



MEDLEY PHARMACEUTICALS

LETOSE *Syrup/Tablets*

(Iron III hydroxide Polymaltose complex)

Composition:

Each 5ml of the LETOSE (sugar free) syrup contains:

Iron III hydroxide Polymaltose complex (IPC) Eq. to elemental iron.....50mg

Each LETOSE chewable tablet contains:

Iron III hydroxide Polymaltose complex (IPC) Eq. to elemental iron.....100mg

Properties:

LETOSE is an iron preparation for the treatment of latent iron deficiency and iron deficiency anemia. Iron is an important constituent of hemoglobin, myoglobin and the enzymes that contain iron. The treatment of iron deficiency in the infants up to 1 year of age is of extreme importance.

Iron deficiency at this age can impair the development of brain. In general iron deficiency can cause chronic fatigue, lack of concentration, irritability, nervousness, headache, loss of appetite, susceptibility to stress and infections, paleness, cracks to the corners of mouth (irrhagades), dry skin, brittle hairs and nails as well as loss of interest in play in children.

The iron in LETOSE exists as Iron (III) hydroxide complex, where individual particles are embedded into a carbohydrate polymer (polymaltose).

This prevents iron from causing any harm to the gastrointestinal system. The protection inhibits the interaction of iron with food. Moreover it ensures the bioavailability of iron.

The structure of IPC is similar to the ferritin, the naturally occurring iron storage protein. Due to this similarity iron is absorbed through natural mechanism. IPC has no pro-oxidative properties such as there are with bivalent iron salts.

Indications:

The treatment of latent iron deficiency and iron deficiency anemia, (manifest iron deficiency), prophylactic iron deficiency during pregnancy.



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Medley Pharmaceuticals
41-A, P.S.I.E. Jhang Bahtar Road,
Wah Cantt- Rawalpindi



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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 the normalization of hemoglobin. Afterwards the therapy should be continued for several weeks for pregnant women, at least until the end of 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.

Age Group	Manifest iron deficiency	Latent iron deficiency	Prophylactic iron deficiency
Infants (up to 1 year)	(25-50mg iron) daily		
Children (1-12 years)	(50-100mg iron) daily	(25-50mg iron) daily	
Children (> 12 years) Adults and nursing mother	(100-130mg iron) daily	(25-50mg iron) daily	
Pregnant Women	(200-300mg iron) daily	(100 mg iron) daily	(50-100 mg iron) daily

Administration:

The daily dose can be divided into separate doses or can be taken at one time.

LETOSE should be taken during or immediately after the meal.

LETOSE (Sugar free) syrup can be mixed with fruits and vegetable juices or with bottle feeds. The slight coloration does not affect either the taste or efficacy:



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In case of immediate iron need (Low Hb, concomitant EPO treatment etc) parenteral iron preparation should be for iron substitution so that the iron is more rapidly available.

Interactions with other medicaments and other form of interactions:

Until now interactions have not been observed. Since the iron is complex-bound, ionic interactions with the food components (phytin, oxalates, tannins etc) and the concomitant administration of the medicaments (tetracyclines, antacids) are unlikely to occur. The haemocult test (selective for Hb) for the detection of occult blood is not impaired and therefore no need to interrupt iron therapy.

Pregnancy and lactation pregnancy category A:

Reproduction studies in animals did not show any fatal risk. Controlled studies in the pregnant women after the first trimester have not shown any undesirable effects in mother and neonates. There is no evidence of risk during the trimester and negative influence on fetus is unlikely to occur. The administration of LETOSE is unlikely to cause any undesirable effects to the nursed child. During pregnancy and lactation LETOSE should be used only after consulting a Medical Doctor or a Pharmacist.

Undesirable Effects:

Occasionally Gastrointestinal irritation such as sensation of repletion, pressure at the epigastric region, nausea, constipation or diarrhea can occur.

A dark coloration of stool due to iron is of no clinical significance.

LETOSE does not cause teeth staining.

Over dosage:

Any case of over dosage, neither intoxication nor iron over load have been reported to date.

Storage:

Store in cool dry place. Keep away from sunlight and out of reach of children. Store at room temperature between 15-30 °C.

Presentation:

LETOSE (sugar free) syrup is available in 60ml amber colored bottle.

LETOSE chewable tablets are available in pack of 2×10's in Alu-Alu pack.



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