

Fantomalt®

Iron (III) hydroxide polymaltose complex

فینٹومالٹ

آئرن (III) ہائیڈروآکسائیڈ پولی مالٹوز کمپلیکس

Composition:

Syrup: Each 5ml (teaspoonful) contains:

Iron (III) hydroxide polymaltose complex equivalent to Elemental Iron..50mg.

Tablets : Each tablet Contains:

Elemental Iron (Iron III hydroxide polymaltose complex) 100mg.

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 poly-nuclear 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. This molecule is so large that diffusion through the membrane of the mucosa is about 40 times smaller than the ion for the hexaquo-iron (II) unity. 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.

Clinical particulars

Therapeutic indications:

Prevention and Treatment of all kinds of iron deficiencies particularly Iron deficiency anaemia, The liquid formulation is specially for: the prophylactic therapy of iron deficiency to cover the recommended dietary allowances (RDA) during pregnancy & lactation, children, Adolescents, women capable of bearing children, and adults.

Posology and methods of administration:

Dosage and duration of therapy are dependent upon the extent of iron deficiency. The daily dose can be divided into separate doses. Or taken at once during or after meals.

In case of manifested iron deficiency, the therapy takes about 3-5 months until a normal hemoglobin value is achieved. Afterwards, the therapy should be continued for several weeks with a dosage such as described for latent iron deficiency to replenish the iron stores.

Age Group	Manifested Iron deficiency	Latent iron deficiency	Prophylactic Therapy (RDA)
Infants (Up to 1 year)	2.5 - 5 ml daily	—	—
Children (Up to 12 years)	50 - 100 mg daily	2.5 - 5 ml daily	—
Children (Above 12 years), adults and nursing women	100 - 300 mg daily	50 - 100 mg daily	
Pregnant Women	200 - 300 mg daily	100 mg daily	50 - 100 mg daily

Contraindications

Iron overload (e.g. Haemochromatosis, haemosiderosis) or disturbances in iron utilization. (e.g. Lead anaemia, sidero-achrestic anaemia, thalassaemia) and anaemias not caused by iron deficiency (e.g. Haemolytic anaemia).

Interactions:

Until now interactions have not been observed. Since the iron is complex bound, ionic interactions with foodstuff components (Phytin, oxalates, tannin etc.) and concomitant administration of medicaments are unlikely to occur. The haemoccult-test (selective for haemoglobin) for the detection of occult blood is not impaired and therefore, iron therapy must not be interrupted.

Pregnancy and Lactation:

Reproduction studies in animals didn't show any foetal risk. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects in mother and neonates. There is no evidence of a risk during the first trimester and the possibility of a negative influence to the foetus is unlikely to occur.

Mothers milk contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into mother's milk. The administration of IPC is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation, IPC should be used on prescription only.

Undesirable effects:

Occasionally, gastro-intestinal irritations such as sensation of repletion, pressure in the Epigastric region, nausea, constipation or diarrhoea may occur. A dark colour of the stool is of no clinical significance.

Overdosage:

In case of overdosage neither intoxication nor iron overload have been reported till date.

Presentation:

Syrup: 60ml Syrup filled in amber coloured pet bottles packed in unit cartons.

Syrup: 120ml Syrup filled in amber coloured pet bottles packed in unit cartons.

Tablets: Blister pack of 10 tablets.

Tablets: Blister pack of 20 tablets.

Special precautions for storage:

ذائقہ کی ہدایت کے مطابق استعمال کریں۔

Store in a dry place below 30°C

Protect from direct sunlight.

Keep out of reach of children.

Prevent Syrup from freezing.

ہدایات:

نمک جگہ پر 30°C گریٹ سے کم درجہ حرارت پر رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

سورج کی روشنی سے بچائیں۔

سیرپ کو ٹھنڈ ہونے سے بچائیں۔



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