Ferfix™

فرفكس

(Iron (III)-Hydroxide Polymaltose Complex)

50mg/5mL Syrup

DESCRIPTION

FERFIX (Iron (III)-hydroxide polymaltose complex) syrup is an iron preparation for the treatment of latent iron deficiency, manifest iron deficiency and the prevention of iron deficiency before, during and after pregnancy (during lactation).

Iron (III) hydroxide polymaltose complex (IPC) is a water soluble iron oxide, macromolecular complex of polynuclear iron (III) hydroxide and partially hydrolyzed dextrin (polymaltose). The complex is stable and does not release ionic iron under physiological conditions. The iron in the polynuclear "cores" is bound in a similar structure as in the case of physiologically occurring ferritin. Due to these chemical and pharmacological properties IPC is suitable for oral iron substitution.

The iron in FERFIX (Iron (III)-hydroxide polymaltose complex) syrup exists as iron (III) hydroxide complex where the individual particles are embedded into a carbohydrate polymer (polymaltose). This prevents iron from causing any harm in the gastrointestinal system. This protection also inhibits interactions of iron with food.

QUALITATIVE & QUANTITATIVE COMPOSITION

FERFIX (Iron (III)-hydroxide polymaltose complex) syrup is available for oral administration as:

FERFIX Syrup contains:
Each 5mL contains:
Iron (III) hydroxide polymaltose equivalent to elemental Iron...50mg.

CLINICAL PHARMACOLOGY

Iron is an essential constituent of the body, necessary for hemoglobin formation and for the oxidative processes of living tissues. The structure of IPC is similar to ferritin, the naturally occurring iron storage protein. Due to this similarity, iron is absorbed through natural mechanism. IPC has no pro-oxidative properties such as there are with bivalent iron salts. Transferrin, which circulates through the interstitial spaces in the liver, spleen and bone marrow and more slowly in the muscles and skin, is responsible not only for the transportation of incorporated iron but also for recycled iron from decomposed cells for its reuse in the body.

Incorporation in hemoglobin: In order to be bound to transferrin and ferritin, iron supplements must necessarily be in a Fe^{+3} level of oxidation. Iron is transported to the bone marrow as ferric ion (Fe^{+3}) bound to transferrin and is reduced to the ferrous form (Fe^{+2}) for its release in the erythroid progenitor cells and is finally transferred to the protoporphyrin for the synthesis of hemoglobin.

Pharmacokinetics

In iron (III) hydroxide complex, Iron absorption correlates with the plasma ferritin value. The quantity of iron absorbed is dependent on the iron deficiency in the individual to be treated, and on the iron dosage; i.e. the greater the iron deficit at equivalent therapeutic iron dosage, the higher the iron absorption. Iron which is not absorbed is excreted in the feces. As a result of elimination through the epithelial cells of the intestinal tract and the skin, as well as in the sweat, bile, and urine a total of only about 1mg of iron is secreted per day.

THERAPEUTIC INDICATIONS

FERFIX (Iron (III)-hydroxide polymaltose complex) syrup is indicated for:

- The treatment of latent iron deficiency.
- Manifest iron deficiency.
- Prophylactic therapy of iron deficiency before, during and after pregnancy (during lactation).

DOSAGE AND ADMINISTRATION

The dose and duration of treatment depend on the degree of iron deficiency. The daily dose divided into individual doses or can be administered as a single dose. FERFIX (Iron (III)-hydroxide polymaltose complex) syrup must be administered during or immediately after meals.

Age Group	Manifest Iron deficiency	Latent Iron deficiency	Prophylactic therapy
Infants (up to 1 year of age)	2.5-5mL/day (25-50mg Iron)	2.5-5mL/day (25-50mg Iron)	2.5-5mL/day (25-50mg Iron)
Children (1-12 years)	5-10 mL/day (50-100mg Iron)	2.5-5mL/day (25-50mg Iron)	2.5-5mL/day (25-50mg Iron)
Children (12 years or more), adults and nursing mothers	10-30mL/day (100-300mg Iron)	5-10mL/day (50-100mg Iron)	5-10mL/day (50-100mg Iron)
Pregnant women	20-30mL/day (200-300mg Iron)	10mLday (100mg Iron)	5-10mL/day (50-100mg Iron)

FERFIX (Iron (III)-hydroxide polymaltose complex) syrup can be mixed with fruit and vegetable juices or with bottle feed. The slight coloration does not affect either the taste or the efficacy. In case if immediate iron need (low Hb, concomitant EPO treatment etc.) parenteral iron preparations should be used for iron substitution so that the iron is more rapidly available.

CONTRAINDICATIONS

FERFIX (Iron (III)-hydroxide polymaltose complex) syrup is contraindicated in patients:

- Who show hypersensitivity to iron.
- Receiving repeated blood transfusions.
- With iron overload (e.g. hemochromatosis, hemosiderosis).
- Who have disturbances in iron utilization (e.g. thalassemia, sidero-achrestic anemia, lead anemia).
- Who have anemia not caused by iron deficiency (e.g. hemolytic anemia or megaloblastic anemia caused by vitamin B_{12} deficiency).

ADVERSE REACTIONS

The side effects reported are occasional gastrointestinal irritation such as sensation of repletion, epigastric pain, nausea, constipation and diarrhea. There may be a dark coloration or black stools which is of no clinical significance. It does not cause teeth staining.

PRECAUTIONS

In cases of anemia due to infections or malignancy, the substituted iron is stored in the reticulo-endithelial system, from

which it is mobilized and utilized only after curing the primary disease.

Pregnancy and Lactation

There is no evidence of risk during first trimester and a negative influence on the fetus is unlikely. Its administration is unlikely to cause undesirable effects to the nursed child.

During pregnancy and lactation FERFIX (Iron (III)-hydroxide polymaltose complex) syrup should be used only if clearly required after consultation with the physician.

DRUG INTERACTIONS

Until now interactions have not been observed. Since the iron is complex bound, ionic interactions with food components (phytin, oxalates, tannin etc.) and concomitant administration of drugs (tetracyclines, antacids) are unlikely to occur.

The haemoccult test (selective for Hb) for the detection of occult blood is not impaired and therefore there is no need to interrupt iron therapy.

OVERDOSAGE

In case of overdosage, initially epigastric pain, diarrhea and vomiting can occur and may include metabolic acidosis, convulsions and coma after apparent recovery. Initially an emetic should be given and then gastric lavage and general supportive measures should be employed.

STORAGE

Store below 25°C.

Protect from sunlight and moisture.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

FERFIX (Iron (III)-hydroxide polymaltose complex) 50mg/5mL syrup is available in a pack size of 60mL and 120mL.

Keep out of the reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:
Opal Laboratories (Pvt.) Ltd.,
LC-41, L.I.T.E., Landhi,
Karachi-Pakistan.
For:

Getz pharma (PVT) LIMITED
www.getzpharma.com
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