Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT (FPP)

AMIFER® Junior
Iron 50 mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: 5 ml (1 spoon) contains iron hydroxide polymaltose complex, equivalent to 50 mg elementary iron.

Excipients with known effect: AMIFER Junior contains sucrose, sorbitol (E420); methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). Please refer to section 4.4 for further details.

Excipients: For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution, syrup, bottle of 150 ml.
Dark red-brown solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

AMIFER® Junior is an iron supplement containing 50 mg of elemental iron per 5 ml of syrup (equal to one spoonful supplied in the package). AMIFER® Junior is a product belonging to the class of antianemic agents and is used to prevent and correct iron deficiency before and during the stage of iron deficiency anemia. AMIFER® Junior is a medicine for the treatment of newborns and children; however, it can also be used in adults.

4.2. Posology and mode of administration

Posology

Recommended dosage in children is 2 mg iron/kg/day.

- Infants and children (6 months - 2 years):
  1/4 spoon (= 1.25 ml) once a day (= 12.5 mg of iron).
- Children (2 - 5 years):
  1/2 spoon (= 2.5 ml) 1 - 2 times a day (= 25 – 50 mg of iron).
- Children (6 -12 years):
  1 spoon (= 5 ml) 1 - 2 times a day (= 50 - 100 mg of iron).
- Adolescents, adults and elderly:
  1 spoon (= 5 ml) 2 times a day (= 100 mg of iron).

AMIFER Junior must be used for the term, recommended by the Health Care Professional. The dosage and duration of treatment depends on the degree of iron deficiency. In case of manifest iron deficiency with anemia, treatment up to normalisation of the hemoglobin level lasts on average from 3 to 5 months. The treatment is then pursued for several weeks with the dosage established for a latent iron deficiency without anemia and this in order to replenish the iron reserves. The treatment of latent iron deficiency without anemia lasts approximately 1 to 2 months.

Following the elimination of the symptoms of iron deficiency, it must be used for at least an additional month for replenishment of stores

Method of administration

Oral administration.

AMIFER Junior must be taken with or after meals, it may be taken by mixing with fruit or vegetable juices; not with milk (iron formulations must be taken at least 2 hours after milk or calcium products).

4.3. Contraindications

- Hypersensitivity to iron or to any of the excipients ingredients, listed in section 6.1.
- Conditions leading to an iron overloading (hemochromatosis, hypersiderosis, chronic hemolysis).
- Anemia which is not accompanied by iron deficiency (such as hemolytic anemia).
- An iron use disorder (lead to anemia, sideroachrestic anemia).
- Thalassemia.
- Progressive and chronic arthritis.
- Conditions, requiring regular and continuous blood transfusions.
- HIV infection without clinically proven iron deficiency anemia.
- Severe liver and kidney diseases.

4.4. Special warning and precautions for use

- Caution must be exercised in case of
  - gastric ulcer,
  - alcoholism or conditions which disturb iron absorption from intestines.
- AMIFER Junior contains sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- AMIFER Junior contains sorbitol (E420): Patients with rare hereditary problems of fructose intolerance should not take this medicine,
- AMIFER Junior contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may yield (possibly delayed) allergic reactions.

- During administration of oral iron formulations, the color of stool may darken; this is normal and does not require any measures, it does not cause false positive results during tests for occult blood in stool, therefore, there is no need to discontinue treatment during this test.
- In various diseases and in cancer-related anemia, the taken iron is stored in liver, yet following the treatment of these diseases and cancer, it departs from liver and becomes useable.

4.5. Interactions with other medicinal products and other forms of interactions

- Antacids decrease iron resorption.
- Iron formulations must be taken at least 2 hours after milk or calcium products
- There is reciprocal interference in resorption between tetracyclines, cholestyramine, ciprofloxacin, levofloxacin, norfloxacin, ofloxacin, temafloxacin, penicillamine, and salts of iron.
- Iron salts decrease the resorption of methyldopa.
- If one of the above-mentioned medicinal combinations is required, make sure to allow 2-3 hours between oral intakes.
- Interaction studies were performed only in adults.

4.6. Fertility, pregnancy and lactation

AMIFER Junior may be used during pregnancy and lactation if recommended by the physician or pharmacist.
The iron requirement in a pregnant woman is between 440 mg and 1.05 g.

Data from a small number of pregnant women after the first trimester have not shown any adverse effects on pregnancy or the health of the foetus or newborn. Reproduction studies in animals have not shown any direct or indirect toxicity that may affect pregnancy, embryonic development, and foetal development. However, the administration during pregnancy must be cautious.

Every day, almost 0.15 to 0.3 mg of iron is excreted in breast milk. Iron is transported through the placenta by the active route because by a concentration gradient.

The breast milk naturally contains iron bound to lactotransferrine. The amount of iron from the Iron hydroxide polymaltose complex likely to pass through breast milk is not known. It is unlikely that the intake of AMIFER Junior by the lactating mother can cause adverse effects in breastfed infants.

4.7. Effects on the ability to drive and use machines

There were no adverse effects related to driving or operating machinery. It is unlikely for iron preparations to have an impact on the ability to drive or operate machines.

4.8. Undesirable effects

AMIFER Junior occasionally causes side effects in some patients. The following convention was used for classification of adverse reactions: Very common (≥1 / 10), frequent (≥ 1/100, <1/10), uncommon (≥ 1/1000, <1/100), rare (≥ 1/10 000, <1/1000), Very rare (<1 / 10,000).

- The use of AMIFER Junior should be discontinued and a physician or pharmacist notified immediately and the nearest hospital emergency department should be consulted if any of the following occur (very rare: <1 / 10,000):
  - severe allergy to AMIFER® Junior: difficulty in breathing, swelling of the face, lips, tongue or throat, sudden decrease in blood pressure, generalized and severe redness, itching (urticaria), asthma.
- common: ≥ 1/100, <1/10):
  - indigestion,
  - abdominal pain,
  - nausea or vomiting,
  - burning sensation in the stomach,
  - bitter liquid in the mouth,
  - slight abdominal pain,
  - itching of blisters on the skin,
  - rashes,
  - redness,
  - headache,
  - variation in color of urine and stool.

4.9. Overdose

Symptoms

- Diarrhea, stomach pain and vomiting may occur in case of overdose.
- In the most severe cases, metabolic acidosis, severe muscle spasms and coma can be observed.
- Inadvertent administration of iron-containing products causes lethal (fatal) toxicity in children under 6 years of age.
- In case of overdose, a doctor or pharmacist or poison control center should be consulted promptly.

Treatment

- Administer an emetic.
- Emesis should be followed by a gastric lavage and possibly by a symptomatic treatment, if necessary.

Antidote

- Deferoxamine (iron chelator) orally or parenterally.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Trivalent iron, oral preparation, ferric oxide polymaltose complexes.

ATC code: B03AB05**.**

Ferric ion is a component of many enzymes necessary for energy transfer (e.g. cytochrome oxidase, xanthine oxidase, and succinic dehydrogenase), and it is also present in compounds necessary for the transfer and use of oxygen (e.g. hemoglobin and myoglobin).

The administration of iron preparations corrects erythropoietic abnormalities arising from iron deficiency. Iron administration also eliminates other symptoms due to iron deficiency such as tongue sores, dysphagia, nail and skin dystrophy, as well as cracking of the lips.

5.2. Pharmacokinetic properties

Absorption

Iron absorption is very complex and is influenced by several factors including the form in which it is administered, dose, and iron reserve, erythropoietic degree and diet. In healthy subjects, approximately 5-10% of dietary iron is absorbed and almost 10% to 30% of iron deficient subjects. It is reported that inorganic iron is absorbed twice as much as dietary iron.

Although iron absorption takes place along the gastrointestinal tract, it is greater at the duodenum in the proximal portion of the jejunum and decreases progressively in the distal portion.

AMIFER Junior is rapidly absorbed from the gastrointestinal tract after oral administration. The amount absorbed is dependent on the degree of iron deficiency of the patient. The more important the iron deficiency, the greater the iron absorption.

Distribution

Ferric iron combines with the apoferritin protein to produce ferritin, which is stored in mucosal cells which are detached and excreted in the stool at the end of their life. The concentration of iron in a male adult is 50 mg/kg body weight and 35 mg/kg body weight in a female adult. Iron is found in the human body only in the form of a complex with a protein or in the heme molecule. Approximately 70% of iron is found in hemoglobin, 25% as ferritin iron reserve, and hemosiderin, 4% in myoglobin, 0.5% in heme enzymes and 0.1% in transporters. Iron reserves in the form of ferritin and

hemosiderin are localised in the liver, reticuloendothelial system, bone marrow and in the spleen. In women, iron reserves tend to be less than half those of man. In patients with negative iron balance, iron stores decrease before the hemoglobin concentration is reduced.

Elimination

Iron metabolism is using a simple system. The large amount of iron emanating from the destruction of hemoglobin is preserved and reused by the body.
Non-absorbed iron is excreted in the faeces.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sucrose,
Liquid sorbitol non-crystalising (E420),
Methyl Parahydroxybenzoate (E218),
Propyl Parahydroxybenzoate (E216),
Cream Flavour,
Deionized Water.

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store below 30°C.
In case you notice irregularities on the product and/or package, do not use it.

6.5. Nature and contents of container

AMIFER Junior is presented in a honey-colored glass bottles, containing 150 ml of syrup, together with a plastic measuring spoon (indicating 1.25 ml-2.5ml-5 ml). The syrup has a characteristic smell, and appears as a dark red-brown solution.

6.6. Special precautions for disposal and other handlings

No special requirements for disposal. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACURING SITE ADDRESS

7.1. Marketing Authorization Holder

Dafra Pharma GmbH
Mühlenberg 7
4052 Basel
Switzerland.

7.2. Manufacturer

Santa Farma İlaç Sanayi A.Ş.
GEBKİM Kimya İhtisas Organize Sanayii Bölgesi
Çerkeşli Yolu Üzeri Erol Kiresepi Cad. No: 8, 41455
Dilovası – KOCAELİ
Turkey

8. MARKETING AUHORISATION NUMBER

See list of MAs per country

9. DATE OF FIRST REGISTRATION

See list of MAs per country:

10. DATE OF REVISION OF THIS TEXT

October 2019