Patient Information Leaflet

AMIFER® FORTE

100 mg iron / 0.350 mg folic acid, Film-coated tablet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. If you have any questions or if you get any side effects not listed in this leaflet, talk to your doctor or your healthcare professional. Do not pass this medicine on to others.

1. What is Amifer® Forte and what it is used for?

Amifer® Forte is an iron supplement. Each tablet contains 100 mg elementary iron and 0.350 mg folic acid. Amifer® Forte is a product belonging to the class of antianemics used to prevent and treat iron deficiencies before and during the stage of iron deficiency anemia (decrease in the number of functional red blood cells following an iron deficiency) as well as in the prevention and the treatment of folic acid deficiencies during pregnancy and breast-feeding.

2. What you need to know before you take AMIFER® Forte

Do not take Amifer® Forte

- If you are allergic to iron, folic acid, or any of the other ingredients of this medicine, listed in section 6.
- If you have a condition leading to iron overloading (hemochromatosis, hypersiderosis, chronic hemolysis), anemia not caused by an iron deficiency (such as hemolytic anemia or an anemia caused by vitamin B12 deficiency), thalassemia, severe liver or kidney disease, HIV infection without clinically proven iron deficiency anemia.
- If you need regular and continuous blood transfusions.

Warnings and precautions

- Talk to your doctor before taking Amifer® Forte: Anemia must always be treated under the supervision of a doctor. A blood cell count should be done 2-4 weeks after starting the treatment.
- Caution is necessary if you suffer from alcoholism, intestinal inflammation, or gastric ulcer.
- During administration of oral iron formulations, the color of the stool may darken; this is normal and does not require any special measures. This will not cause false positive results during tests for occult blood in the stool. Therefore, there is no need to stop the treatment during this test.

- The film coating of the Amifer® Forte tablet contains Ponceau red 4R, which may cause allergic reactions. If these warnings apply to you or have affected you at any time in the past, please talk to your doctor or pharmacist.

Children and adolescents

Accidental administration of iron-containing products can cause fatal toxicity in children below 6 years of age. The patients must urgently consult a doctor or contact the poison control center.

Other medicines and Amifer® Forte

Tell your doctor or pharmacist if you are taking, have recently taken or have recently taken any other medicines, including medicines obtained without prescription.

Taking Amifer® Forte with food and drink

No interaction with food or other medicines is expected. However, due to the possibility of an interaction with products containing calcium (e.g. milk), at least 2 hours must be left between the administration of a calcium containing product and iron.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you must tell your doctor that you are taking medicines.

You may take Amifer® Forte as an iron and folic acid supplement in pregnancy in case your doctor recommends it. Consult your doctor or pharmacist immediately in case you realize that you are pregnant during treatment.

Breast-feeding: You may take Amifer® Forte as an iron and folium acid supplement during breast-feeding in case your doctor recommends it. Iron is excreted into the breast milk. This excretion remains unchanged regardless of the mother's iron level and the amount of iron taken with food.

Driving and using machines

Amifer® Forte does not have an effect on the ability to drive and use machines.

Important information about some of the ingredients of Amifer® Forte

The film coating of the Amifer® Forte tablet contains Ponceau 4R red (E124).

3. How to take Amifer® Forte

Always take this medicine exactly as your doctor or healthcare provider has told you.

Amifer® Forte is only for oral use. The recommended dose for Amifer® Forte is 1 tablet a day.

If deemed appropriate by your doctor, 1 tablet may be taken two times a day. Do not forget to take your medication on time. Your doctor will tell how long you have to take Amifer® Forte. Do not prematurely discontinue your treatment, because the duration of the treatment depends on the status of iron metabolism and normalization of blood values. Once blood values are normalized, it is recommended to continue treatment for at least a month to build up iron stores in the body.

Use in children

Amifer® Forte is not used in children (in a pediatric population Amifer® Junior Syrup can be used).

Use in the elderly

No dosing adaptation is necessary.

Use in patients with renal/hepatic failure

Do not take Amifer® Forte in case of severe liver and kidney diseases.

If you take more Amifer® Forte than you should

Diarrhea, stomachache and vomiting may be seen after overdose with Amifer® Forte and in more severe cases, metabolic acidosis, severe muscle spasms and coma. Accidental administration of iron-containing products may cause fatal (deadly) toxicity in children below 6 years of age. Therefore, the medicine should be stored out of reach of children. In case of overdose promptly consult your doctor or poison control center.

If you forget to take Amifer® Forte

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking Amifer® Forte

Your doctor will tell you how long you should take your medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- If any of the following side effects occurs, stop taking Amifer® Forte, inform your doctor IMMEDIATELY and go to the nearest hospital emergency room: swelling of hands, feet, ankles, face, lips or in particular hindrance of swallowing or breathing due to swelling of mouth or throat; severe skin rashes or asthma. In case you have one of these side effects, it means that you have a severe allergy to Amifer® Forte. These serious side effects are very rare.
- If you experience any of the following mild side effects of Amifer® Forte, inform your doctor: indigestion, abdominal discomfort, nausea, vomiting, burning sensation in the stomach, bitter fluid in the mouth, mild abdominal pain, itchy blisters on the skin, rashes, redness, headache, change in urine and stool color.
- In case you observe any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. How to store Amifer® Forte

Keep out of the reach and sight of children.

Store below 30°C.

Do not use this medicine after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

6. Contents of the pack and further information

What Amifer® Forte contains

The active substances are Iron (in the form of iron hydroxide polymaltose complex) and Folic acid.

The other ingredients are:

- The tablet core: crospovidone, macrogol, povidone, magnesium stearate, microcrystalline cellulose
- The film-coating: Opadry II 85F26721 containing polyvinyl alcohol, macrogol, titanium dioxide (E 171), talc, red and yellow iron oxide (E172), and Ponceau red 4R lacquer (E124).

What Amifer® Forte looks like and contents of the pack

Film-coated tablets, red-brown, round, biconvex.

Box of 30 tablets in blister.

Amifer® Forte is a prescription medicine.

Manufacturer

Santa Farma İlaç Sanayi A.Ş. GEBKİM - 41455 Dilovası - KOCAELİ, Turkey

Marketing authorization holder

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