SUMMARY OF PRODUCT CHARACTERISTICS

(S P C)

H E M A F E R ®

1. NAME OF THE MEDICINAL PRODUCT

HEMAFER®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION (in active substance)

Each teaspoon (=5.0 ml) of syrup or each ml of the solution (≈ 15 drops) contains Ferric Hydroxide Polymaltose Complex, which corresponds to 50mg Iron (III).

Each (single dose) vial contains Ferric Hydroxide Polymaltose Complex, which corresponds to 100mg Iron (III).

Each chewable and each effervescent tablet contains Ferric Hydroxide Polymaltose Complex, which corresponds to 100mg Iron (III).

3. PHARMACEUTICAL FORM

- Oral solution, drops
- Syrup
- Oral solution, single dose
- Chewable tablet
- Effervescent tablets

4. CLINICAL PARTICULARS

4.1. Therapeutical indications

Therapeutically:

- Sideropenic anaemias of any aetiology which are usually revealed with difficulty.

Prophylactically:

- Cases of chronic blood loss or cases that favour the appearance of sideropenia (pregnancy, chronic bleeding conditions, after gastrectomy, diet given to babies poor in iron or in special cases such as twins, premature babies, low body weight infants etc).

4.2. Posology and method of administration

Premature infants: 1 drop (3.33mg) per kg body weight daily.

Infants (up to 1 year old): 25-50mg of elemental iron per day, i.e. ½ to 1 teaspoon of syrup or 5 –15 drops per day.

Children (1 –12 years): 50-100mg of elemental iron per day, i.e. 1 to 2 teaspoons of syrup or 15 –30 drops per day.

Children older than 6 years old can be also administered with 1 chewable and/or one effervescent tablet per day.

Children older than 12 years old and Adults: For mild sideropenic conditions 100mg of elemental iron per day are taken at any time that suits the patient. The effervescent tablets are administered after being dissolved into ½ -1 glass of water. The chewable tablets can also be swallowed if the patient prefers that.

If a larger dose is required (hemoglobin under 9g%), the daily dose should be doubled. In order to replenish the iron stores, it is recommended to continue the treatment for at least one more month after normalization of the levels of hemoglobin, hematocrit and red blood cells.

Duration of therapy in weeks:

Adolescents older than 12 years old and adults who receive 100mg of elemental iron once a day and whose haemoglobin is above 9g%, the duration of therapy in weeks is determined by the following table:

Body Weight	Duration of therapy in weeks					
	Hb 6.0g%*	***Hb 7.5g%****	***Hb 9.0g%***	***Hb 10.5g%***	***Hb 12.0%g***	***Hb 13.5%g***
35	7	6	7	6	5	4
40	8	7	8	7	6	5
45	9	7	8	7	6	5
50	9	8	9	7	6	5
55	10	9	9	8	6	5
60	11	9	10	8	7	5
65	12	10	10	9	7	5
70	12	11	11	9	7	5
75	13	11	11	9	7	6
80	14	12	12	10	8	6
85	15	13	12	10	8	6
90	15	13	13	11	8	6

* The therapy of choice for the fast turn over of iron deficiency, in patients whose haemoglobin values are below 9g%, is the parenteral administration. If this route is not possible, the daily dose should be doubled to 200mg of elemental iron for the first two weeks, after which the dose can be reduced to 100mg per day. The dosage should be always determined by a physician.

All the pharmaceutical forms of **HEMAFER®** are administered anytime of the day regardless of meals.

4.3. Contraindications

The medicines can help patients, however they can also cause problems when they are not administered according to the physicians' instructions.

For this specific medication you should inform your doctor if:

- You or your child is allergic to any of the drug's excipients.
- If you suffer from any liver disease.

In general, this medication is contraindicated in:

- Every non-sideropenic anemia, unless there are clear indications for coexisting iron deficiency.

- In particular, iron administration is contraindicated in chronic haemolytic anemias (thalassemia, sickle cell syndromes), in sideroblastic anemias (such as those requiring the administration of pyridoxine), anemias due to chronic diseases or late dermal porphyria.
- Hepatic cirrhosis is a relative contraindication due to a significant, many times, quantity of iron deposited in the liver.
- Especially, the oral administration of iron is contraindicated when peptic disturbances appear, which do not allow the continuation of the oral therapy, in organic conditions of the gastrointestinal tract (e.g. active gastroduodenal ulcer, gastrorrhagia), inflammatory conditions of the intestine (ulcerative colitis, Chrohn disease), syndrome of bad absorption etc.

4.4. Special warnings and precautions for use

Generally

- It is recommended that the administration of iron should be interrupted in case of severe intolerance symptoms.
- The liquid iron forms can cause staining of the teeth. It is recommended that they are ingested along with fruit juices.
- People who take iron usually have dark-brown faeces.

Children

The tablets should be administered with caution to children at the age of 6 and older, always according to the physician's instructions, who will recommend the dosage form.

4.5. Interaction with other medicinal products and other forms of interaction

Before using the medicine inform your doctor for any other medicines you take or give to your child.

- Antacids, pancreatic extracts and cholestiramine, milk or eggs reduce iron absorption.
- Allopurinol increases the deposition of iron in the liver in cirrhotic patients.
- Iron prevents the absorption of tetracyclines. These substances should be administered with a 2-hours' time interval difference from one another.

4.6. Pregnancy and lactation

It is indicated as therapeutic or prophylactic treatment during pregnancy or after pregnancy as well as during lactation.

4.7. Effects on ability to drive and use machines

The administration of the medication does not affect the ability to drive or operate machinery.

4.8. Undesirable effects

Along with the desirable effects each medication can cause certain adverse effects. Even though these adverse effects appear rarely, when they do appear, your physician should be informed so he can give the appropriate advice.

- Rarely, peptic disturbances such as nausea, vomiting, epigastric or abdominal pain, diarrhoea or constipation can appear.
- During chronic administration haemosiderosis may appear.

4.9. Overdose

Poisoning cases due to iron preparations have not been reported; the acute toxicity of iron polymaltose is very low and poisoning after accidental overdose could be considered irrelevant. However in case of an accidental overdose call the Poisoning Control Center.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Therapeutical Category: Antianemic preparations

ATC Code: B03AB05

The iron hydroxide polymaltose complex is very soluble in water and the content iron is not ionized as it happens in most salts of iron. For this reason, it does not affect the gastrointestinal tract, it does not stain the teeth and it is well tolerated. Thanks to this property, **HEMAFER®** could be administered before, during or after meals. It is an iron source for all sideropenic anaemias, because it is quickly absorbed, it has a high degree of constructive metabolism and it results in actual haemoglobin increase. Iron preparations are the exclusive medication for the therapy of sideropenic anemias.

The administration route of choice for iron is the oral route.

The parenteral administration is rarely justified. In case it is absolutely necessary, the intramuscular route should be preferable. Intravenous route should be preferred only on special situations and always in hospital, because there is danger of anaphylactic reactions that sometimes could cause death.

5.2. Pharmacokinetic properties

The mean iron intake by the daily dietary is 18-20mg. From this quantity only the 5-10% is absorbed (1-2 mg/daily) in normal

conditions. The absorption is increased (20-30% of the ingestion) in the occasion of iron deficiency or haemopeoisis increase. The iron is absorbed by duodenum and the upper part of jejunum via active transfer mechanism and its absorption is affected by the administration dose. High doses result in increase of the absorbed iron quantity, although the percentage of the absorption is reduced.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

✓ ***Oral solution, drops 50 mg/ml***

Sucrose, Methylparaben 218, Propylparaben 216, Polysorbate 80, Lemon essence, Water purified.

✓ ***Syrup 50 mg/5ml***

Sorbitol solution 70%, Sucrose, Methylparaben 218, Propylparaben 216, Lemon essence, Ethanol, Edetate disodium, Water purified.

✓ ***Oral solution, single dose 100 mg/5ml VIALS***

Sucrose, Methylparaben 218, Propylparaben 216, Sorbitol solution, Lemon essence, Water purified.

✓ ***Chewable tablet 100 mg/tab***

Sodium cyclamate, Vanillin, Macrogol 6000, Essence of chocolate, Dextrates, Cellulose microcrystalline, Talc (purified).

✓ ***Effervescent tablet (100) mg/tab***

Tartaric acid, Polyethylene glycol 6000 powder, Citric acid anhydrous, Sodium bicarbonate anhydrous, Sodium carbonate anhydrous, Raspberry flavour in powder, Sodium saccharine, Sodium cyclamate, Magnesium sulfate, Sorbitol dc.

6.2. Incompatibilities

None known.

6.3. Shelf life

✓ ***Oral solution, drops 50 mg/ml***

60 months.

✓ ***Syrup 50 mg/5ml***

60 months.

✓ ***Oral solution, single dose 100 mg/5ml VIALS***

60 months.

✓ ***Chewable tablet 100 mg/tab***

60 months.

✓ ***Effervescent tablet (100) mg/tab***

36 months.

6.4. Special precautions for storage

HEMAFER® should be kept at temperature less than 25° C. It should be also kept in its original packaging.

6.5. Nature and contents of container

✓ ***Oral solution, drops 50 mg/ml***

Cardboard box that contains a brown glass bottle of 30 ml with a dosimetric cap made by polyethylene along with a Patient Information Leaflet.

✓ ***Syrup 50 mg/5ml***

Cardboard box that contains a brown glass bottle of 125 ml sealed with an aluminium stopper, along with a Patient Information Leaflet.

✓ ***Oral solution, single dose 100 mg/5ml VIALS***

Cardboard box that contains 10 brown glass vials of 5 ml, sealed with a polyethylene stopper, along with a Patient Information Leaflet.

✓ ***Chewable tablet 100 mg/tab***

Cardboard box that contains 30 chewable tablets packed in 3 ALU-ALU blisters of 10 tablets each, along with a Patient Information Leaflet.

✓ ***Effervescent tablet (100) mg/tab***

Cardboard box that contains 12 effervescent tablets cylindrical, chocolate brown color, packed in 3 aluminium - PVC sandwich strips of 4 tablets each, along with a Patient Information Leaflet.

6.6. Special precautions for disposal and other handling

See §4.2. Dosage and administration.

6.7. Marketing Authorization Holder

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7. MARKETING AUTHORIZATION NUMBER

8. DATE OF FIRST AUTHORIZATION

9. DATE OF LAST REVISION OF THE TEXT