Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Apmalt Syrup (Iron (III) Hydroxide Polymaltose Syrup 125 mg/5 mL

2. Qualitative and quantitative composition

Each 5 mL contains:
Iron (III) Hydroxide Polymaltose complex equivalent to Elemental Iron 125 mg

Excipients with known effect:: Each 5ml of Apmalt syrup contains 30g liquid sorbitol (non-crystallising), 0.18g methyl Hydroxybenzoate, 0.02g propyl Hydroxybenzoate and 22g of sucrose.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup
Reddish brown to dark brown coloured solution.

4. Clinical particulars

4.1 Therapeutic Indications

In the treatment of anaemia due to iron deficiency. Treatment and prophylactic therapy of iron deficiency during pregnancy. This product should only be used in pregnancy after the first thirteen weeks.

4.2 Posology and method of administration

Adults:
100 to 200mg (4 ml to 8 ml) Iron daily.

Children aged 1-12 years:
50 to 100mg (2 ml to 4 ml) Iron daily.

Depending on the severity of the anaemia.

Apmalt Syrup can be mixed with fruit and vegetable juices or with bottle-feed. The slight colouration does not affect either the taste or the efficacy.

Medical advice should be sought if symptoms do not improve after four weeks of use of this product as these symptoms may reflect an underlying disease process.

Route of Administration:

Oral.

4.3 Contraindications

1. Use in patients with iron storage or assimilation diseases.
2. Use in patients with a known hypersensitivity to the active ingredient.
3. Use in individuals with haemochromatosis and iron overload syndromes.

4.4 Special warnings and precautions for use

1. All medications containing iron should be kept out of reach of children.
2. The response to iron therapy should be regularly monitored.
3. The additional requirements for folic acid should be borne in mind when treatment with iron is carried out during pregnancy.
4. In cases of anaemia due to infection or malignancy, the substituted iron is stored in the reticulo-endothelial system, from which it is mobilised and utilised only after curing the primary disease.
5. Caution is advised in individuals with a family history of haemochromatosis or an iron overload syndrome. It should be noted that these conditions may be under diagnosed.
6. Overdose may be fatal.
7. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Until now interactions have not been observed. Since the iron is complex-bound, ionic interaction 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.

4.6 Fertility, pregnancy and lactation

This product should only be used in pregnancy after the first thirteen weeks.

Pregnancy Category A

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 a negative influence on the foetus is unlikely.

Breast milk naturally contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into breast milk. The administration of Apmalt Syrup is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation Apmalt Syrup should be used only after consulting a physician.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Very rarely gastro-intestinal discomfort, vomiting, constipation or diarrhoea can occur.

A dark colouration of the stool is of no clinical significance.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

In cases of overdosage neither intoxication nor iron overload have been reported to date because the iron from the active substance Ferric-Hydroxide-Polymaltose Complex is not present in the gastro-intestinal tract as free iron and is not taken up by the organism by passive diffusion.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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 (Mw) of approximately 50 kD, which is so large that diffusion through the membrane of mucosa is about 40 times smaller than that of the hexaqua-iron(II) units. The complex is stable and does not release ionic iron under physiological conditions. The iron in the poly-nuclear cores is bound in a similar structure as in the case of physiologically occurring ferritin. Due to this similarity, only the iron (III) of the complex is absorbed by an active absorption process. By means of competitive ligand exchange, any iron binding protein in the gastro-intestinal fluid and on the surface of the epithelium, take up iron (III). The absorbed iron is stored mainly in the liver, where it is bound to ferritin. Later in the bone marrow, it is incorporated into haemoglobin.

Iron (III)-Hydroxide Polymaltose Complex has no pro-oxidative properties such as there are in iron II) salts. The susceptibility of lipoproteins such as Very Low Density Lipoprotein (VLDL) + Low Density Lipoprotein (LDL) to oxidation is reduced. Ferrum Hausann Syrup does not cause teeth staining.

5.2 Pharmacokinetic properties

Studies using the twin-isotope technique (55Fe and 59 Fe) show that absorption of iron measured as haemoglobin in erythrocytes is inversely proportional to the dose given (the higher the dose, the lower the absorption). There is a statistically negative correlation between the extent of iron deficiency and the amount of iron absorbed (the higher the iron deficiency, the better the absorption). The highest absorption of iron is in the duodenum and jejunum. Iron which is not absorbed is excreted via the faeces. Excretion via the exfoliation of the epithelial cells of the gastro-intestinal tract and the skin as well as perspiration, bile and urine only amount to approximately 1 mg of iron per day. For women, iron loss due to menstruation has also to be taken into account.

5.3 Preclinical safety data

No LD50 for Iron (III) Hydroxide Polymaltose could be determined in animal studies with white mice and rats up to an orally administered dose of 2,000 mg of iron per kilogram body weight.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose
Sorbitol 70% (non-crystallising)
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Mixed Fruit Flavour
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light

6.5 Nature and contents of container

125 mL Amber Glass bottle is packed in a carton alongwith Pack insert.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder and manufacturing site addresses

Marketing authorisation holder

Ajanta Pharma Limited
Ajanta House,
Charkop, Kandivli (West),
Mumbai- 400 067, India
E-Mail :info@ajantapharma.com

Manufacturing site address:

Ajanta Pharma Ltd.
Plot no: 31-O, MIDC Area,
Chikalthana Aurangabad 431210,
Maharashtra, India
E-Mail :info@ajantapharma.com

8. Marketing authorisation number(s)

CTD10080

9. Date of first authorisation

24-Dec-2022

10. Date of revision of the text

16-Sep-2023

11. Dosimetry

Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals

Not Applicable