PATIENT INFORMATION LEAFLET

EMFER 100 mg/5 ml Solution for IV Injection and Infusion

Administrated into veins via injection (intravenous) or infusion.

Active ingredient: Each ampoule (5ml) contains 2700 mg complex of ferric hydroxide sucrose equivalent to 100.0 mg (20 mg/ml) iron (III).

Excipients: Sodium hydroxide and water for injection

▼ This medicine is subject to additional monitoring. This triangle will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, consult your doctor or your pharmacist.*
- *This medicine has been prescribed for you personally; you should not pass it on to others.*
- *During use of this medicine please tell to your doctor that you use this medicine when you go to the doctor or hospital.*
- *Follow the information in the leaflet exactly. Do not use **lower** or **higher** dosages rather than recommended dosages regarding the medicine.*

In this patient information leaflet:

1. What is EMFER and what is used for?

EMFER contains 2700 mg complex of ferric hydroxide sucrose equivalents to 100.0 mg (20 mg/ml) iron (III) in each ampoule (5ml). EMFER is a medicine developed in order to be administrated into the veins in cases of anemia due to iron insufficiency.

Each box contains 5 ampoules of EMFER.

Iron, which is an active ingredient of EMFER, is an agent that is necessary to carry oxygen in blood. Iron is an agent that is included in the structure of hemoglobin, which is found in blood, and it’s purpose is to carry oxygen.

EMFER is used in;

- Iron deficiency anemia that develops when the iron absorption from the gastrointestinal system is impaired,
- Iron deficiency anemia that develops in patients with active gastrointestinal bleeding,
- Iron deficiency anemia in patients with total or subtotal gastrectomy,
- Cases of iron deficiency anemia which can not be tolerated by oral iron therapy,
- Iron deficiency anemia resistant to oral iron therapy,
- In the cases which there is a need for rapid iron supply,
- Patients who are on hemodialysis treatment with erythropoietin (EPO) for chronic renal failure will be initiated if Hgb <10 g / dL and used until Hgb> 11.5 g / dL or ferritin> 500 ng / dL.

EMFER should be administered after necessary and appropriate blood tests (such as hematocrit, hemoglobin, ferritin level, erythrocyte count test).

2. What you need to know before using EMFER
Do not use EMFER at following conditions:
If;

- You are allergic to EMFER or any excipients of it,
- You have any known hyper-sensitivities to one of the iron medicines administrated into vein except EMFER.
- You have anemia independent from iron insufficiency,
- You have excess iron or iron usage problems,
- You have got asthma, eczema or other allergic reactions,
- You are in the first three months of your pregnancy, do not use EMFER

Use EMFER carefully in following conditions:

- Iron medicines that are administrated into vein can cause serious and potential (containing anaphylactic/ anaphylactoid reactions) hyper-sensitivity reactions. After administration of EMFER, some life-threatening allergic reactions like fainting, decrease in blood pressure, breathing distress, eclampsia can rarely be seen. Allergic reactions can be seen in patients that had been administrated before too.
- Risks are higher for patients with severe asthma, eczema or other atopic allergic and patients with known allergies to medicines. In cases of immune system sicknesses or infections (ex. systemic lupus erythematous, rheumatoid arthritis) hyper-sensitive reactions to parenteral iron complexes are higher too.
- EMFER must only be administered in places where all resuscitation equipments are provided and in the presence of personnel trained in fields of immediately evaluating and managing anaphylactic reactions. After every EMFER injections patient must be observed in the way of adverse effects for at least 30 minutes. If hyper-sensitivity reactions or intolerance symptoms occur during the administration, treatment must be stopped immediately. Materials including heart-respiration resuscitation equipments and 1:1000 injectable adrenalin solutions in order to manage acute anaphylactic/anaphylactoid reactions. Antihistaminics and/or corticosteroids can be given as additional treatment if necessary.
- Because of the facts that iron excretion of body is limited and excess iron in tissues can be dangerous, blood tests (hemoglobin, hematocrit, serum ferritin and transferrin saturation) must be done regularly in patients who are using EMFER. Iron treatment must be stopped in patients suspected from excess iron supplement.

- EMFER must be used in recommended doses to reduce the possibility of side effects.

Please consult your doctor,even if these statements were applicable to you at any time in the past.

Pregnancy
Before use this medicine, consult your doctor or your pharmacist.

EMFER must not be used in the first three months of pregnancy. It can be used as of the 4. month. EMFER has been used in 4 months or more pregnant women who were suffering from anemia and no side effects have been seen in pregnancy or fetus/new born children health. No significant side effects have been reported until now. Precautions should be taken when it is administered to pregnants.

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

Breast-feeding

Before use this medicine, consult your doctor or your pharmacist.

It is not known if EMFER is excreted with mother milk or not. If it is excreted, the effects of this iron on baby are also not known.A decision on whether to continue/discontinue breast- feeding or to continue/discontinue therapy with EMFER should be made taking into account the benefit of breast- feeding to the child and the benefit of EMFER therapy to the mother.

Driving and using machinery

With usage of EMFER, dazedness, confusion or memory confusion can be seen. If you have noticed one of these effects, you must avoid driving or using machines until you feel better.

Important information on some excipients in contents of EMFER
This medicine contains less than 1 mmol (23 mg) sodium in each dosage, so there are not any side effects expected due to this dosage of sodium.

Use with other medicines
Because of the fact that EMFER can reduce the absorption of oral iron medicines from intestines, oral iron medicines and EMFER must not be used at the same time. Oral iron treatment must be started at least 5 days later from the last EMFER dose.

As the drugs containing levotroxine are taken with EMFER and their absorption is impaired, it is necessary to take two drugs with a minimum interval of 4 hours.

If you have been using prescribed or non-prescribed medicines until now or you have used in the past, please inform your doctor about these.

3. How to use EMFER?

Instructions for proper use and dosage/administration frequency:

EMFER must be administered by experienced health experts, in places with sufficient technical equipments.

In adults, 1-2 ampoules (100-200 mg) of EMFER is used for 1-3 times per week. In hemodialysis patients total dose is 1000mg administered in 10 doses. Recommended dose can be repeated if necessary. Dosage administration frequency must not be more than 3 per week.

Patients must be carefully observed in the way of hyper-sensitivity reactions symptoms and signs during and after every EMFER administration.

After every EMFER injections patient must be observed in the way of adverse effects for at least 30 minutes.

Administration route and method:

EMFER is only used intravenously.

Different age groups:

Use in children:
There is no enough data for effectiveness or reliability on use of children.

Use in geriatrics:

There is no need for dose adjustment for geriatrics.

Special use conditions:

Renal / Liver disorders:

There is no need to adjust dosage for patients suffering from renal or liver disorder.

If you notice that effects of EMFER is too low or too high, speak to your doctor or pharmacist.

If you have taken more than required dosages of EMFER:

Your doctor will determine the right dose for you and inject it intravenously

If you have taken more than required dosages of EMFER, speak to your doctor or pharmacist.

If you forget taking EMFER:

Do not take double dosage for balancing of forgotten dosage.

Possible effects with finishing of EMFER treatment:

None

4. What are possible side effects?

Like all other medicines, side effects can be seen in patients who are sensitive to ingredients of EMFER.

If you get one of those below, stop using EMFER and inform your doctor IMMEDIEATELY or apply to the emergency room of the nearest hospital.

Side effects are categorized below:

Very common	: It can be seen in minimum 1 patient of 10 patients.
Common	: It can be seen in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: It can be seen less in than 1 of 100 patients but, more than 1 patient of 1000 patients.
Rare	: It can be seen in less than 1 of 1000 patients but more than 1 patient of 10000 patients.
Very rare	: It can be seen less in than 1 of 10.000 patients.
Unknown	: It is not estimated from available data.

Distention in hands, feet, wrists, face, lips or especially distention in mouth or throat that can make swallowing or breathing harder.

These are all very serious side effects.

If any of these side effects occur on you, you are seriously allergic to EMFER. You may need immediate medical attention or to be taken to hospital.

These very serious side effects occur quite rarely.

If you get one of those below, inform your doctor immediately or apply to the emergency room of the nearest hospital.

If rash or distention appears in any place of your skin or your lips.

These are all very serious side effects. Emergency medical intervention might be required.

These serious side effects occur very rarely.

If you get one of those below, inform your doctor.

If you feel change of taste (especially metallic taste), decrease in blood pressure, palpitation, fever and shivering, pain in injection area, itching and distention, headache, dizziness, having trouble breathing, muscle cramps, muscle pain, nausea, diarrhea and skin rashes during the administration.

These are EMFER's slight side effects.

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

If you feel any possible side effects which are not listed in this leaflet inform your doctor or your pharmacist.

Reporting of side effects

If you feel any side effects not listed in this leaflet speak to a doctor, pharmacist or nurse. Furthermore report the side effects you feel by clicking "Reporting Medicine Side Effect" in www.titck.gov.tr or by calling 0 800 314 00 08 side effect report line Turkey Pharmacovigilance Center. By reporting side effects you can help provide more information on the safety of this medicine

5. Storage of EMFER:

Keep EMFER out of the reach and sight of children and store in original pack.

Store at room temperature, below 25°C in a dry place and protect from light.

Do not freeze.

Please use EMFER in accordance with expiry date.

Do not use EMFER after expiry date which is stated on pack.

Do not use EMFER if you notice damage on product and/or packaging.

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This patient information leaflet is approved on *22 / 08 / 2017*