165mm

155mm

Note: Product contains lactose.

Instructions:
- Store below 30˚C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

Dosage: As directed by the physician.

نوٹ : پروڈکٹ میں لیکٹوز شامل ہے۔
خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات : دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے
بچا کر خشک جگہ پر رکھیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Kaizen
Pharmaceuticals (Pvt.) Ltd.

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Ferinza

(Ferric Maltol)

30mg Capsule

فیرنزا

(فیرک مالٹول)

۳۰ ملی گرام کیپسولز

Composition:
Each capsule contains:
Iron (as Ferric Maltol) 30mg

CLINICAL PHARMACOLOGY
Mechanism of Action:
Ferric maltol contains iron in a stable ferric state as a complex with a trimaltol ligand. The complex is designed to provide, in a controlled way, utilizable iron for uptake across the intestinal wall and transfer to the iron transport and storage proteins in the body (transferrin and ferritin, respectively). The complex dissociates on uptake from the gastro-intestinal tract and the complex itself does not enter the systemic circulation.

Pharmacodynamics:
Ferric maltol has been shown to increase serum iron parameters, including ferritin and transferrin saturation (TSAT) in adults and pediatric patients 10 years and older.

PHARMACOKINETICS
Absorption and Elimination
Ferric maltol is rapidly absorbed after oral administration. Maximum plasma concentrations of maltol and maltol glucuronide are reached within 1–1.5 hours. Maltol is rapidly metabolized to maltol glucuronide, mainly eliminated through urine. Maltol has a short half-life of approximately 0.7 hours, with no significant accumulation after 7 days of treatment. Serum iron levels and transferrin saturation peak within 1–3 hours after administration. Food, particularly a high-fat meal, reduces and delays iron absorption

INDICATIONS:
- Ferinza Capsule is indicated for the treatment of iron deficiency in adult and pediatric patients 10 years of age and older.

SPECIAL POPULATION
Pregnancy
A moderate amount of data on the oral use of ferric iron in pregnant women indicate no malformities nor feto/neonatal toxicity. Systemic exposure to the intact ferric maltol complex is negligible.
Ferinza may be considered during pregnancy if necessary.

Breastfeeding
No effects of oral ferric iron have been shown in breastfed newborns/infants of treated mothers. Ferric maltol is not available systemically and is therefore unlikely to pass into the mother's milk. Ferinza can be used during breast feeding if clinically needed.

Fertility
There are no data on the effect of ferric maltol on human fertility. No effects on fertility are anticipated since systemic exposure to ferric maltol is negligible.

DOSAGE & ADMINISTRATION

Adults and adolescents aged 12 years and older

The recommended dose is one capsule twice daily, morning and evening, on an empty stomach.

Treatment duration will depend on the severity of iron deficiency but generally at least 12-weeks treatment is required. It is recommended the treatment is continued as long as necessary to replenish the body's iron stores according to blood tests.

The elderly and patients with hepatic or renal impairment

No dose adjustment is needed in elderly patients or patients with renal impairment (eGFR ≥ 15 ml/min/1.73 m2). No clinical data on the need to adjust the dose in patients with impaired hepatic function and/or renal impairment (eGFR <15 ml/min/1.73 m2) are available.

Paediatric population

This medicinal product should not be used in children under 12 years of age, as the capsules do not allow appropriate dosing.

ROUTE OF ADMINISTRATION

For oral administration only.

METHOD OF ADMINISTRATION

The capsules should be taken whole on an empty stomach (with half a glass of water), as the absorption of iron is reduced when it is taken with food.

ADVERSE REACTIONS

The most **common** adverse reactions include:

- Abdominal pain
- Flatulence
- Constipation
- abdominal discomfort or distension
- diarrhea
- discolored faeces and nausea.

Uncommon

- Headache
- small intestinal bacterial overgrowth
- vomiting, acne, erythema
- joint stiffness, pain in the extremities
- thirst, and increased blood levels of alkaline phosphatase
- Increased thyroid-stimulating hormone (TSH) and Increased gamma-glutamyl transferase (GGT)

CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients.
- Haemochromatosis and other iron overload syndromes.
- Patients receiving repeated blood transfusions.

WARNINGS AND PRECAUTIONS

- Iron deficiency or iron deficiency anemia (IDA) diagnosis should be made based on blood tests; it is important to investigate the cause of the iron deficiency and to exclude underlying causes of anemia other than iron deficiency.
- Ferinza is not recommended for use in patients with inflammatory bowel disease (IBD) flare or in IBD patients with haemoglobin (Hb) <9.5 g/dl.
- Concomitant administration of ferric maltol with intravenous iron, dimercaprol, chloramphenicol or methyldopa is to be avoided.
- This medicinal product contains lactose: patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.
- This medicinal product also contains Allura Red AC (E129) and Sunset Yellow FCF (E110):

these may cause allergic reactions.

- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free

EFFECT OF OTHER DRUGS ON FERINZA

No interaction studies have been performed with ferric maltol. Based on an in vitro study maltol is glucuronides through UGT1A6.

Food has been shown to inhibit uptake of Fouracre: The treatment should be taken on an empty stomach.

Intravenous administration of iron salts:

Concomitant administration of Ferinza and intravenous iron may induce hypotension or even collapse due to the fast release of iron resulting from saturation of transferrin caused by intravenous iron.

Medicinal products that may impact absorption and distribution of iron from Ferinza:

Absorption of oral iron may be reduced by calcium and magnesium salts (such as magnesium trisilicate). Administration of iron preparations with such compounds should be separated by at least 2 hours.

Impact of Ferinza on absorption of other medicinal products :

Oral iron is known to reduce the absorption of penicillamine, bisphosphonates, ciprofloxacin, entacapone, levodopa, levofloxacin, levothyroxine (thyroxine), moxifloxacin, mycophenolate, norfloxacin and ofloxacin. These medicinal products should be given at least 2 hours apart from Ferinza.

Absorption of both iron and antibiotic may be reduced if oral iron is given with tetracycline. Administration of iron preparations and tetracyclines should be separated by 2 to 3 hours.

OVERDOSAGE

Iron overdose is dangerous and can be life-threatening in children, infants and toddlers requiring immediate attention.

Symptoms:

Early signs and symptoms include nausea, vomiting, abdominal pain and diarrhea. The vomit and stools may be grey or black. In mild cases early features improve but in more serious cases there may be evidence of hypoperfusion (cool peripheries and hypotension), metabolic acidosis and systemic toxicity. In serious cases there can be recurrence of vomiting and gastrointestinal bleeding, up to 12 hours after ingestion. Shock can result from hypovolemia or direct cardiotoxicity. Evidence of hepatocellular necrosis appears at this stage with jaundice, bleeding, hypoglycemia, encephalopathy and positive anion gap metabolic acidosis. Poor tissue perfusion may lead to renal failure. Rarely, gastric scarring causing stricture or pyloric stenosis (alone or in combination) may lead to partial or complete bowel obstruction 2-5 weeks after ingestion.

Ingestion of 20 mg/kg elemental iron is potentially toxic and 200-250 mg/kg is potentially fatal. No single method of assessment is entirely satisfactory - clinical features as well as laboratory analysis must be taken into account. Serum iron levels measured at about 4 hours after ingestion is the best laboratory measure of severity.

Treatment

Supportive and symptomatic measures reflecting best standard medical care should be implemented. The use of deferoxamine should be considered: for detailed information see product information provided by the manufacturer. Hemodialysis does not remove iron effectively but should be considered on a supportive basis for acute renal failure as this will facilitate removal of the iron- deferoxamine complex.

PRESENTATION

Ferinza 30 mg capsule is available in packs of 1x10's, 3x10's & 7x8's