EUROFER®-IRON SYRUP

Product Description
Each 100 ml contains:
Iron (III) Hydroxide Polymaltose complex equivalent to 1.0 g iron. The syrup is dark brown.

Pharmacological action
Iron is an essential constituent of the body, being necessary for haemoglobin formation and for the oxidative processes of living tissue.

Pharmacodynamics
Iron (III) Hydroxide Polymaltose complex (IPC) is a complex of ferric hydroxide and isomaltose. It is highly water-soluble over a broad pH-range, thus facilitating the absorption in the gut.
Iron is indicated for the treatment or prevention of iron-deficiency anaemia. Iron deficiency and iron-deficiency anaemia can, if left untreated, have adverse effects on both physical and mental capacity and on performance. The goal of iron deficiency anaemia therapy is to supply sufficient iron to replenish haemoglobin and storage iron deficit.

Pharmacokinetics
Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and by some dietary acids (such as ascorbic acid) and occurs more readily when the iron is in the ferrous state or is part of the haem complex (haem-iron). Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Normally only about 5 to 15% of the iron ingested in food is absorbed. Apart from haemorrhage, iron is mainly lost from the body in the faeces, urine, from skin, and sweat, but the total loss is very small.
IPC is equally bioavailable as iron salts at comparable doses.

Indications

EUROFER iron syrup is indicated for the treatment or prevention of iron-deficiency anaemia.

Directions for use

Adults:	10 ml daily
Children:	5 ml daily
Pregnancy and breast-feeding:	Dose adjustment is not necessary, the normal adult dose may be used (see also: Pregnancy and breast-feeding).

Dosage can be adjusted according to the physician's prescription, depending on the severity of the anaemia being treated. For oral use only.

Contraindications
- Patients with haemochromatosis, haemosiderosis, thalassemia, sideroblastic anaemia, chronic haemolysis, or lead-induced anaemia
- Patients that are hypersensitive to iron or to any of the other ingredients
- Patients receiving repeated blood transfusions.

Pregnancy and Breast-feeding
Iron deficiency anaemia is likely to develop during pregnancy and breast-feeding.
During pregnancy and breast-feeding EUROFER®-Iron syrup should be used on medical advice.

Side effects
Occasionally, gastrointestinal effects like gastrointestinal discomfort, vomiting, constipation, diarrhoea, epigastric pain and black stools may occur.

Interactions
Iron salts are not well absorbed orally, and food may further impair their absorption. Compounds containing calcium and magnesium, including antacids and mineral supplements, and bicarbonates, carbonates, oxalates, or phosphates, may impair the absorption of iron by the formation of insoluble complexes. Zinc salts may also decrease the absorption of iron. The absorption of both iron salts and tetracyclines is diminished when taken together orally. If treatment with both drugs is required, a time interval of about 2 to 3 hours should be allowed between them. During a clinical study in 22 patients, no inhibiting effect of Iron (III) Hydroxide Polymaltose complex on tetracycline absorption was observed (Potgieter et al., Arzneimittel-Forschung/Drug Research 57(6A), 2007). A suitable interval is also advised if an iron supplement is needed in patients given trientine. Iron is chelated by acetohydroxamic acid, reducing the absorption of both. Iron should not be given with dimercaprol as toxic complexes may form. The response to iron may be delayed in patients receiving systemic chloramphenicol.
Some agents, such as ascorbic acid and citric acid, may actually increase the absorption of iron.

Overdosage and treatment
Gastrointestinal discomfort, diarrhoea and vomiting. Symptoms, which may not appear for several hours, include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory failure may follow if diarrhoea and haemorrhage are severe. Hours or days later after apparent recovery metabolic acidosis, convulsions and coma may occur. If the patient survives, symptoms of acute liver necrosis may develop and may lead to death due to hepatic coma.
Treatment: In acute poisoning use the desferrioxamine procedure. If desferrioxamine is not available, empty the stomach immediately by emesis and lavage using a solution of sodium bicarbonate and leave some of the solution in the stomach. Fluid loss should be replaced by the intravenous administration of compound sodium lactate injection or sodium chloride and dextrose injection. Exchange transfusions may be necessary in severe cases. In treating iron poisoning, speed is essential to block absorption of iron from the gastrointestinal tract.

Presentation
Bottle containing 30 ml or 120 ml packed in a carton box.

Storage
Store in a cool, dry place (below 30°C).

Keep out of reach of children / Jauhi dari kanak-kanak

Manufactured under license for
Eurodrug Laboratories S.A., Belgium
by Osoth Inter Laboratories Co., Ltd.,
Chonburi, Thailand.

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