phytomenadione formulations have any reproductive toxicological effects when the medicine is given at the recommended dosages. As with all medications, however, Phytomenadione should be given to pregnant women only if the benefit to the mother outweighs the risk to the fetus.

As Vitamin K_1 does not readily cross the placental barrier, it is not recommended that Phytomenadione be given to expectant mothers as prophylaxis of haemorrhagic disease in the newborn.

Lactation: Only a small fraction of administered Vitamin K_1 enters the breast milk. At therapeutic doses, administration of Phytomenadione to nursing mothers accordingly does not pose a risk to their infants. However, Phytomenadione is not recommended for nursing mothers as prophylaxis of haemorrhagic disease in the newborn.

Use in elderly

Elderly patients tend to be more sensitive to reversal of anticoagulation with Inj. K MM. The dosage for this patient group should therefore be at the lower end of the ranges recommended.

Contraindication

Inj. K MM is contraindicated in patients with known hypersensitivity to any of its constituents.

Inj. K MM 10mg/ml ampoules should not be administered intramuscularly because the IM route exhibits depot characteristics and continued release of Vitamin K_1 would lead to difficulties with the re-institution of anticoagulation therapy. Furthermore, IM injections given to anticoagulated subjects cause a risk of haematoma formation.

Drug Interactions

Vitamin K_1 antagonises the effect of coumarin-type anticoagulants.

Coadministration of anticonvulsants can impair the action of Vitamin K_1.

Overdosage

No overdose effects are known

Commercial Pack

Inj. K MM™ : Each box contains 5 ampoules of 10 mg/ml Phytomenadione BP.

Inj. K MM™ Pediatric: Each box contains 10 ampoules of 2 mg/0.2 ml Phytomenadione BP.

Manufactured by
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