



**MEDLEY PHARMACEUTICALS**

## **MALTOLEY**

### **Chewable Tablets and Syrup**

#### **(Iron (III) Hydroxide Polymaltose Complex+ Folic acid)**

#### **COMPOSITION**

Each tablet contains 100 mg of element iron as Iron (III) Hydroxide Polymaltose complex (IPC) and 0.35mg Folic acid

Each 5ml syrup contains 100 mg of element iron as Iron (III) Hydroxide Polymaltose complex (IPC) and 0.35mg Folic acid

#### **Properties**

**Maltoley** 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 Maltoley 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 hemoglobin, myoglobin and the enzymes which contains. Iron deficiency is particularly frequent during pregnancy and lactation and manifests itself in chronic fatigue, lack of concentration, irritability, nervousness, headache, loss of appetite, susceptibility to stress and infection, paleness, crack at the corners of the mouth (rhagades), dry skin, brittle hair and nails. The iron in **Maltoley** 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 natural 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**

##### **Tablet**

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



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ISO 9001-2008 Certified Company  
**Medley Pharmaceuticals**  
41-A, P.S.I.E. Jhang Bahtar Road,  
Wah Cantt- Rawalpindi



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*Manifest iron deficiency:* One tablet 2 to 3 time daily until normalization of hemoglobin. After wards 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 year or above:**

10ml (2 teaspoonfuls) once daily or 2.5ml (1 teaspoonful) twice daily

#### **Children 2-6 year:**

5ml (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 a time. Maltoley tablet can be swallowed whole and should be taken during or immediately after a meal. In case of immediate iron need (low Hb, concomitant EPO treatment etc) parenteral iron preparation should be used for iron substitution so that iron is more rapidly available.

### **Contra-indications**

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

### **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 (phyin, oxalates. Tannin ect.) and concomitant administration of medicaments (tetracycline's, antacids) are unlikely to occur. The heamoccult I test (selective for Hb) for the detection of occult blood is not impaired and therefore 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 woman after the first trimester have not shown any undesirable effects on mother and neonates. There is no evidence of risk during the first trimester and a negative influence on the foetus is unlikely. The administration of **Maltoley** is unlikely to cause undesirable effect to the nursed child .

During pregnancy and lactation **Maltoley** should be used only after consulting a registered medical practitioner.



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### **Undesirable effects**

Occasionally gastrointestinal irritations such as a sensation of repletion, pressure in the epigastric region, nausea, obstipation or diarrhea can occur. A dark coloration of the stools due to Iron in of no clinical significance.

### **Overdose**

In case of over dosage neither intoxication nor iron overload have been reported to data

### **Storage**

Below 30 c in original container.

### **Presentation**

3x10's tablets in Alu-Alu packing

Syrup in 60ml amber glass bottle

**(Company Logo Ect.)**



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