

PATIENT INFORMATION LEAFLET

SANTAFER Fort 100 mg/ 0.35 mg Film Coated Tablets

Administered orally

- **Active Substance:** Each film coated tablet, contains 322.58 mg Iron III Hydroxide Polymaltose Complex, equivalent to 100 mg elemental iron and 0.350 mg folic acid.
- **Excipients:** Contains crospovidone, polyethyleneglycol 6000, PVPK30, magnesium stearate, microcrystalline cellulose. The coating contains polyvinyl alcohol, PEG 3350, titanium dioxide (E 171), talc, red iron oxide (E172), yellow iron oxide (E172) and Ponceau 4R Lac (E124).

Please read the PATIENT INFORMATION LEAFLET carefully before starting the use of this pharmaceutical, since it contains important information for you.

- *Keep the patient information leaflet. You may need to read it again later.*
- *In case you have additional questions, please consult to your physician or your pharmacist.*
- *This pharmaceutical has been personally prescribed for you; do not give it to other persons.*
- *During the use of this pharmaceutical, tell your physician that you are using this pharmaceutical during your visit to the physician or hospital.*
- *Please comply with the instructions herein. Do not use a dose, **lower or higher** than the recommended dose.*

In these Patient Information Leaflet:

- 1. What is SANTAFER FORT and what is it used for?**
- 2. Issues prior to the use of SANTAFER FORT**
- 3. How is SANTAFER FORT used?**
- 4. What are the possible side effects?**
- 5. Storage of SANTAFER FORT**

Sections are presented.

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

- SANTAFER FORT, is a film coated tablet, containing iron III hydroxide polymaltose complex and folic acid. Each film coated tablet contains iron III hydroxide polymaltose complex, equivalent to 100 mg elementary iron and 0.350 mg folic acid and presented in packages, containing 30 film coated tablets. Tablets are red-brown, round, biconvex film-coated tablets. With oral administration, used in iron deficiency or in case there is a need for iron supplementation, which is found in all cells in body and which has considerable role in many physiological processes of vital importance, such as blood production and transport of oxygen to tissues.

SANTAFER FORT is used for,

- Prevention and treatment of anemia related to iron deficiencies of various causes,
- In particular, for iron supplement and iron deficiency treatment in pregnancy and breastfeeding periods.

2. Issues prior to the use of SANTAFER FORT

DO NOT USE SANTAFER FORT in case of following

If you;

- Are hypersensitive to iron or any of the excipients.
- Have iron overloading (hemochromatosis, chronic hemolysis),
- Are allergic (hypersensitive) to iron
- Have other anemia which is not accompanied by iron deficiency (such as hemolytic anemia),
- Have iron use disorder (lead anemia, sidero-achrestic anemia),
- Have thalassemia (Mediterranean anemia),
- Have progressive and chronic arthritis,
- Have conditions requiring regular and continuous blood transfusion,
- Have HIV infection and if your iron deficiency anemia is not clinically proven,
- Have severe liver and kidney diseases.

USE SANTAFER FORT WITH CAUTION in case of following

If you have gastric ulcer, your physician will decide whether to use SANTAFER FORT or not.

During administration of oral iron formulations, the color of stool may darken; this is normal and does not require any measures.

Does not cause false positive results during tests for occult blood in stool. Therefore, there is no need to discontinue treatment during this test.

Caution must be exercised in case of alcoholism and diseases, which disturb iron absorption from intestines.

In various diseases and in cancer-related anemia, the administered iron is stored in liver, yet following the treatment of diseases and cancer, it departs from liver and become useable.

Accidental administration of iron-containing products cause fatal (deadly) toxicity in children. Therefore, the medicine should be stored out of reach of children. In case of overdose promptly consult your physician or poison control center.

“In case these warnings apply to you, even if for any period in the past, please consult to your physician.”

The use of SANTAFER FORT with food and beverage

SANTAFER FORT must be taken with or after meals.

SANTAFER FORT must not be taken with milk. It must not be taken with products or drugs containing calcium. At least 2 hours interval must be taken between iron formulations and milk or calcium products.

Pregnancy

Please consult your physician or pharmacist before using the pharmaceutical.

You may use SANTAFER FORT as an iron supplement in pregnancy in case your physician recommends.

Consult your physician or your pharmacist immediately in case you realize that you are pregnant during treatment.

Lactation

Please consult your physician or pharmacist before using the pharmaceutical.

You may use SANTAFER FORT as an iron supplement in lactation in case your physician recommends.

Iron is excreted into breast milk. This excretion does not change according to the existing iron level of mother and the quantity of iron taken with food. Therefore, the administration of iron formulations to lactating mother, does not yield an iron intoxication in the baby or the removal of existing iron deficiency in the baby.

Driving and Operating Machinery

SANTAFER FORT has no effects on the ability to drive vehicles or to operate machinery.

Important information concerning some of the excipients contained in SANTAFER FORT

Ponceau 4R contained in SANTAFER FORT, may cause allergic reactions.

Use with other pharmaceuticals

Iron III hydroxide polymaltose complex does not have any ionic interaction with food or concomitant drugs (tetracyclines, antacids).

When taking drugs containing levothyroxine (used to treat thyroid diseases) with SANTAFER FORT, two drugs should be taken at least 2 hours apart as absorption will be impaired.

In case you are using or have recently used any prescription or nonprescription pharmaceuticals please report these to your physician or your pharmacist.

3. How is SANTAFER FORT used?

- **Instructions for appropriate usage and dosage/application frequency:**

Recommended normal dose for SANTAFER FORT is 1 tablet a day.

If deemed appropriate by physician, 1 tablet may be taken two times a day.

- **Administration route and method:**

Administered orally

- **Different age groups**

Use in children:

Is not used in children.

In order to provide a better dose adjustment in children, elementary iron 10 mg/ ml Syrup and elementary iron 50 mg/1 ml oral drops forms may be used.

Use in elderly:

The dose determined for adults is used.

- **Special usage conditions:**

Renal/Hepatic failure:

Do not use SANTAFER FORT in case of severe liver and kidney diseases.

Follow these instructions, unless you have been given different directions by your physician.

- Do not forget to take your medication on time.
- Your physician will tell you the duration of your treatment with SANTAFER FORT. Do not prematurely discontinue treatment; because the duration of treatment depends on the status of iron metabolism and normalization of blood values. After normal blood values are

provided it is recommended to maintain treatment at least for 1 month for filling of iron stores in body.

In case you have an impression that SANTAFER FORT is too weak or too strong, talk to your physician or your pharmacist.

If you used more SANTAFER FORT than you should have:

Diarrhea, stomachache and vomiting may be seen with overdose of SANTAFER FORT and in more severe cases metabolic acidosis (rapid and deep breathing, warm and red skin of the skin due to vasodilatation of the vessels, low blood pressure), severe muscle spasms (sudden muscle contraction that develops involuntarily suddenly in the muscle or muscle group) and coma (deep state of unconsciousness) may be seen.

In case, you used SANTAFER FORT at an amount that is more than you were supposed to, talk to a physician or a pharmacist.

If you forget to use SANTAFER FORT

Take your tablet as soon as you remember and continue as before.

Do not take double doses to compensate for forgotten doses.

Effects which may occur on termination of treatment with SANTAFER FORT

N/A.

4. What are the possible side effects?

Like all pharmaceuticals, side effects can be seen in people that are sensitive to the contents of SANTAFER FORT.

The side effects have been described as shown in the following categories:

Very Common	: may affect more than 1 in 10 people
Common	: may affect up to 1 in 10 people
Uncommon	: may affect up to 1 in 100 people
Rare	: may affect up to 1 in 1,000 people
Very rare	: may affect up to 1 in 10,000 people
Not known	: frequency cannot be estimated from the available data

If any of the following occurs, stop taking SANTAFER FORT and inform your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital.

- Swelling of hands, feet, ankles, face, lips or in particular hindrance of swallowing or breathing due to swelling of mouth or throat.
- Severe rashes

All these are serious side effects.

In case you have one of these, it means that you have a serious allergy to SANTAFER FORT. You may need emergency medical attention or hospitalization.

Serious side effects are seen very rarely.

Very Common

- Stool discoloration

Uncommon

- Headache
- Feeling of gastrointestinal fullness
- Nausea
- Vomiting
- Constipation
- Diarrhea
- Tooth discoloration
- Abdominal discomfort
- Abdominal pain
- Itchy skin, rash, redness
- Itchiness

Rare

- Urine discoloration

Very rare

- Asthma (Disease characterized by laboured breathing due to narrowing of the respiratory tract)
- Skin reactions

In case you observe any side effects, which are not mentioned in these usage instructions, please inform your physician or your pharmacist.

5. Storage of SANTAFER FORTE

Keep SANTAFER FORT away from reach and sight of children and in package.

Do not purchase the cut or opened packages.

Store in the original package.

Store below 25°C.

Use in compliance with expiry date.

Do not use SANTAFER FORT after the expiry date on the package.

Marketing Authorization Holder:

SANTA FARMA ILAC SAN. A.S. H. Edip Adivar / Borucicegi Sokak No: 16 Sisli, Istanbul, Türkiye

Manufacturing site:

Kocaeli, Gebze, V (Kimya) Ihtisas OSB Erol Kiresepi Cad. No: 8, Dilovası, KOCAELI, Turkey

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