Fersip Syrup*

فرسِپ سیرپ

COMPOSITION:

Each 5 ml contains:

Iron III Hydroxide Polymaltose Complex eq.
To Elemental Iron*..... 50 mg

DESCRIPTION

The Iron (III) Hydroxide Polymaltose Complex (IPC) is a water-soluble iron oxide, macromolecular complex of polynuclear iron (III) hydroxide and partially hydrolysed dextrin (polymaltose). The polynuclear iron (III) hydroxide cores are superficially surrounded by a number of non-covalently bound polymaltose molecules resulting in an overall complex molecular mass of approximately 52,300 Daltons.

CLINICAL PHARMACOLOGY

FERSIP is an iron preparation for the treatment of latent iron deficiency & iron deficiency anemia. Iron is an important constituent of haemoglobin, myoglobin, and the enzymes which contain iron. Iron deficiency can cause chronic fatigue, lack of concentration, irritability, nervousness, headache, loss of appetite, susceptibility to stress and infection, paleness, cracks at the corners of the mouth (rhagades), dry skin, brittle hair and nails as well as loss of interest in play in children.

In FERSIP, the polynuclear iron(III)-hydroxide core is superficially surrounded by a number of non-covalently bound polymaltose molecules resulting in an overall average molecular weight which is so large that the extent of diffusion through the membrane of the mucosa is about 40 times less than that of the hexaquo-iron (II) complex. Iron polymaltose is stable and does not release large amounts of iron under physiological conditions. The polynuclear core of iron polymaltose is hypothesized to have a structure similar to that of the core of the physiological iron storage protein, ferritin. Due to this similarity, iron is absorbed through natural mechanism. IPC has no pro-oxidative properties such as there are with bivalent iron salts. Due to these chemical and pharmacological properties IPC is suitable for oral iron substitution.

Pharmacokinetic Properties:

The iron absorbed from iron polymaltose is used in the bone marrow for haemoglobin (Hb) synthesis or is stored, mainly in the liver, bound to ferritin. Iron that is not absorbed is excreted via the faeces. The iron of FERSIP is absorbed by a controlled mechanism. There is a good correlation between the percentage of erythrocyte uptake (incorporation in Hb) and the absorption quantified by whole body count. The highest absorption of iron from iron polymaltose is in the duodenum and ileum. Administering FERSIP with food in iron deficient subjects increases iron uptake into erythrocytes.

INDICATIONS AND USAGE

Treatment of latent iron deficiency and iron deficiency anemia (manifest iron deficiency). Prophylactic therapy of iron deficiency during pregnancy.

CONTRAINDICATIONS

Known hypersensitivity to iron polymaltose or to any of the excipients, iron overload (e.g. heamochromatosis, haemosiderosis) or disturbance in iron utilization (e.g. lead anaemia, sidero-achrestic anaemia, thalassaemia) and anaemias not caused by iron deficiency (e.g. haemolytic anaemia).

ADVERSE REACTIONS

Treatment-emergent adverse reactions reported by patients treated with iron polymaltose during clinical trials are listed in the Table 1.

System Organ Class	Adverse Drug Reactions
Gastrointestinal Disorders	
Very Common (≥1/10)	Discoloured faeces*
Common (≥1/100, <1/10)	Diarrhoea, Nausea, Dyspepsia
Uncommon (≥1/1000, <1/100)	Vomiting, Constipation, Abdominal pain, Tooth discoloration**
Skin and Subcutaneous Tissue Disorders	
Uncommon (≥1/1000, <1/100)	Rash, Pruritus
Nervous System Disorder	
Uncommon (≥1/1000, <1/100)	Headache

*Discoloured faeces were very commonly reported as an adverse event (23% of patients) and are a well-known ADR of oral iron medications.

**Tooth Discoloration was reported as an adverse event in 0.6% of the patients and is a known ADR of oral iron medications.

No additional adverse drug reactions were identified.

Laboratory abnormalities:

No data available.

DRUG INTERACTIONS

Concomitant administration of parenteral iron and FERSIP is not

recommended since the absorption of oral iron would be inhibited. Until now interactions have not been observed. Since the iron is complex-bound, ionic interaction with food components such as phytins, oxalates, tannin etc and concomitant administration of medicaments (tetracyclines, antacids) are unlikely to occour. FERSIP can be taken during or immediately after food intake.

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

USE IN SPECIFIC POPULATION

Use in pregnancy (Category A) & lactation:

Pregnanacy Category A: Reproduction studies in animals did not show any foetal risk. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects on mother and neonates. There is no evidence of a risk during the first trimester and a negative influence on foetus is unlikely. The administration of FERSIP is unlikely to cause undesirable effects to the nursed child.

During pregnancy and lactation, FERSIP should only be used after consulting a medical practitioner.

Paediatric use:

Iron polymaltose (FERSIP) has not been clearly shown to be effective in children < 12 years of age. The use of FERSIP in children < 12 years of age is not recommended.

Geriatric use:

Clinical experience with iron polymaltose (FERSIP) in the elderly is limited. For use in elderly patients consult a medical practitioner.

WARNINGS AND PRECAUTIONS

All other causes of anaemia should be considered and treated prior to initiating therapy with FERSIP.

Regular monitoring of the haematologic response i.e. Hb levels and serum ferritin levels, is required during FERSIP therapy as a risk of iron overload and liver damage exists if too much FERSIP is ingested by haemachromatosis patients over a long period of time. Do not administer to patients with iron overload or haemochromatosis. Infections or tumor may cause anaemia. Since iron can be utilised only after correcting the primary disease, a benefit/risk evaluation is advisable.

DOSAGE AND ADMINISTRATION

Dosage and duration of therapy are dependent upon the extent of iron deficiency.

Manifest iron deficiency:

In cases of manifested iron deficiency, the therapy takes about 3-5 months until a normalisation of the haemoglobin. Afterwards the therapy should be continued for several weeks or for pregnant women, at least until the end of the pregnancy with a dosage such as described for latent iron deficiency to replenish the iron stores.

Latent iron deficiency:

The therapy takes about 1-2 months.

	Manifest iron deficiency	Latent iron deficiency	Prophylactic therapy
Infants (up to 1 Year)	2.5 – 5 ml daily (20 – 50 mg iron)	——	——
Children (1 – 12 Years)	5 – 10 ml daily (50 – 100 mg iron)	2.5 – 5 ml daily (20 – 50 mg iron)	——
Children (>12 Years), Adults & Nursing Women	10 – 30 ml daily (100 – 300 mg iron)	5 – 10 ml daily (50 – 100 mg iron)	——
Pregnant Women	20 – 30 ml daily (200 – 300 mg iron)	10 ml daily (100 mg iron)	5 – 10 ml daily (50 – 100 mg iron)

The daily dose can be devided into separate doses or can be taken at one time. FERSIP syrup should be taken during or immediately after a meal. FERSIP syrup can be mixed with fruit & vegetable juices or with bottle feed. The slight colouration does not affect either the taste or the efficacy. In case of 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.

OVERDOSAGE

In cases of overdose neither intoxication nor iron overload have been reported up to date.

STORAGE/PRECAUTIONS: Store in a cool, dry and dark place between 15 - 30 °C. Keep out of the reach of children.

PRESENTATION: FERSIP Syrup is available in a bottle containing 120 ml approx.

*Scotmann Specs.

خوراک: ڈاکٹر کی ہدایت کے مطابق۔
احتیاط: روشنی، نمی اور گرمی سے بچائیں۔
15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
مستند ڈاکٹر کے نسخہ پر فروخت اور استعمال کریں۔

Complete Medical Information available only for doctors on request.

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