

Femotol™ 30

Iron (Ferric) 30 mg as Ferric Maltol

Composition

Femotol™ Capsules: Each capsule contains Ferric Maltol INN equivalent to Iron 30 mg.

Pharmacology

Ferric Maltol delivers iron for uptake across the intestinal wall and transfers to transferrin and ferritin. It has been shown to increase serum iron parameters, including ferritin and transferrin saturation. Ferric Maltol dissociates upon uptake from the Gastrointestinal Tract allowing iron and maltol to be absorbed separately. The iron is absorbed across the intestinal wall and transfer to transferrin and ferritin. It increases serum iron parameters, including ferritin and transferrin saturation. Total serum iron peak values were reached 1.5 to 3 hours after administration. Food has been shown to decrease the bioavailability of iron after administration of ferric maltol. Around 60% of ferric maltol is excreted in the urine as glucuronide conjugate. Iron and ferric maltol are not excreted in the urine and unabsorbed ferric maltol is eliminated in the feces.

Indication

Femotol™ is an iron replacement product indicated for the treatment of iron deficiency in adults.

Dosage and Administration

The recommended dosage of **Femotol™** is 30 mg twice daily. It should be taken with half glass of water on an empty stomach. It can be taken 1 hour before or 2 hours after a meal. Do not open, break, or chew Femotol™ capsules. Treatment duration will depend on the severity of iron deficiency but generally at least 12 weeks of treatment is required. The treatment should be continued as long as necessary until ferritin levels are within the normal range. Or as directed by the physician.

Contraindication

Femotol™ is contraindicated in patients with a history of:

- Hypersensitivity to the active substance or to any of the excipients.
- Hemochromatosis and other iron overload syndromes Use may result in iron overdose
- Receiving repeated blood transfusions. Use may result in iron overload

Warning and Precaution

Increased Risk of Inflammatory Bowel Disease ((BD) Flare, Iron Overload, Risk of Overdosage in Children Due to Accidental Ingestion

Side effects

Common side effects: Flatulence, diarrhea, constipation, and feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension.

Rare side effects: Headache, small intestinal bacterial overgrowth, acne, erythema etc.

Use in Pregnancy and Lactation

Pregnancy: Ferric Maltol is not absorbed systemically as an intact complex following oral administration and maternal use is not expected to result in fetal exposure to the drug.

Lactation: There are no data on the presence of Ferric Maltol in human milk, the effects on the breastfed child the effects on milk production.

Use in Children & Adolescents

Safety and effectiveness of Ferric Maltol in children & adolescents (17 years & under) has not yet been established.

Drug Interactions

With medicine: Avoid concomitant use of Ferric Maltol with dimercaprol.

With food & others: Food has been shown to decrease the bioavailability of iron.

Overdose

No data are available regarding overdose of Ferric Maltol in patients. Acute iron ingestion of 20 mg/kg elemental iron is potentially toxic and 200- 250 mg/kg is potentially fatal.

Storage Condition

Store below 30° C. Keep all medicines out of reach of children.

How Supplied: **Femotol™** Capsule: Each box contains 10X6 Capsule in blister pack.

Manufactured by-



SQUARE
PHARMACEUTICALS PLC.

Salgaria, Pabna, Bangladesh

TM - Trade Mark

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