

Mediflic® Syrup

(Iron Polymaltose Complex)

Composition

Each teaspoonful (5ml) contains:

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

Description

The Iron (III)-hydroxide polymaltose complex (IPC) is a water-soluble iron oxide macromolecular complex of polynuclear iron (III)-hydrolysed 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 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 daily dietary allowances (RDA) during pregnancy and lactation for children, adolescents, women capable of bearing children and adults.

Posology and methods of administration

Dosage and duration of therapy are dependant 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 manifested iron deficiency, the therapy takes about 3-5 months until normalization of the haemoglobin 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 (Up to 1 year)	2.5-5 ml daily		
Children (Up to 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 anaemia, thalassaemia) and anaemias not caused by iron deficiency (e.g haemolytic anaemia) Hypersensitivity to iron.

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 did not show any foetal risk. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects on mothers and neonates. There is no evidence of a risk during the first trimester and the possibility of the negative influence to the foetus is unlikely to occur.

Mother's milk contain 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.

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 the case of overdose neither intoxication nor iron overload have been reported upto date.

Dosage

As prescribed by the physician.

Instructions

Store at 2 – 25°C.

Protect from sunlight & moisture.

Keep medicines out of the reach of children.

Presentation

Mediflic syrup is available in bottle of 60 ml.

Mfg. Lic. No.: 000167

Manufactured by:

Mediate Pharmaceutical (Pvt) Ltd.

150/151, Sector 24, Korangi Industrial

Area, Karachi, Pakistan



Marketed by:

OBS Pharma (Pvt) Ltd.

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