

SUMMARY of PRODUCT CHARACTERISTICS

1. NAME OF THE HUMAN MEDICINAL PRODUCT

SANTAFER Fort 100 mg/ 0.35 mg Film Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

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:

Ponceau 4R Lac (E124) (0.111 mg)

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets

Red-brown, round, biconvex film coated tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Supplementation of iron and folic acid requirement in pregnancy and lactation periods,
- The treatment of all iron deficiencies with different causes and anemias related to iron deficiency.

4.2. Posology and method of administration

Posology/frequency and duration of administration:

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.

The duration of treatment is determined by physician. Following clinical elimination of the symptoms of iron deficiency, it must be used for at least an additional month for replenishment of iron stores.

Method of administration:

SANTAFER FORT must be taken with or after meals.

Additional information for special populations

Renal/Hepatic failure:

SANTAFER FORT must not be used in case of severe liver and kidney diseases.

Pediatric population:

In pediatric population, elementary iron 10 mg/ ml syrup and elementary iron 50 mg/1 ml oral drops forms may be used.

Geriatric population:

Normal doses may be used, there is no need for dose adjustment.

4.3. Contraindications

- For persons with hypersensitivity to the active agent or any of the excipients.
- All anemias without iron deficiency (e.g.: Hemolytic Anemia)
- Iron overload (hemochromatosis, chronic hemolysis),
- Hypersensitivity to iron, iron use deficiency (lead anemia, sideroachrestic anemia)

- Thalassemia
- Severe liver or kidney diseases
- Regular and continuous blood transfusions,
- In patients with HIV infection, iron supplementary treatment must not be administered unless anemia related to iron deficiency is proven.

4.4. Special warnings and special precautions for use

- Anemia must always be treated under supervision by a physician.
- If the treatment is not successful (after 3 weeks the hemoglobin level does not increase approximately 2-3 g / dL), the treatment should be reconsidered.
- Patients, receiving repeated blood transfusion must be warned against iron overload, since iron is administered with erythrocyte.
- Caution must be exercised in patients with alcoholism and intestinal inflammation.
- Must be administered cautiously to patients with gastric ulcer.
- 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.
- In anemia, associated with infection or malignancy, administered iron is stored in reticuloendothelial system and is used with mobilization following the treatment of primary disease.
- It should not be taken with milk.
- Accidental administration of iron containing products cause fatal toxicity in children. In case of overdose the patients must be warned promptly to consult a physician or poison control center. Keep out of the reach of children.
- Ponceau 4R, contained in SANTA FER FORT, may cause allergic reactions.

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

Since iron III ion in iron III hydroxide polymaltose complex is complex ion, any ionic interaction with food or concomitant drugs (tetracyclines, antacids) is not expected.

However, due to the possibility of an interaction with formulations containing calcium, a time of at least 2 hours must be left between the administration of calcium and iron.

Since the absorption of levothyroxine containing products is impaired when taken with SANTA FER FORT, two drugs should be taken with a break of at least 2 hours.

Additional information on special populations

Pediatric population:

There are no special warnings regarding drug interactions in children.

4.6. Pregnancy and lactation

General recommendation

Pregnancy category: A

Despite this pregnancy category, the physician makes his final decision on whether the pregnant woman should use the drug or not; It should be given by making a detailed benefit-risk assessment according to the week of gestation, the present / detected disease and other characteristics of the pregnant woman.

Although the risk categories help the healthcare staff about the potential risk of the drug in pregnancy, the physician's assessment is essential.

Women with childbearing potential/ Contraception

There is no information about its use in women of childbearing potential.

Pregnancy

It is used as an iron supplement during pregnancy.

Well-managed epidemiological studies do not show that the Iron III Hydroxide Polimaltose complex has adverse effects on pregnancy or on the health of the fetus / newborn child.

SANTAFER FORT can be used during pregnancy after consulting a doctor.

Lactation

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. SANTAFER FORT may be used during lactation after consultation to physician.

Fertility

No effects of SANTAFER FORT on fertility have been determined.

4.7. Effects on ability to drive vehicles and operate machinery

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

4.8. Undesirable effects

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10.000$ to $< 1/1000$); very rare ($< 1/10.000$); unknown (unpredictable with the available data).

Immune System Disorders

Very rare: Allergic reactions, asthma

Nervous system disorders

Uncommon: Headache

Gastrointestinal diseases

Uncommon: Feeling of fullness, feeling of epigastric heaviness, nausea, constipation, diarrhea, abdominal pain, vomiting and reversible discoloration on teeth.

Skin and subcutaneous disorders

Uncommon: Urticaria, rashes, exanthem, itching

Very rare: Localized skin reactions

Renal and urine tract diseases

Rare: Change in urine colour

Note: Discoloration of stool may be frequently seen in connection with iron.

Iron III hydroxide polymaltose does not cause undesired effects, such as tooth coloring and metallic taste in mouth seen with bivalent ionized iron salt preparations.

4.9. Treatment of overdose

In the event of overdose, epigastric pain, diarrhea and vomiting may occur initially, and in more advanced cases metabolic acidosis, convulsions and coma may occur. In cases of overdose, It is recommended to use desferrioxamine (initially 1000 mg IV, then 500 mg every 4 hours for up to two doses) or calcium disodium EDTA (167 mg / m² every 4 hours as IM; as IV infusion for 8-24 hours or 1 mg / m² divided into every 12 hours).

Desferrioxamine has a teratogenic effect.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antianemic preparations, Iron and folic acid combination

ATC code: B03AD04

SANTAFER FORT contains iron III hydroxide polymaltose complex, equivalent to 100 mg elementary iron and 0.350 mg folic acid. This combination has been developed especially for the treatment and prophylaxis of iron deficiency in pregnancy and lactation. Iron is found in all cells in body and has vital functions. Ionic iron is present in the structure of enzymes (cytochrome oxidase, xanthin oxidase, succinic dehydrogenase), which play a role in energy transfer. In case of iron deficiency, the deficiency of these vital functions, is seen.

With the application of iron during pregnancy and lactation, the increasing iron requirement of the mother and infant are met and in case there is a deficiency, it is treated. Folic Acid (Vitamin B9) is transformed to tetrahydrofolate in vivo and plays a role in various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and related DNA synthesis and various amino acid transformations and formate forming and use.

Recommended Daily Allowance Quantities (RDA):

Age group	Iron (mg)	Folate (mcg/day)
Children		
0-6 months	6	65
7-12 months	10	80
1-3 years	10	150
4-6 years	10	200
7-10 years	10	200-300
Men		
11-14 years	12	300
15-18 years	12	400
19-50 years	10	400
51+	10	400
Women		
11-14 years	15	300
15-18 years	15	400
19-50 years	15	400
51+	10	400
Pregnant women	30	600
Lactating women	15	500

1 mcg folate is equivalent to 0.6 mcg folic acid.

Maximum daily allowable total amount

Age group	Folate (mcg/day)
Children	
0-6 months	UD
7-12 months	UD
1-3 years	300
4-6 years	400
7-10 years	400-600
Men & Women	
11-14 years	600
15-18 years	800
19-50 years	1000
51+	1000
Pregnant women	
≤ 18 years	800
19-50 years	1000
Lactating women	
≤ 18 years	800
19-50 years	1000

UD: Undefined

1 mcg folate is equivalent to 0.6 mcg folic acid.

5.2. Pharmacokinetic properties

Iron:

General characteristics

In Iron III hydroxide polymaltose complex molecule, iron III hydroxide cores are surrounded by polymaltose molecules which are bonded superficially with non-covalent bonds. Therefore, in physiological environment ionic iron is not released and its effective absorption is provided.

Absorption:

Iron is absorbed from intestines on duodenum and proximal jejunum. The absorption of the iron from intestines, varies from person to person and iron deficiency. Daily iron requirement of a normal adult is 0.5 to 1 mg. This value may increase to 1 to 2 mg per day in women during menstruation.

Distribution:

70 % of total iron in body is stored in red blood cells in the form of hemoglobin, 10-20 % stored in the form of ferritin and hemosiderin, and 10 % in myoglobin. Less than 1 % is found in trace quantities in cytochromes and other enzymes containing iron.

Metabolism:

No relevant information has been reported.

Elimination:

Non-absorbed part of iron is excreted in feces.

Folic acid:**General characteristics**

Folic acid is a member of B group of vitamins. Folic acid is reduced to tetrahydrofolate in vivo. Tetrahydrofolate is the coenzyme of various metabolic processes, including purine and pyrimidine nucleotides and therefore DNA synthesis; it has a role in some amino-acid transformations, format formation and use. Deficiency results in megaloblastic anemia.

Absorption:

Folic acid is rapidly absorbed from gastrointestinal tract, mainly from duodenum and jejunum and is transferred to portal circulation in unchanged form.

Distribution:

In plasma and liver it is transformed to metabolically active form 5-methyltetrahydrofolate. Folate metabolites undergo enterohepatic circulation. Folate is excreted into breast milk.

Elimination:

Surplus folate metabolites are excreted in urine without change.

5.3. Pre-clinical safety data

Iron III hydroxide polymaltose complex + folic acid combination has been used for many years in clinical practice as antianemic and its safety and efficacy is known.

6. PHARMACEUTICAL PROPERTIES:**6.1. List of Excipients**

Crospovidone (Kollidon CL)

Polyethyleneglycol 6000

PVP K30

Magnesium Stearate

Microcrystalline Cellulose

Coating Opadry II 85F26721:

polyvinyl alcohol (40 %),

PEG 3350 (20.2%),

titanium dioxide (E 171) (14.94 %),

talc (14.8 %),

red iron oxide (E172) (7.34 %),

yellow iron oxide (E172) (1.98 %)

ponceau 4R lacquer (E124) (0.74 %).

6.2. Incompatibilities

No known incompatibilities.

6.3. Shelf-life

36 months.

6.4. Special warnings for storage

Store below 25°C.

6.5. Nature and Content of the Package

30 film coated tablets in PVC/PE/PVDC/Aluminum foil blisters in a box

6.6. The disposal of remnants of human medicinal product and other special precautions

No specific requirements.

7. MARKETING AUTHORIZATION HOLDER

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

8. MARKETING AUTHORIZATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Initial authorization date: -

Dare of authorization: -

10. DATE OF RENEWAL OF SmPC

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