PATIENT INFORMATION LEAFLET

FERTAMIR 100 mg sachet with effervescent granule

Taken orally.

- **Active Substance**: Each sachet contains 307.69 mg Iron III polymaltose complex (equivalent to 40 mg Fe^{+3}).
- **Excipients:** Sodium bicarbonate, sodium carbonate anhydrous, mannitol E421, powdered sugar (sucrose), citric acid anhydrous F3500, tartaric acid, povidone K-30 (PVP-30), cherry flavor, sucralose.

Please read this LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep these instructions for use. You can need to read again.*
- *If you have other questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *Tell your doctor if you go to a doctor or the hospital when you use this medicine.*
- *Follow strictly to what is written in these instructions. Do not use **high or low doses** other than the recommended dose for the medication.*

What is in this leaflet:

The headlines are involved in.

1. What FERTAMIR tablets are and what they are used for?

- FERTAMIR contains 307.69 mg iron III polymaltose complex (equivalent to 100 mg Fe^{+3}) as active ingredient.
- 20 and 30 sachets containing granules to prepare oral solution. The granules are brown.

- Iron III hydroxide polymaltose application eliminates the decrease in blood production in anemia caused by iron deficiency and the resulting effects.
- It is used in the treatment of iron deficiency anemia (anemia) with all types of iron deficiencies of different origin and in the prevention of such anemias, in the treatment of iron deficiency in pregnancy, lactation and childhood.

2. What you need to know before you take FERTAMIR tablets?

DO NOT USE FERTAMIR in the following cases.

- If you are hypersensitive to iron or any of the excipients it contains,

- If there is iron overload (hemochromatosis, chronic hemolysis)

- If you are hypersensitive to iron

- Other anemias without iron deficiency (such as hemolytic anemia)

- If you have iron use disorder (lead anemia, sideroacrestic anemia)

- If you have thalassemia (Mediterranean anemia) disease

- If you have conditions that require regular blood transfusions regularly

- You have HIV infection and your anemia due to iron deficiency has not been clinically confirmed

- Do not use if you have serious liver and kidney disease.

USE FERTAMIR CAREFULLY in the following cases.

• If you have a stomach ulcer, use it under the control of a doctor.

- The color of the stool may darken during the use of oral iron medications, this is normal and does not require any precautions.

- It does not cause an error during the search for hidden blood in the stool. Therefore, there is no need to discontinue treatment during this examination.

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

- In anemia that develops due to various diseases or cancer, the iron taken is stored in the liver and becomes separated and used only after the treatment of diseases and cancer.

- Inadvertent ingestion of iron-containing products in children can lead to fatal poisoning. Keep out of the reach of children.

Diseases that may be at the basis of iron deficiency or iron deficiency anemia should be detected by your doctor and these diseases should be treated appropriately.

Anemia should always be treated under the supervision of a doctor. If treatment is not successful (no increase in hemoglobin level after 3 weeks), treatment should be reviewed by your doctor.

If repeated blood transfusions are done, iron overload may occur.

"If these warnings are valid for you, even at any time in the past, please consult your doctor."

Using FERTAMIR with food and drink

FERTAMIR should be taken with or after meals.

Milk and eggs reduce iron absorption.

It should not be taken with tea, coffee and milk. It should not be taken with products and medicines containing calcium. At least 2 hours should be left in between.

Pregnancy

Consult your doctor or pharmacist before using this medication.

You can use FERTAMIR as an iron supplement during pregnancy, as recommended by your doctor.

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

Breast-feeding

Consult your doctor or pharmacist before using this medication.

You can use FERTAMIR as an iron supplement during breastfeeding with the advice of your doctor.

Iron passes into breast milk. This transition does not change according to the current iron level of the mother and the amount of iron taken with food. For this reason, giving iron

supplements to the nursing mother does not cause an iron poisoning in the baby or the elimination of iron deficiency in the baby.

Driving and using machines

It has no effect on the ability to drive and use machines.

Important information about some of the ingredients of FERTAMIR

This medicinal product contains 2.37 mmol (54.55 mg) sodium per dose. This should be considered for patients on a controlled sodium diet.

FERTAMİR contains 1290.00 mg sucrose as powdered sugar in each dose. If you have been told by your doctor that you have intolerance to some sugars due to the sucrose it contains, contact your doctor before taking this medicinal product.

Concomitant use with other drugs

FERTAMIR does not interact with other drugs other than the ones mentioned below.

The together application of FERTAMIR and iron with the vascular route is not recommended on the grounds that it may reduce FERTAMIR absorption.

Tetracycline (a type of drug used against bacteria, antibiotics), cholestramine (a drug used to relieve cholesterol when blood cholesterol levels rise), antacids (a group of drugs used to relieve stomach acid-related complaints), penicillamine (in a disease called Wilson's and severe a drug used in metal poisoning) and if it should be taken with oral gold compounds, it should be used every few hours.

Concomitant use with salicylates (medicines such as aspirin), phenylbutazone and oxyphenbutazone (anti-inflammatory drugs used in rheumatic diseases) can cause irritation to the inner surface of the intestine.

Benzidine test, which is used to search blood in urine and feces, may be positive during iron treatment.

It should be used with caution in those with bowel tumors.

Vitamin C is known to increase iron absorption.

At least 2 hours should pass between the two as they may interact with calcium-containing drugs.

Since the drugs containing levothyroxine (used in the treatment of thyroid diseases) are taken together with FERTAMİR, the two drugs should be taken at least 2 hours apart.

If you are currently using any prescription or non-prescription medication, or if you have used it recently, please inform your doctor or pharmacist about them.

3. How to use FERTAMIR?

Instructions for proper use and dose / frequency of administration:

Always take FERTAMİR exactly as your doctor says. If you are not sure, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not give it to others. Even if their symptoms are the same as yours, they can harm them.**Application way and method:**

FERTAMIR is for oral use only.

Melt the contents of the sachet in 1 glass (200 ml) of water. Stir until it is a homogeneous mixture. After preparing, drink the solution immediately.

It can be taken by mixing with fruit and vegetable juices.

It is used in children (≥ 12 years) and adults in doses equivalent to 100-200 mg of elemental iron. Unless otherwise recommended by the doctor, 1 sachet should be used 1-2 times a day.

The duration of treatment depends on the degree of anemia and the normalization of the number of red blood cells. In the case of significant iron deficiency, reaching the normal blood value is an average of 3-5 months of treatment. The duration of treatment in hidden iron deficiency is 1-2 months.

Different age groups:

Use in children:

ERTAMİR sachet containing 100 mg effervescent granules is currently not available in children under 12 years of age, enough data to recommend a dosage regimen for routine use.

Use in the elderly:

Its use in the elderly is just like in adults.

Special use cases:

Kidney / Liver failure:

Do not use FERTAMIR in serious liver and kidney diseases.

If you have an impression that the effect of FERTAMIR is too strong or weak, talk to your doctor or pharmacist.

If you have used more FERTAMIR than you should:

With excess intake, diarrhea, stomach pain and vomiting may occur, and in more advanced cases, metabolic acidosis, severe muscle spasms and coma may occur.

Accidental taken / ingestion of iron-containing products in children under the age of 6 leads to fatal poisoning. Therefore, keep these medicines out of the reach of children. In case of overdose, consult your doctor immediately.

If you have used more than you should use from FERTAMİR, talk to a doctor or pharmacist.

If you forget to use FERTAMİR

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

Skip the missed dose and take the next dose at the time you need to take it.

Effects that may occur when treatment is terminated with FERTAMİR

None.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in FERTAMİR.

The following side effects may occur as a result of using FERTAMIR:

Side effects are listed as shown in the following categories:

Very common: It can be seen in at least 1 of 10 patients.

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.

Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare: Less than one in 10,000 patients can be seen.

Not known: It can be seen in too few patients that cannot be determined by the available data.

If one of the following occurs, stop using FERTAMİR and IMMEDIATELY tell your doctor or apply to the emergency department of the nearest hospital:

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

These are all very serious side effects.

If you have one of these, you have a serious allergy to FERTAMIR. You may need an emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor right away or contact the emergency department of the nearest hospital:

• Asthma (difficulty breathing)

All these are serious side effects. Emergency medical attention may be required.

Serious side effects are very rare.

Very common:

• Change in stool color

Common:

•Diarrhea

• Nausea

• Feeling full

• Discomfort in the abdomen

Unusual:

• Headache

• Abdominal pain

• Vomiting

• Constipation

• Color change in teeth

• Hives (Urticaria), Skin rash

• Itching

Rare:

• Change in urine color

Very rare:

•Allergic reactions

• Asthma (difficulty breathing)

• Regional skin reactions

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

5. Storage of FERTAMIR

Keep FERTAMIR in places and in its packaging where children cannot see, access.

Store at room temperature below 25ºC. Drink the prepared solution immediately, do not save it.

Use in accordance with the expiration date.

Do not use FERTAMIR after the expiration date printed on the cardboard and sachet packaging.

Do not dispose of expired or unused drugs! These measures will help you protect the environment.

License owner:

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06520 Balgat-ANKARA

Production place:

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These instructions for use were approved on 02/05/2019.