VITAMIN K TABLETS

1. Name of Drug Product

VITAMIN K TABLETS

(Trade) Name of Product

VITAMIN K TABLETS

Strength

Each Uncoated Tablets contains:
Menadione Sodium Bisulphite

Equivalent to Menadione .....10 mg

Excipient .....Q.S.

Pharmaceutical Dosage Form

Tablets for Oral Administration

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Qualitative Declaration

Each Uncoated Tablets contains:
Menadione Sodium Bisulphite

Equivalent to Menadione .....10 mg

Excipient .....Q.S.

3. PHARMACEUTICAL DOSAGE FORM

Tablets for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of haemorrhage or threatened haemorrhage associated with a low blood level of prothrombin or factor vii. The main indication is obstructive jaundice (before and after surgery).

4.2 Posology and Method of Administration

Menadione Sodium Bisulphite 10mg Tablets are for oral administration.

Adults

Usual therapeutic dose: 10-40mg daily

Children

If, on the recommendation of a physician, a children's dosage is required, it is suggested that 5-20mg daily be given.

The elderly

Recommendations for use in the elderly do not differ from those for other adults.

4.3 Contraindications

Administration to neonates, infants or to mothers in the pre- and post-natal periods. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special Warnings and Precautions for Use

None.

4.5 Interaction with Other Drugs, Other Forms of Interactions

Large doses of Menadione Sodium Bisulphite may decrease patient sensitivity to anticoagulants.

4.6 Fertility, pregnancy and lactation

There is evidence of hazard if Menadione Sodium Bisulphite is used in human pregnancy. It is known to be associated with a small risk of haemolytic anaemia, hyperbilirubinaemia and kernicterus in the infant if administered to the mother in late pregnancy or during labour. Menadione Sodium Bisulphite is therefore contra-indicated during late pregnancy.

4.7 Effects on ability to drive and operate machine

None known.

4.8 Undesirable effects

Menadione Sodium Bisulphite may induce haemolysis (especially in the newborn infant) in the presence of erythrocyte glucose-6-phosphate dehydrogenase deficiency or low concentrations of alpha-tocopherol in the blood.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdoses

No information is available.

5. Pharmacological properties

5.1 Pharmacodynemic property

Menadione Sodium Bisulphite is a water-soluble vitamin K analogue. The presence of vitamin K is essential for the formation within the body of prothrombin, factor VII, factor IX and factor X. Lack of vitamin K leads to increased tendency to haemorrhage.

5.2 Pharmacokinetic properties

Menadione is absorbed from the gastro-intestinal tract without being dependent upon the presence of bile salts. Vitamin K is rapidly metabolised and excreted by the body.

5.3 Pre-clinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch
Talcum
Sodium Metabisulphite
Sod. Methyl Paraben
Sod. Propyl Paraben
Gelatin
Purified Water
Magnesium Stearate
Aerosil
Sodium Metabisulphite

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

24 months from the date of manufacture.

6.3 Special Precautions for Storage

Do not store above 25°C. Blister: Store in the original package in order to protect from moisture.

6.4 Nature and Contents of Container

100 tablets packed in 1 container, Such 20 container Packed in 1 Carton. Such 36 Carton in 1 Shipper.

6.5 Special precaution for disposal and other handling

No special requirements

7. Applicant Information

TOPSEA STANDARD PHARMACEUTICAL COMPANY LTD.
No. 12 Ekwueme Street, Iyiowa, Odekpe, Ogbaru LGA,
Anambra State, Nigeria.

Manufacturer

MANCARE PHARMACEUTICAL PVT. LTD.
Plot No. 59, 60, 85 & 86, V.M.I.E., Dowali Village,
Vasa (W), District Thane, Maharashtra, India.

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