

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SANTAFER® 100 mg/2 ml IM Ampoule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each 2 ml ampoule contains 100 mg of elemental iron, equivalent to 322.58 mg of iron III hydroxide polymaltose complex.

Excipients:

Injection water

3. PHARMACEUTICAL FORM

Injection solution

Dark red-brown solution

4. CLINICAL FEATURES

4.1. Therapeutic Indications

SANTAFER® is indicated for:

- Iron deficiency anemia occurring in cases of impaired iron absorption from the gastrointestinal tract,
- Iron deficiency anemia in patients with active gastrointestinal bleeding,
- Iron deficiency anemia in patients with total or subtotal gastrectomy,
- Iron deficiency anemia in patients who cannot tolerate oral iron therapy,
- Iron deficiency anemia that is resistant to oral iron therapy,
- Conditions requiring rapid provision of iron,
- Iron deficiency in patients with chronic renal failure, whether dialyzed or not, who are receiving erythropoietin (EPO) therapy.

SANTAFER® should not be used in the first trimester of pregnancy.

It may be used in the second and third trimesters if deemed necessary by the physician.

4.2. Posology and Method of Administration

Posology:

For adults, the recommended dose is 1 ampoule (100 mg) per day.

Lower doses are recommended for children based on age and weight.

The duration of treatment is determined by the physician through monitoring of hemoglobin levels. After hemoglobin levels return to normal, treatment should continue for as long as the physician deems necessary to replenish iron stores.

Due to insufficient clinical experience, the use of parenteral iron preparations is not recommended in children under the age of 14.

During the treatment, oral iron intake should be discontinued.

Dosage Frequency and Duration:

For adults, the daily dose is 1 ampoule (100 mg of elemental iron).

The maximum daily dose for adults is 2 ampoules (200 mg of elemental iron).

Method of Administration:

SANTAFER® should only be administered intramuscularly (IM) and deep.

Special Population Information:**Renal/Liver Insufficiency:**

SANTAFER® is used in patients undergoing hemodialysis due to chronic renal failure and receiving erythropoietin (EPO) until hemoglobin reaches 11.5 g/dL or ferritin is greater than 500 ng/dL.

SANTAFER® should not be used in severe liver or kidney failure.

Pediatric Population:**Maximum Daily Dosages:**

Children up to 5 kg: 0.5 ml (1/4 ampoule, 25 mg of elemental iron)

Children between 5-10 kg: 1.0 ml (1/2 ampoule, 50 mg of elemental iron)

Geriatric Population:

Normal doses can be used; no dose adjustment is necessary.

4.3. Contraindications

SANTAFER® should not be used in:

- Individuals with known hypersensitivity to any of the active or excipient ingredients.
- Anemias that do not involve iron deficiency (e.g., hemolytic anemia).
- Iron overload conditions (e.g., hemochromatosis, chronic hemolysis).
- Hypersensitivity to iron or iron metabolism disorders (e.g., lead anemia, sidero-acrestic anemia).
- Thalassemia.
- Severe liver and kidney diseases.
- Acute phase of renal infections.
- Intravenous use.
- Uncontrolled hyperparathyroidism.
- Bronchial asthma.
- Progressive chronic polyarthritis.
- Alcoholism.

4.4. Special Warnings and Precautions for Use

Rarely, anaphylactic-type reactions may occur due to hypersensitivity to parenteral iron. Therefore, parenteral iron therapy should only be used in patients where oral treatment is insufficient. It is useful to test for sensitivity with a test dose (0.5 ml IM) before the full administration.

Epinephrine and glucocorticoids should be readily available in case of a reaction.

Extra caution should be taken in patients with a tendency to allergies.

Patients with liver or kidney failure and those with allergies should be warned.

Patients with angiocardomyopathy may experience an increased incidence of cardiovascular complications.

Special caution should be exercised with patients who have bronchial asthma, especially those with low iron-binding capacity or folic acid deficiency, as they may be at risk for allergic or anaphylactic reactions.

Parenteral iron can adversely affect bacterial or viral infections, so SANTAFER® should be used with caution in patients with acute or chronic infections who have elevated ferritin levels.

In anemia due to infection or malignancy, the iron administered is stored in the reticuloendothelial system and, following the treatment of the primary condition, is mobilized and used.

Accidental ingestion of iron-containing products in children can cause fatal poisoning. Store the product out of the reach of children. In case of overdose, patients should be advised to contact a doctor or the National Poison Control Center (UZEM).

4.5. Interactions with Other Medicinal Products and Other Forms of Interaction:

As with all parenteral iron preparations, SANTAFER® can reduce the absorption of oral iron, so it should not be used simultaneously with oral iron preparations. Oral iron therapy should begin at least 1 week after the last injection.

Concurrent use with ACE inhibitors (e.g., Enalapril) may increase the systemic effects of parenteral iron preparations.

4.6. Pregnancy and Lactation

General advice:

Pregnancy category: C

Despite this pregnancy category, the healthcare provider should make the final decision on whether to use the medication based on a detailed benefit-risk assessment considering the gestational week, the patient's existing/diagnosed condition, and other factors.

Risk categories assist healthcare personnel in understanding the potential risks of the drug during pregnancy, but the provider's evaluation is essential.

Women of childbearing potential/Contraception

Well-managed epidemiological studies have not shown any adverse effects of SANTAFER® on pregnancy or the health of the fetus/newborn.

SANTAFER® can be used during pregnancy.

Pregnancy

Especially in the 2nd and 3rd trimesters, the increased iron requirements may lead to iron deficiency, so iron supplementation is recommended.

SANTAFER can be used during pregnancy after consulting a healthcare provider.

Lactation period

Iron is passed into breast milk. This transition does not change based on the mother's current iron levels or the amount of iron she consumes through food. Therefore, providing iron supplements to a breastfeeding mother will not cause iron intoxication in the infant or resolve existing iron deficiency in the baby. It can be used after consulting a healthcare provider.

Fertility

There is no effect on fertility.

4.7. Effects on the ability to drive and use machines

There is no effect on the ability to drive and 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 the available data)

Immune system disorders

Rare: Anaphylactic reaction

Respiratory, thoracic, and mediastinal disorders

Rare: Dyspnea (difficulty breathing)

Gastrointestinal disorders

Rare: Abdominal discomfort, nausea, vomiting

Skin and subcutaneous tissue disorders

Rare: Skin rashes, urticaria (hives)

Musculoskeletal, connective tissue, and bone disorders

Rare: Arthralgia (joint pain), myalgia (muscle pain)

General disorders and administration site conditions

Rare: Local skin reactions at the injection site, sometimes sterile abscesses, pain at the injection site, swelling of lymph nodes, fever, headache, dizziness

Reporting of suspected adverse reactions

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal

product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9. Overdose and treatment

To date, no overdose with the iron III hydroxide polymaltose complex has been reported. An overdose may manifest as hemosiderosis due to acute iron overload. Chronic iron overload may present as hemochromatosis. This can occur in cases of misdiagnosed iron deficiency anemia that do not respond to treatment. Conditions like thalassemia may require treatment (e.g., I.V. deferoxamine administration).

SANTAFER® cannot be removed by hemodialysis due to its high molecular weight when administered in high doses. Periodic serum ferritin checks may help recognize iron accumulation early.

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 poses a potential risk. In children, ingesting a total of 0.5 g of iron may lead to life-threatening situations, and doses of 1-2 g may result in fatal outcomes.

Poisoning may progress through four characteristic phases: In the first 6 hours after ingestion, nausea, vomiting, and diarrhea occur. In high doses (over 20 mg/kg), hypotension, shock, acidosis, and convulsions may be observed. The second phase may show some improvement in mild cases. In the third phase (12-18 hours later), liver damage, tubular necrosis, cardiovascular shock, and coagulopathy (blood clotting disorders) are possible. The fourth phase (within 2-6 weeks) may involve the development of esophageal, stomach, and duodenal stenosis (narrowing).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Trivalent Parenteral Iron Preparations

ATC code: B03AC

Mechanism of action:

SANTAFER® is developed for the treatment and prevention of iron deficiency. Iron is a cofactor for various enzymes responsible for energy transport and is found in hemoglobin and myoglobin, which are necessary for oxygen transport and usage.

5.2. Pharmacokinetic properties

General properties:

In the iron III hydroxide polymaltose complex molecule, the iron III hydroxide cores are surrounded by non-covalently bound polymaltose molecules. In this way, ionic iron is not released in the physiological environment, ensuring that it is absorbed in its active form.

Absorption:

Iron in the iron III hydroxide polymaltose complex, when administered parenterally, passes from the application site into the bloodstream and is utilized by the body.

The normal daily iron requirement for an adult human is 0.5-1 mg. This amount increases to 1-2 mg per day during menstruation in women.

Distribution:

In normal adults, 70% of the body's total iron is found in red blood cells in the form of hemoglobin. 10-20% is stored in ferritin and hemosiderin, and around 10% is found in myoglobin. Less than 1% is present in trace amounts in cytochromes and other iron-containing enzymes.

Biotransformation:

No relevant information has been reported.

Elimination:

The portion of iron that is not absorbed is excreted through feces.

Linearity/Non-linearity:

No relevant information has been reported.

5.3. Preclinical safety data

LD50 > 250 mg/kg (in mice)

LD50 > 100 mg/kg (in rats)

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Injection water

6.2 Incompatibilities

There is no evidence that SANTAFER® is incompatible with any drugs or substances.

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

Ampoule, amber-colored, Type I glass

6.6 Disposal of unused medicinal products 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:

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8. MARKETING AUTHORIZATION NUMBER

[To be completed nationally]

9. INITIAL MARKETING AUTHORIZATION DATE / MARKETING AUTHORIZATION RENEWAL DATE

[To be completed nationally]

10. PACKAGE LEAFLET RENEWAL DATE

[To be completed nationally]