

PATIENT INFORMATION LEAFLET

FERROVEN® 100 mg/5ml I.V. Solution for Injection

Active ingredient: Each 5 ml ampoule contains 1754,39 mg complex of iron hydroxide sucrose equivalent to 100 mg (20 mg/ml) iron (III).

Excipients: Water for injection, Sodium hydroxide (1 N).

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any occurring side effect. You can find out how to report a side effect at the end of section 4.

Before usage of this medicine read this PATIENT INFORMATION LEAFLET carefully, because it contains important information for you.

- *Ensure you keep this patient information leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital*
- *Strictly follow these instructions. Do not take **lower or higher** doses than the recommended dose*

In this patient information leaflet:

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1. What FERROVEN® is and what it is used for?

FERROVEN® contains 350.8 mg ferric hydroxide sucrose complex equivalent to 20 mg of iron (III) per mL.

FERROVEN® is a medicine developed to be used as intravenous solution in cases of anemia due to iron deficiency.

FERROVEN® is presented in cardboard boxes with 5 colorless glass ampoules containing 5 ml of brown solution.

Iron, the active ingredient of FERROVEN® is a substance required in blood for oxygen transport. Iron is present in the structure of a substance called hemoglobin in blood cells and is responsible for carrying oxygen.

FERROVEN® is used for;

- In iron deficiency anemia due to conditions associated with impaired gastric or intestinal absorption of iron,
- Iron deficiency anemia due to active gastric or intestinal bleeding,

- If iron deficiency and anemia have developed due to the removal of all or part of the stomach,
- In patients with iron deficiency anemia and cannot tolerate oral iron,
- In patients who develop anemia due to iron deficiency and in whom oral iron is not adequately effective,
- If your doctor has decided that your iron stores need to be replenished quickly and hence to administer iron,
- In the presence of iron deficiency in patients with chronic kidney disease with or without dialysis (blood clearing) dependence receiving erythropoietin (EPO) (a hormone that stimulates blood production) treatment,

FERROVEN® should not be recommended during the first trimester of pregnancy. In the second and third trimesters of pregnancy, it should be used only when the physician considers it necessary.

2. Before using FERROVEN®:

Do not use FERROVEN®

If;

- You are allergic (hypersensitive) to any of the ingredients of FERROVEN®,
- If there is known hypersensitivity to other intravenous iron preparations
- You have too much (excess) iron in your body
- You have anemia which is not caused by a shortage of iron,
- You have allergic diseases such as asthma, eczema,
- You are in the first three months of pregnancy

Take special care with FERROVEN®:

- Following administration of FERROVEN®, in rare cases, life-threatening allergic reactions such as fainting, low blood pressure, respiratory distress and convulsion may occur. Such events are observed during intravenous use of many drugs containing iron. Therefore necessary equipment for emergency life support must be ready for use as a precaution during intravenous administration of FERROVEN®.
- The risk of hypersensitivity reactions increases for patients with known drug allergies, including a history of severe asthma, eczema or other atopic (genetically predisposed to) allergy. Hypersensitivity reactions to parenteral iron complexes also increase in cases of immune systems disorders (e.g., systemic lupus erythematosus, rheumatoid arthritis) or infection.
- FERROVEN® should only be administered where all resuscitation equipment is available and in the presence of personnel trained to evaluate and manage emergency conditions such as allergic shock. After each injection of FERROVEN®, you should be observed for drug-related side effects for at least 30 minutes. If hypersensitivity reactions (excessive response of the immune system) or signs of intolerance occur during administration, your treatment must be stopped immediately. To manage acute allergic shock and similar reactions, equipment for cardiorespiratory resuscitation and materials including an injectable 1:1000 adrenaline solution should be made available. Where necessary, antihistamines (medications used for allergy treatment) and/or corticosteroids (medications used to suppress the immune system) can be added to your treatment.
- Since iron excretion from the body is limited and excess iron in the tissues can be dangerous, periodic blood tests (hemoglobin, hematocrit, serum ferritin and transferrin saturation) should be performed in patients receiving FERROVEN®.

Iron therapy should be discontinued in patients with suspected iron overload.

- Caution is required in patients with hepatic failure.
- It must be administered with caution in patients with acute and chronic infection.
- FERROVEN® should be used at the recommended dose to reduce the possibility of undesirable side effects.
- Accidental ingestion of iron-containing products in children can lead to fatal poisoning. Keep out of reach of children.

Please consult your doctor if these warnings apply to you even at any time in the past.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

No adequate and well-controlled studies are available on the use of FERROVEN® in pregnant women. Therefore, a careful benefit/risk assessment must be carried out prior to use during pregnancy, and FERROVEN® must not be used during pregnancy unless clearly necessary. Iron deficiency anemia in the first trimester (3-month period) of pregnancy can be treated with oral iron in many cases.

FERROVEN® should not be given during the first three months of pregnancy. It can be used from the fourth month of pregnancy. FERROVEN® is used after 4th month of pregnancy in many pregnant women diagnosed with anemia and no side effects of the medicine have been observed on the pregnancy or the health of the fetus/newborn. No significant side effects have been reported so far. Should be used with caution in pregnant women.

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

Lactation

Before using this medicine, consult your doctor or pharmacist.

It is not known whether the iron contained in FERROVEN® is excreted in human milk and if it is excreted, the effects of iron on the baby. Therefore FERROVEN® should be used during lactation if the benefit is judged to outweigh the potential risk for both the mother and the fetus.

Driving and using machinery

Dizziness, confusion or light-headedness may occur following the administration of FERROVEN®. Do not drive or use machinery until the symptoms have ceased.

Important information on some excipients present in FERROVEN®

FERROVEN® contains less than 1 mmol (23 mg) sodium in each dose, so in fact, it does not contain sodium.

Taking with other medicines

FERROVEN® should not be used with oral iron preparations since it may reduce intestinal absorption of iron. Oral iron therapy should start at least 5 days after the last dose of FERROVEN®.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How to use FERROVEN®?

Instructions for proper use and dosage/administration frequency:

In adults, 1-2 ampoule (100-200 mg iron) FERROVEN® is used for 1-3 times per week. In hemodialysis patients, total dose is 1000 mg to administer in 10 doses. Recommended dose may be repeated if required. Administration frequency should not be more than 3 times per week.

Oral iron intake should be discontinued during administration.

Care must be taken during the administration of FERROVEN® and for signs and symptoms of hypersensitivity reactions following each administration. After receiving an injection of FERROVEN®, you should stay at the relevant health center for at least 30 minutes, consult healthcare workers if you suspect any side effect.

Route and method of administration:

FERROVEN® should only be administered intravenously.

Different age groups:

In children: Parenteral iron preparations are not recommended for children under 14 years of age due to lack of clinical experience.

In elderly: Dose adjustment is not necessary.

Special usage:

Renal/Hepatic insufficiency: Dose adjustment is not required in patients with renal/hepatic insufficiency. Dose administration frequency should not be more than 3 times in a week.

FERROVEN® should be used in patients with hepatic insufficiency, only if necessary, after the benefit-risk evaluation.

If you have the impression that the effect of FERROVEN® is too strong or weak, talk with your doctor or pharmacist.

If you take more FERROVEN® than you should

Your doctor will decide the optimal dose for you and administer intravenously.

If you take more FERROVEN® than was prescribed, tell your doctor or pharmacist immediately.

If you forget to take FERROVEN®

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking FERROVEN®

None

4. Possible side effects?

Like all medicines, FERROVEN® may cause side effects in patients sensitive to its ingredients.

Side effects are classified in categories as shown below:

Very common	:in at least 1 patient of 10.
Common	:in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	:in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	:in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	:in less than 1 of 10.000 patients.
Unknown	:Cannot be estimated based on available data

If any of the following reactions happen, stop taking FERROVEN® and tell your doctor immediately or contact the emergency department at your nearest hospital:

- Swelling of the hands, wrists/ankles, face, lips or especially of the mouth or throat causing difficulty in breathing.

These are all very serious side effects. If you experience one of them, it means you are severely allergic to FERROVEN®. You may need urgent medical intervention or to be hospitalized. All of these very serious side effects are very rare.

If you notice any of the following side effects, tell your doctor immediately or contact the emergency department at your nearest hospital:

- Swelling or flushing of your skin or lips.

These are all serious side effects. You may need urgent medical intervention. Serious side effects are very rare.

Common

- Transient taste disorders during administration (in particular a metallic taste)
- Pain in injection site

Uncommon

- Nausea
- Vomiting
- Stomach pain
- Diarrhea
- Low blood pressure
- Muscle cramps, muscle pain
- Fever and shivering
- Palpitations, increased heart rate
- Difficulty in breathing
- Injection site disorders such as burning, swelling
- Rash, itching, numbness of the skin, redness and swelling
- Headache
- Chest pain and chest tightness
- Urticaria

Rare

- High blood pressure
- Fainting
- Feeling hot

- Tiredness, weakness

Isolated cases

- Dizziness, reduction in the level of consciousness
- Swelling of joints

These are mild side effects of FERROVEN®.

These side effects disappear when the dose is reduced or the treatment is discontinued.

Tell your doctor or pharmacist if you notice any other effects not listed.

Reporting side affects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to use FERROVEN®?

Do not store above 25°C. Do not freeze. Store in the original package.

Use in compliance with the expiry date.

Do not use FERROVEN® after the expiry date which is stated on the packaging.

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This leaflet has been approved <{DD month YYYY}>.

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