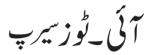
PRESCRIBING INFORMATION

I-Tose® Syrup (Iron Polymaltose Complex)



Composition: Each 5 ml contains: Iron.. ...50mg as Iron (III) hydroxide polymaltose complex (Brookes Specs) Mfg. Specs. Brookes

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

from 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, ironic interactions with food stuff 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 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.

 $\label{lem:constraint} Undesirable\ effects: \\ Occasionally\ gastro-intestinal\ irritations\ such\ as\ sensation\ of\ repletion,\ pressure\ in\ the\ epigastric\ region,\ nausea,\ constipation\ or\ diarrhoea\ can\ occur.\ A\ dark\ coloration\ of\ the\ stool\ is\ of\ no\ clinical\ significance.$

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

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

Presentation: Bottle of 60ml

خوراك اور طريقه استعال: خوراک اور علاج کے دورانیہ کانحصار آئرن کی کی پر مخصر ہے۔روزانہ کی خوراک کوقتیم شدہ،خوراک کے طور پر دی جاسکتی ہے، یا یکشت کھانے کے دوران یابعد میں دی جاسکتی ہے۔ ظاہر شدہ آئرن کی کمی کو دور کرنے کے لیئے ،علاج کی مدت میں 3 سے 5 ماہ تک لگ سکتے ہیں جسکے بعد Haemoglobin اینے مقررہ ریٹی میں آجاتا ہے مزید چند ہفتوں تک خوراک دی جانی چاہئے تا کہ آئرن کی مناسب مقدار جسم میں موجود رہے۔ ا سورن. 15سے 30 ڈگری سنٹی گریڈ درجہ حرارت پر روثنی سے بھا کرر کھیئے۔



Manufactured by:

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