Ferromax®

Ferric Maltol INN

Composition

Ferromax® capsule: Each capsule contains Ferric Maltol INN 231.50 mg equivalent to 30 mg Iron.

Pharmacology

Ferromax® delivers iron for uptake across the intestinal wall and transfer to transferrin and ferritin. It has been shown to increase serum iron parameters, including ferritin and transferrin saturation (TSAT).

Indication

Ferromax® is indicated for the treatment of iron deficiency in adults.

Dose and administration

Route of administration: **Ferromax®** capsule should be taken in oral route, preferably on an empty stomach, at least 1 hour before or 2 hours after meals. Do not open, break or chew **Ferromax®** capsule.

The recommended dosage of **Ferromax®** is 30 mg twice daily. 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.

Contraindication

Ferric maltol is contraindicated in patients with known hypersensitivity to ferric maltol or any other components of this product. It is also contraindicated in patients with a history of hemochromatosis and other iron overload syndromes and in patients receiving repeated blood transfusions.

Warning and precaution

Avoid use of ferric maltol in patients with an active inflammatory bowel disease (IBD) flare, as there is potential risk of increased inflammation in the gastrointestinal tract. Do not administer to patients with evidence of iron overload or patients receiving intravenous iron. Assess iron parameters prior to initiating ferric maltol and monitor iron parameters while on therapy. Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. In case of accidental overdose, patient should be treated immediately.

Side effects

The most common side effects are flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea and vomiting.

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 or the effects on milk production. Ferric maltol is not absorbed systemically as an intact complex by the mother following oral administration and breastfeeding is not expected to result in exposure of the child to ferric maltol.

Use in children and adolescents

Safety and effectiveness of ferric maltol have not been established in pediatric patients.

Drug interaction

Drug interaction with medication: Concomitant use of iron products with dimercaprol may increase the risk of nephrotoxicity. Avoid concomitant use of ferric maltol with dimercaprol. Concomitant use of ferric maltol may decrease the bioavailability of some drugs, including mycophenolate, ethynyl estradiol, ciprofloxacin and doxycycline. For oral drugs where reductions in bioavailability may cause clinically significant effects on its safety or efficacy, separate the administration of ferric maltol by at least 4 hours.

Drug interaction with food and others: Food has been shown to decrease the bioavailability of iron after administration of ferric maltol.

Overdose

No data is available regarding overdose of ferric maltol in patients. Early signs and symptoms of iron overdose may include nausea, vomiting, abdominal pain and diarrhea. In more serious cases there may be evidence of hypoperfusion, metabolic acidosis and systemic toxicity. Dosages of ferric maltol in excess of iron needs may lead to accumulation of iron in storage sites leading to hemosiderosis.

Storage

Store in a cool (below 25°C) and dry place protected from light. Keep away from the reach of children.

Packing

Ferromax® capsule: Each box contains 32 capsules in blister pack.

® Registered Trade Mark

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