

PRESCRIBING INFORMATION

I-Tose[®] Syrup
(Iron Polymaltose Complex)

آئی-ٹوز سیرپ

Composition:

Each 5 ml contains:

Iron.....50mg

as Iron (III) hydroxide polymaltose complex (Brookes Specs)

Mfg. Specs. Brookes

Description:

The Iron (III) hydroxide polymaltose complex (IPC) is a water- soluble iron oxide, macromolecular complex of polymolecular 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. This molecule is so large that diffusion through the membrane of the mucosa is about 40 times smaller than the one 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 physiological 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 daily dietary allowances (RDA) during pregnancy and lactation, for children, adolescents, women capable of bearing children and adults.

Dosage 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 can be taken at one time during or after meal. In case of manifest iron deficiency the therapy takes about 3-5 months until a normalization of the 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)
Infant (Upto 1 year)	2.5 - 5 ml daily	-	-
Children (1-12 years)	5 - 10 ml daily	2.5 - 5 ml daily	-
Children (> 12 years), adults and nursing women	10-30 ml daily	5- 10 ml daily	-
Pregnant Women	20-30 ml daily	10 ml daily	5- 10 ml daily

Contra-indications:

Iron overload (e.g. haemochromatosis, haemosiderosis) or disturbances in iron utilization (e.g. lead anaemia, sidero achrestic, 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 food stuff components (phytin, oxalates, tannin etc) and concomitant administration of medicaments are unlikely to occur. The haemocult –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 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 possibility of a negative influence to the foetus is unlikely to occur.

Mother's milk contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into the 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.

Undesirable effects:

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

Overdose:

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

Storage:

Store at temperature 15 - 30 °C away from light.

Presentation:

Bottle of 60ml

خوراک اور طریقہ استعمال:

خوراک اور علاج کے دورانیہ کا انحصار آئرن کی کمی پر منحصر ہے۔ روزانہ کی خوراک کو تقسیم شدہ، خوراک کے طور پر دی جاسکتی ہے، یا یکمشت کھانے کے دوران یا بعد میں دی جاسکتی ہے۔ ظاہر شدہ آئرن کی کمی کو دور کرنے کے لیے، علاج کی مدت میں 3 سے 5 ماہ تک لگ سکتے ہیں۔ جسکے بعد Haemoglobin اپنے مقررہ ریج میں آجاتا ہے مزید چند ہفتوں تک خوراک دی جانی چاہیے تاکہ آئرن کی مناسب مقدار جسم میں موجود رہے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیے۔

brookes**Manufactured by:**

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