



MEDLEY PHARMACEUTICALS

MaltoMed **(Iron (III) hydroxide Polymaltose complex + Folic Acid)**

Composition

Each tablet contains 100mg of elemental iron as Iron (III) Hydroxide Polymaltose Complex (IPC) and 0.35 mg folic acid

Each 5ml syrup contains iron (III) hydroxide polymaltose complex eq to elemental iron 50mg and 0.34mg folic acid.

Properties

MaltoMed is a combination of iron and folic acid for the treatment of iron deficiency and the prevention of iron and folic acid deficiency before, during and after pregnancy (during lactation). In **MaltoMed** the content of folic acid is according to the WHO guidelines. Folic acid is an important vitamin for the development of the unborn child. Folic acid deficiency in the first weeks of pregnancy can lead to malformations in the child. Iron is an important constituent of haemoglobin, myoglobin, and the enzymes which contain iron. Iron deficiency is particularly frequent during pregnancy and lactation and manifests itself as chronic fatigue, lack of concentration, irritability, nervousness, headache, loss of appetite, susceptibility to stress and infection, paleness, cracks at the corners of the mouth (rhagades), dry skin, brittle hair and nails. The iron in **MaltoMed** exists as Iron (III) – Hydroxide Polymaltose Complex, where individual particles are embedded into a carbohydrate polymer (polymaltose). This prevents the iron from causing any harm in the gastrointestinal system. This protection inhibits interactions of the iron with food. Moreover, it ensures the bioavailability of the iron.

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

Indications

Treatment of latent and manifest iron deficiency and prevention of iron and folic acid deficiency before, during and after pregnancy (during lactation)

Dosage

Tablets

Dosage and duration of therapy are dependent upon the extent of iron deficiency.

Manifest iron deficiency one tablet 2 to 3 times daily until normalization of haemoglobin. Afterwards the therapy should be continued with one tablet daily at least until the end of the pregnancy to replenish the iron stores.

Syrup

Children 6 years or above:

10ml (2 teaspoonful) once daily or 5ml (1 teaspoonful) twice daily.

Children 2-6 years:

5ml (1 teaspoonful) once daily or 2.5ml (1/2 teaspoonful) twice daily.

Latent iron deficiency and prevention of iron and folic acid deficiency:

One tablet daily

Administration

The daily dose can be divided into separate doses or can be taken at one time. **MaltoMed** tablets can be swallowed whole and should be taken during or immediately after a meal.



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In case of immediate iron need (low HB concomitant EPO treatment etc.) parenteral iron preparations should be used for iron substitution so that the iron is more rapidly available.

Contra-Indications

Iron overload (e.g haemochromatosis, haemosiderosis) or disturbances in iron utilization (e.g. lead anaemia, sidero-achrestic anaemia, thalassaemia) and anaemia not caused by iron deficiency (e.g haemolytic anaemia).

Interactions with other medicaments and other forms of interactions

Until now interactions have not been observed since the iron is complex-bound, ionic interactions with food components (phytin, oxalates, tannin etc.) and concomitant administration of medicaments (tetracyclines, antacids) are unlikely to occur. The haemoccult test (selective for HB) for the detection of occult blood is not impaired and therefore there is 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 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 a negative influence on the foetus is unlikely. The administration of MaltoMed is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation MaltoMed should be used only after consulting a medical practitioner.

Undesirable effects

Occasionally gastrointestinal irritations such as a sensation of repletion, pressure in the epigastric region, nausea, obstipation or diarrhea can occur. A dark colouration of the stool due to iron is of no clinical significance. MaltoMed do not cause teeth staining.

Overdose

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

Storage

Below 30°C in the original container.

Presentation

10 tablets in Alu-Alu packing.

Syrup in 60ml and 120ml packing.

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