SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

HAEMOJET Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains Elemental Iron 50 mg (As Ferric Hydroxide Polymaltose Complex).

Excipients with Known effect:

- Sorbitol 30.00 gm/100 ml.
- Sucrose 30.00 gm/100 ml.

For a full list of excipients see Section 6.1.

3. PHARMACEUTICAL FORM

Syrup. Reddish brown liquid with caramel flavor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and therapy of the iron deficiency from various etiology;

Preventive treatment of anemia due to the iron deficiency in the period of the intensive growth, adolescents, puberty, pregnancy, lactation.

4.2 Posology and method of administration

Adults and children over 12 years:

5 ml to 10 ml three times per day immediately after meals.

Children (6 – 12 years):

5 ml to 10 ml once or twice per day immediately after meals.

Children (2 – 6 years):

5 ml once or twice per day immediately after meals.

Infants (5 – 10 kg):

2.5 ml to 5 ml once daily immediately after meals.

Premature babies (less than 1500 g):

3 mg of elemental iron/kg body weight daily.

HAEMOJET Syrup can be mixed with fruit juice or vegetable or other liquid if desired.

4.3 Contraindications

- Disturbances in iron utilization (lead anemia), Thalassemia.
- Hypersensitivity or intolerance to iron and overloading of iron in the body.
- Anemia not caused by iron deficiency.

4.3 Special warnings and precautions for use

Administration of iron for longer than 6 months should be avoided except for patients with continued bleeding, menorrhagia, or repeated pregnancies. Iron should not be used to treat hemolytic anemia unless an iron deficient state also exists, since excess storage of iron with possible secondary hemochromatosis can result.

Iron should not be administered to patients receiving repeated blood transfusions, since there is considerable amount of iron in the hemoglobin of transfused erythrocytes.

Hypersensitivity to iron, iron overload chronic polyarthritis, bronchial asthma, renal or hepatic infections.

HAEMOJET Syrup is not recommended for diabetic patients.

Sorbitol:

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

There is no interaction between HAEMOJET Syrup and food or between HAEMOJET Syrup and drugs due to its non-ionic nature.

4.6 Pregnancy and lactation

There is no evidence of a risk during the first trimester and the possibility of a negative influence to the fetus is unlikely to occur.

Mother's milk contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into mother's milk. The administration of HAEMOJET Syrup is unlikely to cause undesirable effects to the nursed child.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

The oral administration of iron preparations sometimes produces gastrointestinal irritation with vomiting and diarrhea.

Continued administration may sometimes produce constipation. The feces may be colored black.

4.9 Overdose

In case of overdose, standard supportive measures should be instituted.
The manifestations of iron intoxication are burning sensation in stomach and esophagus, nausea, diarrhea, constipation. A more severe intoxication may result in CNS disorders, metabolic acidosis, hepatic and renal dysfunction.
Treatment:
If intoxication symptoms include vomiting, gastric lavage with sodium bicarbonate solution instead of emetic agents is recommended. Deferoxamine is used as an additive solution which acts as iron chelator, thereby preventing its absorption.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Heamatinic.

ATC code: B03AB04.

Iron therapy is indicated only for the prevention or cure of iron deficiency. In general terms, making 25 mg of iron per day available to the bone marrow will allow an iron deficiency anemia to respond with a rise of 1% of haemoglobin (0.15 g Hb/100 ml) per day; a reticulocyte response occurs between 4 and 12 days. An increase in the haemoglobin of at least 2 g/dl after 3 weeks of therapy is a reasonable criterion of an adequate response.

Oral iron therapy. The goal of iron therapy is to repair the haemoglobin deficit and replenish

storage iron. When oral therapy is used it is reasonable to assume that about 30% of the iron will be absorbed and to give 180 mg of elemental iron daily for 1-3 months according to the degree of anaemia. Iron stores are less easily replenished by oral therapy than by injection, and oral therapy (at lower dose) should be continued for 3-6 months after the haemoglobin concentration has returned to normal or until the serum ferritin exceeds 50 microgram/1 (or as long as blood loss continues).

5.2 Pharmacokinetic properties

Iron absorption correlates with the plasma ferritin value.

The quantity of iron absorbed is dependent on the iron deficiency in the individual to be treated, and on the iron dosage: i.e. the greater the iron deficit at equivalent therapeutic iron dosage, the higher the iron absorption.

Iron which is not absorbed is secreted in the feces. As a result of elimination through the epithelial cells of the intestinal tract and the skin, as well as the sweet, bile, and urine, a total of only about 1 mg of iron is secreted per day.

5.3 Preclinical safety data

Single dose toxicity (Acute):

Acute toxicity of Iron Hydroxide Polymaltose is very low, it is about 10 times smaller than that of ferrous sulphate.

When administered orally to mice or rats with LD50 values of drug Ion Polymaltose complex is more than 2 mg / kg body weight. Due to the necessity of a large volume of test solution, and the fact that the Iron Polymaltose is practically non-toxic, further testing of higher doses of the drug has not been.

Repeat-dose toxicity (Chronic):

Study of chronic toxicity (6 months) oral doses of 2 mg (therapeutic dose human), 5 mg and 10 mg Fe / kg per day were also conducted in rats.

None of the hematology laboratory studies have revealed no signs of damage in experimental animals, which could be attributed to the substance under investigation. Hematocrit, hemoglobin, red blood cells and white blood cells remained constant in the test period (Hausmann and Mueller, 1984).

Histopathologic studies were performed in animals that received 10 mg iron/kg per day and all the control animals. In the gastrointestinal tract did not reveal changes in the mucous or signs of erosion, inflammation, ulcers or bleeding. Only in the spleen was noted little change. In female rats were observed deposits of iron-containing pigment (more pronounced and the size and

number). It is equally frequently detected in treated as well as in non-treated groups of animals.

Genotoxicity:

Not detected mutagenic activity of Iron Polymaltose Complex during cytogenetic tests in vitro. Mutagenic potential of Iron Polymaltose Complex were studied in a culture of human lymphocytes in vitro (Adams, 1996).

Iron Polymaltose Complex, regardless of the dose did not produce statistically significant increase in metaphase loops containing chromosomal aberrations, both in the presence and absence of S-9 mix, compared with a control solution.

All the substances that make up the group of positive control, namely mitomycin C and cyclophosphamide induced a statistically significant increase in the proportion of aberrant cells.

Carcinogenicity:

A number of studies have shown that supplementary iron added to the diet enhances the development of neoplasia in animals that produce spontaneous tumors, are inoculated with tumor cells, or are exposed to chemical carcinogens. However, high-level (1200 – 1500 mg/kg bw/day) dietary carbonyl iron supplementation had no effect on the initiation or promotion of hepatocarcinoma in the Solt-Farber model of hepatocarcinogenesis in rats.

Reproductive and developmental toxicity:

A multigeneration study in rats showed no adverse effects of 20 mg/kg bw/week maternal iron supplementation (by intramuscular injection, but not during pregnancy) on the numbers of offspring produced or their growth weights, with no significant evidence of excess iron transfer across the placenta. A study of maternal iron poisoning in an ovine model also showed that extremely elevated maternal serum iron concentrations were not accompanied by corresponding increases in foetal serum iron levels.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylparaben Sodium.

Propylparaben Sodium.

Glycerol.

Sorbitol.

Sucrose.

Caramel Flavour.

Citric Acid Anhydrous.

Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep at temperature below 25°C, in original package.

6.5 Nature and contents of container

Carton box containing one amber plastic bottle (containing 100 ml of syrup) and a pamphlet.

6.6 Special precautions for disposal

Not special requirements.

7. MARKETING AUTHORISATION HOLDER

EUROPEAN EGYPTIAN PHARM. IND.

Amriya, Alexandria-Cairo Desert Road, Km 25,

Alexandria- Egypt.

P.O. Box: 111 El Manshia, Alexandria,

Egypt.

8. MARKETING AUTHORISATION NUMBER(S)

25856/2020.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/01/2009.

Renewal Date: 03/12/2020.

10. DATE OF REVISION OF THE TEXT

November 2023.