Maltofer®

Syrup

Composition

1 ml of syrup contains 10 mg of iron as Iron(III)-Hydroxide Polymaltose Complex (IPC), flavouring, sucrose, preservatives (E216, E218), excip. ad solutionem.

Properties

Maltofer syrup is an iron preparation for the treatment of latent iron deficiency and iron deficiency anaemia. Iron is an important constituent of haemoglobin, myoglobin, and the enzymes which contain iron. The treatment of iron deficiency in infants up to one year of age is of extreme importance. Iron deficiency at this age can impair the development of the brain. In general, 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.

The iron in Maltofer syrup exists as Iron(III)-Hydroxide Complex, where individual particles are embedded into a carbohydrate polymer (polymaltose). This prevents the iron from causing any harm in the gastrointestinal system. This protection inhibits interactions of the iron with food. Moreover, it ensures the bioavailability of the iron.

The structure of IPC is similar to ferritin, the naturally occurring iron storage protein. Due to this similarity, iron is absorbed through natural mechanisms.

IPC has no pro-oxidative properties such as there are with bivalent iron salts.

Indications

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

Dosage

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

Manifest iron deficiency: the therapy takes about 3–5 months until a normalisation of haemoglobin value is achieved. 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.

– Due to the low dosages, these indications can only be treated with iron in drop form (Maltofer drops).

Infants (up to 1 year)
Nourrissons (jusqu'à l'âge de 1 an)
Bebés (hasta 1 año)

Children (1–12 years)
Enfants (1–12 ans)
Niños (1–12 años)

Children (>12 years), *adults and nursing mothers*
Enfants (>12 ans), *adultes et femmes qui allaitent*
Niños (>12 años), *adultos y madres lactantes*

Pregnant women
Femmes enceintes
Embarazadas

Manifest iron deficiency

2.5–5 ml daily (25–50 mg Iron)

5–10 ml daily (50–100 mg iron)

10–30 ml daily (100–300 mg iron)

20–30 ml daily (200–300 mg iron)

Latent iron deficiency

2.5–5 ml daily (25–50 mg iron)

5–10 ml daily (50–100 mg iron)

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1 ml daily (100 mg Iron)

Prophylactic therapy

5–10 ml daily (50–100 mg iron)
5–10 ml par jour (50–100 mg de fer)
5–10 ml al dia (50–100 mg de hierro)

Administration
The daily dosage can be divided into separate doses or can be taken at one time. Maltofer syrup should be taken during or immediately after a meal. The supplied measuring cup is used for an exact administration of the dosage.
Maltofer syrup can be mixed with fruit and vegetable juices or with bottle-feed. The slight colouration does not affect either the taste or the efficacy.
In cases 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.

Contra-indications
Iron overload (e.g. haemochromatosis), haemosiderosis) or disturbances in iron utilisation (e.g. lead anaemia, sidero-achrestic anaemia, thalassaemia) and anaemia not caused by iron deficiency (e. g. haemolytic anaemia).

Special warnings and special precautions for use
Notice to diabetics: 0.04 bread units per ml syrup.
In cases of anaemia due to infection or malignancy, the substituted iron is stored in the reticuloendothelial system, from which it is mobilised and utilised only after curing the primary disease.

Interactions with other medicaments and other forms of interaction
Until now interactions have not been observed. Since the iron is complex-bound, ionic interaction with food components (phytin, oxalates, tannin etc.) and concomitant administration of medicaments (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.

Pregnancy and lactation
Pregnancy category A: Reproduction studies with 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 the foetus is unlikely. The administration of Maltofer syrup is unlikely to cause undesirable effects to the nursed child.
During pregnancy and lactation Maltofer syrup should be used only after consulting a medical doctor or pharmacist.

Undesirable effects
Occasionally gastrointestinal irritations such as a sensation of repletion, pressure in the epigastric region, nausea, obstipation or diarrhoea can occur.
A dark colouration of the stool due to iron is of no clinical significance.
Maltofer syrup does not cause teeth staining.

Overdose
In cases of overdosage neither intoxication nor iron overload have been reported to date.

Storage
Below 25 °C in the original container.

Presentation
150 ml bottle, closed with tamper-evident screw cap and supplied with measuring cup for administration.

Information dated July 2001