

PATIENT INFORMATION LEAFLET

SANTAFER® 50 mg / 5 ml Syrup

Taken orally.

- **Active Substance:** 1 ml of syrup contains 32.258 mg of iron(III) hydroxide polymaltose complex, equivalent to 10 mg of elemental iron.
- **Excipients:** Sucrose, sorbitol 70% (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), cream flavor, and deionized 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 available in a carton box, containing 150 ml of syrup in a amber-colored glass bottle, accompanied by a 5 ml graduated plastic spoon. It has a characteristic odor and appears as a dark red-brown syrup.

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

It is used for the treatment of iron deficiency anemia (anemia) and for the prevention of such anemias, as well as for the treatment of iron deficiency during pregnancy, breastfeeding, and childhood.

2. Before using SANTAFER®, what should you pay attention to?

Do NOT use SANTAFER® if you have:

- An allergy to iron or any of the excipients contained in the product,
- Iron overload conditions (such as hemochromatosis, chronic hemolysis),
- An allergy to iron,
- Anemia not associated with iron deficiency (such as hemolytic anemia).
- If you have a disorder of iron utilization (such as lead anemia, sideroachrestic anemia),
- If you have thalassemia (Mediterranean anemia),
- If you have progressive and chronic joint inflammation,
- If you have conditions that require regular blood transfusions,
- If you have HIV infection and your anemia due to iron deficiency has not been clinically confirmed,
- If you have severe liver and kidney diseases, do not use SANTAFER®.

Use SANTAFER® with caution in the following situations:

If you have a stomach ulcer, your doctor will decide whether you should use SANTAFER®.

During the use of oral iron medications, the color of the stool may darken, which is normal and does not require any precautions.

It will not cause errors when testing for hidden blood in the stool. Therefore, there is no need to stop the treatment during this examination.

It should be used with caution in cases of alcoholism and diseases that impair iron absorption from the intestines.

In anemia caused by various diseases or cancer, the iron that is absorbed is stored in the liver and becomes available for use only after the treatment of the disease or cancer and release from the liver.

Accidental ingestion/swallowing of iron-containing products by children can lead to fatal poisoning. Therefore, store this medicine out of reach of children. In case of overdose, contact your doctor or poison control immediately.

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

Use of SANTAFER® with food and drink:

SANTAFER® should be taken with meals or after meals.

It should not be taken with milk or calcium-containing products and medications. A minimum gap of 2 hours should be left between them.

Pregnancy:

Before using the medicine, consult your doctor or pharmacist.

SANTAFER® can be used during pregnancy as an iron supplement if recommended by your doctor.

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

Breastfeeding:

Before using the medicine, consult your doctor or pharmacist.

SANTAFER® can be used during breastfeeding as an iron supplement if recommended by your doctor.

Iron passes into breast milk. This passage does not change based on the mother's current iron levels or the amount of iron taken through food. Therefore, giving iron supplements to a breastfeeding mother will not cause iron poisoning in the baby nor eliminate existing iron deficiency in the baby.

Use of vehicles and machinery:

There is no effect on the use of vehicles and machinery.

Important information about some of the ingredients in SANTAFER®:

Due to the presence of sucrose and sorbitol (E420) in the product, if you have been told by your doctor that you have intolerance (inability to tolerate) to certain sugars, please contact your doctor before taking this medicine.

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

Use with other medications:

When taken with levothyroxine-containing medicines (used in the treatment of thyroid diseases), the absorption of SANTAFER® is impaired. Therefore, these two medications should be taken with at least a 2-hour gap.

If you are currently using or have recently used any prescribed or over-the-counter medications, please inform your doctor or pharmacist.

3. How to use SANTAFER®:

- **Instructions for appropriate use and dosage/frequency of administration:**

- SANTAFER® is taken with meals or after meals by adults, 1 dose (5 ml) 2-3 times a day.
- Use as directed unless otherwise recommended by your doctor.
- It should be used for the duration prescribed by the doctor. After the symptoms of iron deficiency have disappeared, it should be continued for at least one more month to replenish iron stores.

- **Route and method of administration:**

- SANTAFER® is for oral use only.
- It can be mixed with fruit or vegetable juices for easier consumption.

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

1 dose (5 ml) 1-2 times a day.

Use in the elderly:

The application in elderly individuals is the same as for adults.

Special usage situations:**Kidney/Liver failure:**

Do not use SANTAFER® in cases of severe liver or kidney disease.

If you have the impression 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:

Taking too much may cause diarrhea, stomach pain, and vomiting, and in more severe cases, metabolic acidosis (rapid and deep breathing, skin turning warm and red due to dilated blood vessels, low blood pressure), severe muscle spasms (involuntary sudden muscle contractions), and coma (deep unconsciousness).

If you have used more SANTAFER® than you should, consult a doctor or pharmacist.

If you forget to use SANTAFER®:

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

Effects that may occur when you stop using SANTAFER®:

There are no known effects after stopping treatment.

4. Possible side effects:

Like all medicines, SANTAFER® may cause side effects in individuals who are sensitive to any of its ingredients.

The side effects are classified as follows:

Very common	: May affect more than 1 in 10 patients.
Common	: May affect more than 1 in 100 patients but fewer than 1 in 10 patients.
Uncommon	: May affect more than 1 in 1,000 patients but fewer than 1 in 100 patients.
Rare	: May affect more than 1 in 10,000 patients but fewer than 1 in 1,000 patients.
Very rare	: May affect fewer than 1 in 10,000 patients.
Unknown	: Cannot be estimated from the available data.

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

- Difficulty breathing, swelling of the face, lips, tongue, or throat, sudden drop in blood pressure, widespread and severe redness, itching, or hives (urticaria).

These are all very serious side effects.

If you experience any of these, you may be having a serious allergic reaction to SANTAFER®.

You may need urgent medical attention or hospitalization.

These very serious side effects are very rare.

Very common:

- Changes in stool color.

Uncommon:

- Headache.
- Feeling of fullness.
- Nausea.
- Vomiting.
- Constipation.
- Diarrhea.
- Abdominal discomfort.
- Abdominal pain.
- Itchy hives, rash, or redness on the skin.
- Itching.

Uncommon:

- Change in urine color.

Very rare:

- Asthma (a condition characterized by difficulty breathing due to narrowing of the airways).
- Skin reactions.

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

Reporting of side effects:

If you experience any side effects listed or not listed in this leaflet, talk to your doctor, pharmacist, or nurse. You can also report any side effects you experience by clicking on the "Drug Side Effect Notification" icon on the website www.titck.gov.tr or by calling the Drug

Side Effect Notification Line at 0 800 314 00 08, which is operated by the Turkish Pharmacovigilance Center (TÜFAM). Reporting side effects will help improve understanding of the safety of the medicine you are using.

5. Storage of SANTAFER®:

Store SANTAFER® in a place where children cannot see or reach it.

Store at room temperature, below 25°C.

Use in accordance with the expiration date.

Do not use SANTAFER® after the expiration date on the packaging.

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

Do not dispose of expired or unused medicines in the trash! Dispose of them via the collection system specified by the Ministry of Environment and Urbanization.

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