

SUMMARY OF PRIDUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SANTA FER® 50 mg / 5 ml Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each ml of syrup contains 32.258 mg of iron(III) hydroxide polymaltose complex equivalent to 10 mg of elemental iron.

Excipients:

Each ml contains:

- Sucrose 200 mg/ml
- Sorbitol 70% (E420) 200 mg/ml
- Methyl parahydroxybenzoate (E218) 0.7 mg/ml
- Propyl parahydroxybenzoate (E216) 0.3 mg/ml

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

Characteristic odor, dark red-brown syrup.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Used for the treatment and prevention of iron deficiency and iron deficiency anemia of various origins, as well as for the treatment of iron deficiency during pregnancy, lactation, and childhood.

4.2. Posology and method of administration

Posology:

SANTA FER® is used in the following doses equivalent to elemental iron:

- In children: 50–100 mg daily
- In adults: 100–150 mg daily

Dosage frequency and duration:

Unless otherwise recommended by a doctor, the following doses should be used:

Children: 1–2 times daily, 1 dose (5 ml)

Adults: 2–3 times daily, 1 dose (5 ml)

The treatment should be continued for as long as recommended by the doctor.

After the symptoms of iron deficiency have resolved, the medication should be continued for at least one more month to replenish iron stores.

Method of administration:

- SANTAFER® is for oral use only.
- It can be taken with meals or after meals.
- It can be mixed with fruit or vegetable juices.

Additional information for special populations:

Renal/Hepatic impairment:

SANTAFER® should not be used in cases of severe liver or kidney disease.

Pediatric Population:

SANTAFER® should be administered as indicated in the posology section for pediatric patients.

Geriatric Population:

The administration in elderly patients is the same as in adults.

4.3. Contraindications

SANTAFER® should not be used in the following cases:

- Known hypersensitivity to any of the active or excipient ingredients.
- Anemias that are not caused by iron deficiency (e.g., hemolytic anemia).
- Iron overload (hemochromatosis, chronic hemolysis).
- Hypersensitivity to iron, or disorders of iron utilization (e.g., lead anemia, sideroachrestic anemia).
- Thalassemia.
- Severe liver and kidney diseases.
- Regular and continuous blood transfusions.
- In patients with HIV infection, iron supplementation should not be given unless iron deficiency anemia has been clinically confirmed.

4.4. Special warnings and precautions for use

- Anemia should always be treated under the supervision of a doctor.
- If treatment is unsuccessful (if the hemoglobin level does not increase by about 2-3 g/dL after 3 weeks), the treatment should be reassessed.
- Patients who have repeated blood transfusions should be warned about the risk of iron overload, as iron is given alongside erythrocytes.
- Caution should be exercised in cases of alcoholism and intestinal inflammatory conditions.
- Caution is needed when giving to patients with peptic ulcers.
- The use of oral iron preparations can lead to a darkening of stool color, which is normal and requires no action. This will not interfere with tests for hidden blood in the stool. Therefore, treatment does not need to be discontinued during such tests.

- In anemia due to infection or malignancy, the iron is stored in the reticuloendothelial system and becomes mobilized and utilized after treatment of the primary disease.
- Should not be taken with milk.
- Accidental ingestion or swallowing of iron-containing products in children can lead to fatal poisoning. Patients should be advised to contact a doctor or poison control center immediately in case of overdose.

Due to the presence of sugar and sorbitol, patients with rare hereditary fructose intolerance, glucose-galactose malabsorption, or sucrose-isomaltase deficiency should not use this medication.

Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed).

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

- Interactions that may occur when taking divalent iron-containing preparations with food and certain medications (e.g., tetracyclines) are not expected with SANTAFER® since it contains a trivalent iron-hydroxy polymaltose complex. However, it may interact with calcium-containing preparations, so at least a 2-hour interval should be maintained between taking them.

When taken with levothyroxine-containing medications, SANTAFER® may reduce its absorption. Therefore, the two medications should be taken at least 2 hours apart.

4.6 Pregnancy and Lactation

General Advice

Pregnancy Category: A

Despite this pregnancy category, the final decision on whether the pregnant woman should use the medication should be made by the physician after a detailed benefit-risk assessment, taking into account the gestational week, the woman's existing/diagnosed conditions, and other factors.

Although the risk categories assist healthcare professionals in understanding the potential risks of a medication during pregnancy, the physician's judgment is paramount.

Women of Childbearing Potential / Contraception

There is no information indicating that SANTAFER® should not be used in women of childbearing potential.

Pregnancy

Used as an iron supplement during pregnancy.

Well-conducted epidemiological studies have shown that the Iron III Hydroxide Polymaltose Complex does not have adverse effects on pregnancy or on the health of the fetus/newborn. SANTAFER® can be used during pregnancy after consultation with a doctor.

Lactation

Iron passes into breast milk. The transfer is not affected by the mother's current iron status or the amount of iron obtained from food. Therefore, giving iron supplements to a breastfeeding mother will not cause iron intoxication in the infant or resolve existing iron deficiency in the baby. SANTA FER® can be used during lactation after consulting a doctor.

Fertility

There is no effect on fertility.

4.7 Effects on Ability to Drive and Use Machines

There is no effect on the ability to drive or use machines.

4.8 Undesirable Effects

Very Common ($\geq 1/10$); Common ($\geq 1/100$ to $< 1/10$); Uncommon ($\geq 1/1,000$ to $< 1/100$); Rare ($\geq 1/10,000$ to $< 1/1,000$); Very Rare ($< 1/10,000$); Unknown (cannot be estimated from available data)

Immune System Disorders

Very Rare: Allergic reactions, asthma

Nervous System Disorders

Uncommon: Headache

Gastrointestinal Disorders

Uncommon: Fullness, epigastric heaviness, nausea, constipation, diarrhea, abdominal pain, vomiting, reversible discoloration of teeth

Skin and Subcutaneous Tissue Disorders

Uncommon: Urticaria, skin rash, exanthema, itching

Very Rare: Localized skin reactions

Kidney and Urinary Tract Disorders

Rare: Change in urine color

Note: Changes in stool color due to iron are commonly observed.

Iron III Hydroxide Polymaltose does not cause undesirable side effects such as tooth staining or a metallic taste in the mouth, which can occur with iron salts containing divalent ions.

Reporting Suspected Adverse Reactions

It is very important to report suspected drug adverse reactions after marketing authorization. Reporting allows for continuous monitoring of the benefit/risk balance of the drug. Healthcare professionals must report any suspected adverse reactions to the Turkey Pharmacovigilance Center (TÜFAM).

(Website: www.titck.gov.tr; Email: tufam@titck.gov.tr; Tel: 0 800 314 00 08; Fax: 0 312 218 35 99)

4.9. Overdose and Treatment

Acute iron poisoning is rare in adults but more common in young children.

An overdose of more than 20 mg per kilogram of body weight is potentially dangerous. In children, taking a total of 0.5 g of iron can cause life-threatening conditions, and doses of 1-2 g can be fatal.

Four characteristic phases may be observed in poisoning. In the first 6 hours after ingestion, nausea, vomiting, and diarrhea are seen. At higher doses (above 20 mg/kg), hypotension, shock, acidosis, and convulsions may occur. The second phase may show some improvement in mild cases. The third phase (12-18 hours later) may show signs of liver damage, tubular necrosis, cardiovascular shock, and coagulopathy. In the fourth phase (2-6 weeks later), esophageal, gastric, and duodenal stenosis may develop.

Treatment:

If a high dose is taken, gastric lavage should be performed, or if this is not possible, the patient should be induced to vomit. Further measures may include washing out the intestines. If the serum iron concentration is 3.5-5 mg/L (63-85 mmol) and there are strong clinical signs of iron poisoning, chelation therapy (Desferoxamine) should be administered to stimulate iron excretion via the kidneys.

Desferoxamine is given intravenously at 15 mg/kg/hour, with a maximum dose of 80 mg/kg/24 hours. Chelating agents such as sodium-EDTA may also be used.

In cases of shock, intravenous infusion should be used for support.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Antianemic preparations, Trivalent iron preparations

ATC code: B03AB05

Iron is present in all cells of the body and plays a vital role in life functions. Ionic iron is part of enzymes (such as cytochrome oxidase, xanthine oxidase, succinate dehydrogenase) involved in energy transfer. In iron deficiency, the lack of these vital functions becomes apparent. The administration of Iron III Hydroxide Polymaltose Complex helps to alleviate the decrease in blood formation caused by iron deficiency anemia by restoring iron through the Iron III ion.

5.2. Pharmacokinetic Properties

General properties

Absorption:

SANTA FER® is rapidly absorbed from the gastrointestinal system after oral administration. The amount of iron absorbed depends on the individual's level of iron deficiency. The greater the deficiency, the higher the absorption.

Distribution:

The absorbed iron is used in the synthesis of hemoglobin and myoglobin or is transported to iron stores. In this way, the symptoms of iron deficiency are alleviated.

Biotransformation:

No relevant information has been reported.

Elimination:

Iron that is not absorbed from the gastrointestinal tract is excreted via the feces.

Linearity/Non-linearity:

No relevant information has been reported.

5.3 Preclinical Safety Data

Traditional safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity studies do not present any specific hazards to humans.

In animal studies conducted with mice and rats, no LD50 value could be determined for the Iron III Hydroxide Polymaltose complex when iron was orally administered at doses up to 2000 mg per kilogram of body weight.

6. PHARMACEUTICAL CHARACTERISTICS

6.1 List of Excipients

Sucrose

Sorbitol 70% (E420)

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Cream flavor

Deionized water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Storage Precautions

Store below 25°C at room temperature.

6.5 Nature and Contents of the Packaging

The product is presented in a cardboard box, with a 150 ml amber-colored glass bottle with a plastic tamper-proof cap, a 5 ml graduated plastic spoon, and an instruction leaflet.

6.6 Disposal of Unused Medicinal Product and Other Special Precautions

Unused products or waste materials should be disposed of in accordance with the "Regulation on the Control of Medical Waste" and the "Regulation on the Control of Packaging and Packaging Waste".

7. MARKETING AUTHORIZATION HOLDER

Santa Farma Ilac San. A.S.

Halide Edip Adivar Mahallesi, Boru Cicegi Sokak. No: 16 Sisli- Istanbul, Turkey

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8. MARKETING AUTHORIZATION NUMBER

205/28

9. INITIAL MARKETING AUTHORIZATION DATE / MARKETING AUTHORIZATION RENEWAL DATE

Initial authorization date: 09.02.2005

Authorization renewal date: 09.02.2010

10. PACKAGE LEAFLET RENEWAL DATE
