

PATIENT INFORMATION LEAFLET

SANTAFER® 100 mg/2 ml IM Ampoule

It is administered by deep intramuscular injection.

- **Active Substance:** Each 2 ml ampoule contains 322.58 mg of Iron III Hydroxide Polymaltose Complex, equivalent to 100 mg of elemental iron.
- **Excipients:** Injection water.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed specifically for you. Do not give it to others.*
- *When you visit a doctor or hospital, inform them that you are using this medicine.*
- *Follow the instructions exactly as described in this leaflet. Do not use a higher or lower dose than the one prescribed for you.*

This Package Leaflet contains:

1. ***What is SANTAFER® and what is it used for?***
2. ***What should be considered before using SANTAFER®?***
3. ***How to use SANTAFER®?***
4. ***What are the possible side effects?***
5. ***How to store SANTAFER®?***

1. What is SANTAFER® and what is it used for?

SANTAFER® is provided in boxes containing 5 ampoules of 2 ml each.

SANTAFER® contains Iron III Hydroxide Polymaltose Complex as the active ingredient.

It is used in the following conditions:

- When anemia develops due to impaired absorption of iron from the gastrointestinal system,
- When anemia develops due to iron deficiency caused by severe gastrointestinal bleeding,
- When anemia develops due to iron deficiency after total or partial gastrectomy (removal of part or all of the stomach),
- In patients with iron deficiency anemia who cannot tolerate oral iron,
- In patients with iron deficiency anemia for whom oral iron therapy is ineffective,
- When rapid replenishment of iron stores is required, as decided by your doctor,

- In patients with chronic kidney failure (dependent or independent of dialysis) who are receiving erythropoietin (EPO) therapy and have iron deficiency.

SANTAFER® should not be used during the first trimester of pregnancy. It may be used during the second and third trimesters only if deemed necessary by the physician.

2. What should you consider before using SANTAFER®?

Do not use SANTAFER® if:

- You have iron overload (e.g., hemochromatosis, chronic hemolysis),
- You are hypersensitive to iron,
- You have an iron utilization disorder (e.g., lead anemia, sideroachrestic anemia),
- You have thalassemia,
- You have progressive chronic joint inflammation (e.g., rheumatoid arthritis),
- You have alcohol dependency,
- You have uncontrolled high parathyroid hormone levels,
- You have severe liver or kidney disease,
- You are in the first three months of pregnancy,
- You have bronchial asthma,
- You need intravenous administration (do not use intravenously).

Use SANTAFER® with caution if:

- You have an allergic condition (especially if you have bronchial asthma with low iron binding capacity and/or folic acid deficiency, as these patients may be at risk for allergic or anaphylactic reactions),
- Parenteral iron may adversely affect bacterial or viral infections, so SANTAFER® should be used with caution in patients with elevated ferritin levels and acute or chronic diseases,
- In children, accidental ingestion of iron-containing products can lead to fatal poisoning. Keep out of reach of children. In case of overdose, immediately contact your doctor or the National Poison Control Center (UZEM).

"If any of these warnings apply to you, even in the past, please consult your doctor."

Food and beverage interactions:

No interactions with food or beverages have been reported.

Pregnancy:

Consult your doctor or pharmacist before using this medication.

SANTAFER® can be used for iron supplementation during pregnancy.

If you discover you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breastfeeding:

Consult your doctor or pharmacist before using this medication.

Iron passes into breast milk, so careful use is required while breastfeeding, considering potential effects on the baby.

Driving and machine use:

There are no effects on driving or machine use.

Important information about some of the ingredients in SANTA FER®:

No warnings are required for the excipients based on the route of administration and dosage.

Use with other medications:

Do not use with oral iron supplements.

Some blood pressure-lowering drugs (e.g., Enalapril) may increase the systemic effects of parenteral iron preparations.

If you are currently taking or have recently taken any prescribed or over-the-counter medication, please inform your doctor or pharmacist about them.

3. How to use SANTA FER®**Instructions for proper use and dosage/frequency of administration:**

For adults: The daily dose is 1 ampule (2 ml, 100 mg). The maximum daily dose is two ampules (4 ml, 200 mg).

Treatment duration is determined by the doctor based on monitoring hemoglobin levels. Once hemoglobin levels reach normal limits, the treatment continues as deemed necessary by the doctor to replenish iron stores.

Do not stop the treatment early, as this will result in incomplete treatment and insufficient recovery.

Due to insufficient clinical experience, parenteral iron preparations are not recommended for children under 14 years of age.

Oral iron supplementation should be discontinued during the treatment.

Method and route of administration:

SANTA FER® is administered only by deep intramuscular injection.

Use in different age groups:**Use in children:**

Lower doses are recommended based on age and weight.

For children up to 5 kg: 0.5 ml (1/4 ampule, 25 mg elemental iron) per day.

For children between 5-10 kg: 1.0 ml (1/2 ampule, 50 mg elemental iron) per day.

Use in elderly:

The prescribed dose for adults should be followed.

Special use cases:**Kidney/Liver insufficiency:**

SANTAFER® is used in patients with chronic kidney failure undergoing hemodialysis and receiving erythropoietin (EPO) until hemoglobin reaches 11.5 g/dL or ferritin exceeds 500 ng/dL.

The above doses can be used in these cases. However, it should not be used in severe liver and kidney insufficiency.

If you feel that the effect of SANTAFER® is too strong or too weak, consult your doctor or pharmacist.

If you have used more SANTAFER® than you should:

SANTAFER® is administered under medical supervision, so the possibility of administering an excessive dose is unlikely. However, if you experience any serious unexpected effects, immediately contact your doctor. Symptoms of overdose are more severe versions of the common side effects seen with SANTAFER®.

If you have used more than the required amount of SANTAFER®, consult your doctor or pharmacist.

If you forget to use SANTAFER®:

If you miss a dose, take it as soon as you remember, and then continue with the regular schedule.

Do not take a double dose to make up for a forgotten dose.

Effects when treatment with SANTAFER® is discontinued:

There are no known effects when treatment with SANTAFER® is stopped.

4. Possible side effects:

Like all medications, SANTAFER® can cause side effects in people who are sensitive to any of its ingredients.

If any of the following occur, stop using SANTAFER® immediately and inform your doctor or go to the nearest hospital emergency department:

- Swelling of the hands, feet, wrists, face, lips, or especially swelling of the mouth or throat that makes swallowing or breathing difficult.
- Itchy red bumps on the body.

These are very serious side effects.

If you experience any of these, it means you have a severe allergic reaction to SANTAFER®. You may require urgent medical attention or hospitalization.

These very serious side effects are quite rare.

If any of the following occur, immediately contact your doctor or go to the nearest emergency department:

- Shortness of breath
- Local reactions at the injection site and sometimes sterile abscesses (redness, swelling, pain)

These are serious side effects that may require immediate medical intervention. Serious side effects are rare.

If you notice any of the following, inform your doctor:

- Redness, sweating, chills, and fever
- Chest and back pain
- Pain at the injection site
- Redness or swelling at the injection site
- Abdominal pain
- Nausea, vomiting
- Headache, dizziness
- Joint and muscle pain
- A feeling of stiffness in the arms, legs, or face
- Fainting
- Low blood pressure (dizziness, blurring of vision)
- Difficulty breathing
- Rash
- Swelling of lymph nodes
- Abdominal discomfort

These are mild side effects of SANTAFER®. These side effects generally disappear when the dose is reduced or treatment is stopped.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting side effects:

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.

5. Storage of SANTAFER®

Store SANTAFER® in a place out of the sight and reach of children, and in its original packaging.

Store at room temperature below 25°C.

Use in accordance with the expiration date.

Do not use SANTAFER® after the expiration date printed on the box.

If you notice any damage to the product or packaging, do not use SANTAFER®.

Do not dispose of expired or unused medication in the trash! Dispose of it through the collection system designated by the Ministry of Environment and Urbanization.

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]