MENADIONE SODIUM
BISULFITE

MEDIONE
10 mg Tablet
ANTIHEMORRHAGIC

℞

PRODUCT DESCRIPTION:
Menadione Sodium Bisulfite 10 mg tablet is a coated, yellow, round flat tablet bisected on one side, size 5 mm.

FORMULATION:
Each tablet contains:
Menadione Sodium Bisulfite, USP..... 10 mg

PHARMACODYNAMICS AND PHARMACOKINETICS:
The fat-soluble vitamin K compound phytomenadione and menadione require the presence of bile for their absorption from the gastrointestinal tract; the water-soluble derivatives can be absorbed in the absence of bile. Vitamin K accumulates mainly in the liver but it is stored in the body only for short periods of time. Vitamin K does not appear to cross the placenta readily and it is variably distributed into breast milk. Phytomenadione is readily metabolised to more polar metabolites and is excreted in bile and urine as glucuronide and sulfate conjugates.

INDICATIONS:
For the prevention and cure of minor to severe hemorrhage disorders menorrhagia and preoperative precautions.

DOSAGE AND MODE / ROUTE OF ADMINISTRATION:
1 tablet 3 to 4 times a day or as prescribed by the physician.

PRECAUTION:
Phytomenadione formulations solubilised with lecithin and bile salt should be given with caution to patients with severely impaired liver function and to premature neonates weighing less than 2.5 kg, since the bile may displace bilirubin.

PREGNANCY AND LACTATION:
Giving Menadione and menadiol sodium phosphate to neonates, especially to premature infants or to mother during late pregnancy has been associated with the development in the infant haemolytic anemia, hyperbilirubinaemia and kernicterus, and such is not recommended. Phytomenadione has a lower risk of haemolysis. Menadione and Menadiol sodium phosphate have also been reported to cause haemolysis in patients with G6PD deficiency or Vitamin C deficiency. Vitamin K is variably distributed into breast milk: a study found phytomenadione concentrations in the first 10 mL of expressed milk ("fore milk") to be lower than those in the last 10 mL (hind milk). Lipid composition also changes over the course of lactation, with pronounced changes in the first week, and the authors proposed that a mechanism exist whereby Vitamin K concentration in milk is higher in the first few days of life so as to meet the neonate's nutritional requirements at a time when Vitamin K status is prenutritional requirements at a time when Vitamin K is precarious.

INTERACTION:
Vitamin K decreases the effects of oral anticoagulant and is used to counteract excessive effects of these drugs, see uses and administration below. Vitamin K may reduce the response to resumed therapy with anticoagulants for a week or more.

ADVERSE DRUG REACTIONS:
Intravenous dose of phytomenadione have caused severe reactions resembling hypersensitivity or anaphylaxis. Symptoms have included facial flushing, chest constriction and chest pain, dyspnea, cyanosis and cardiovascular collapse, fatalities have been reported. Anaphylactic reactions have generally been associated with an overly rapid rate of infusion but also have been reported even when the solution was diluted and infused slowly. They are generally thought to be due to polyoxyl castor oil which is present as a surfactant is some parenteral formulations: reports of such reactions with formulations that do not contain polyoxyl castor oil are rare. Pain swelling and phlebitis may occur at the injection site when phytomenadione is given. Localised skin reactions including atrophy or necrosis have been reported after intramuscular or subcutaneous injection of phytomenadione.

OVERDOSE AND TREATMENT:
There is no known clinical syndrome attributable of hypervitaminosis of phytomenadione, adverse effects have been reported after overdose in neonates and infants. These include jaundice, hyperbilirubinaemia, increase liver enzymes values, abdominal pain, constipation, soft stools, malaise, agitation, and skin eruptions. Most adverse effects were not considered to be serious, resolved without any treatment.

AVAILABILITY:
Packed in Red PVC by 20's box of 100 in one individual box carton with DMLI seal sticker.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Manufactured by:
DRUGMAKER'S LABORATORIES, INC.
E & E Industrial Complex,
Brgy. San Antonio, San Pedro, Laguna

Distributed by:
DRUGMAKER'S LABORATORIES, INC.
Unit C, G/F Rizalina 2 Bldg, 1675 Quezon Ave.,
West Triangle, D1, Quezon City, Metro Manila

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Registration Number: DRP-5539-01

Date of First Authorization / Renewal of the Authorization: October 19, 2015 / August 28, 2019

Date of Revision of Package Insert: May 2019