

PATIENT INFORMATION LEAFLET

FERIFER 50 mg/ ml oral drops

For oral use only.

- **Active substance:** Each 1 ml (20 drops) solution contains 147 mg iron III hydroxide polymaltose complex (34%) equivalent to 50 mg iron.
- **Excipients:** Sucrose, sodium hydroxide, methyl paraben (E218), propyl paraben (E216), cream essence and purified water.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

- 1. What FERIFER is and what it is used for?**
- 2. What you need to know before using FERIFER?**
- 3. How to use FERIFER?**
- 4. Possible side effects?**
- 5. How to store FERIFER**

1. What FERIFER is and what it is used for?

- FERIFER is an oral drop presented in 30 ml amber colored glass vial (Type III) closed with HDPE cap with LDPE dropper seal in the primary packaging material.
- It has an aromatic smell; it is a red-brown solution.
- FERIFER contains iron III hydroxide polymaltose complex as the active substance.
- It is used for the treatment of iron deficiency of various origins and iron deficiency (anemia) and for the prevention of these types of anemia and in treatment of iron deficiency during pregnancy, breastfeeding and childhood.

2. What you need to know before using FERIFER?

DO NOT use FERIFER

If;

- You have hypersensitivity to iron or any of its excipients
- You have iron overload (hemochromatosis, chronic hemolysis)
- You have anemia not caused by iron deficiency (hemolytic anemia)
- You have disturbances in utilization of iron (lead anemia, sideroacrestic anemia)
- You have mediterranean anemia, which is an inherited blood disorder (thalassemia)
- You have progressive and long-lasting (chronic) joint inflammation
- You have conditions requiring regular blood transfusions
- Your AIDS disease (HIV infection) and if your iron deficiency anemia is not clinically confirmed
- You have serious liver or kidney disease.

Take special care with FERIFER in the following conditions

- If you have stomach ulcer your doctor will decide whether or not you can use FERIFER.
- Dark discoloration of stool may occur during treatment with oral iron preparations; this is an expected condition which does not require any measures.
- It does not cause false results on fecal occult blood tests. Therefore, there is no need to stop treatment during the examination.
- It should be used with caution in alcoholism and conditions that disrupt iron absorption from the intestines.
- If iron is supplemented in anemia of various diseases and cancer, iron is stored in liver and becomes available only after the disease or cancer is cured.
- Accidental ingestion of iron containing products may cause fatal intoxications in children. Keep out of reach of children.

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

FERIFER with food and drink

FERIFER should be used between or after meals.

Avoid taking with milk, calcium-containing products and medicines. There should be at least 2 hours between the two.

Pregnancy

Consult your doctor or pharmacist for advice before using the medicine.

You can use FERIFER as an iron supplement in pregnancy if your doctor recommends it.

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

Breast-feeding

Consult your doctor or pharmacist for advice before using the medicine.

You can use FERIFER as an iron supplement in breast-feeding period if your doctor recommends it.

Iron passes into human milk. This passing does not depend on the current iron level of your mother and the amount of iron taken with food. Therefore, giving an iron drug to a nursing

mother does not lead to an iron poisoning of the baby or the elimination of the iron deficiency present in the baby

Driving and using machines

No effect on ability to drive and use of machines has been reported.

Important information about some of the excipients of FERIFER

Due to the sucrose in its contents, it may be harmful to the teeth. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using this medicine.

Methyl paraben (E218) and propyl paraben (E216) may cause allergic reactions (possibly delayed).

This medicinal product contains 0.003 mmol of sodium per 1 ml (20 drops) which should be taken into consideration by patients on a controlled sodium diet.

Using with other medicine

FERIFER does not have any interaction with other medicines other than the following drugs.

Vitamin C is known to increase iron absorption.

There should be at least 2 hours between the two, as there may be interaction with drugs containing calcium.

When levothyroxine-containing drugs used in the treatment of thyroid diseases are taken together with FERIFER, the absorption of the two drugs should be interrupted for at least 2 hours.

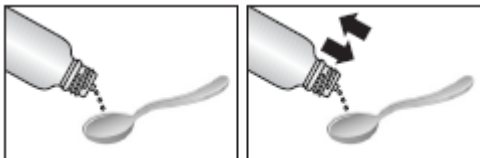
Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use FERIFER?

• Instructions for appropriate method and dose/frequency of administration:

- FERIFER is used as 40 drops (100-200 mg) 1-2 times daily between or after meals in adults.
- Please use at the indicated doses unless recommended otherwise by your doctor.
- It should be used for the period of time recommended by your doctor. Treatment should be continued for at least another month to fill iron stores after iron deficiency symptoms resolve.

• Route and method of administration:



- FERIFER is for oral use only.

- Hold the product at an oblique angle to drop into a spoon. If you have difficulty dropping, shake gently enough to be able to count drops, holding at the same angle. It should not be used by direct dropping into the mouth.

- **Different age groups:**

Use in children:

- Newborns : 1 drop/kg/day (Daily dosage is 1 drop per kg of body weight.)
Children up to age 1 : Start with 5 drops daily. Can be titrated up to daily 20 drops in divided doses.
Children aged 1-12 years : 20 drops 1-2 times daily (50-100 mg)
Children older than 12 years : 20 drops twice daily (100 mg)

Use in elderly:

The safety and effectiveness of FERIFER in elderly patients has not been studied.

- **Special conditions for use:**

Kidney/Liver failure:

Do not use FERIFER in severe liver and kidney diseases.

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

If you use more FERIFER than you should:

Overdose may cause diarrhea, stomach pain and vomiting and, in severe cases the amount of acid in the blood rises above normal (metabolic acidosis), severe muscle cramping (spasms) and coma may occur.

If you may have taken more FERIFER than you should, talk to a doctor or pharmacist.

If you forget to use FERIFER:

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

Effects that may occur when FERIFER treatment is stopped:

None.

4. Possible side effects?

Like all medicines, side effects can occur in people sensitive to the contents of FERIFER.

If any of the following occur stop taking FERIFER and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Difficulty in breathing, swelling of the face, lips, tongue or throat, sudden fall in blood pressure, generalized and severe rash, itching, hives (urticaria)

These are all very serious side effects.

If you have any of them, this means you have serious allergy to FERIFER. You may need emergency medical care or hospitalization.

Very serious side effects occur very rarely.

If you notice any of the following immediately inform your doctor or go to the nearest emergency department:

- Asthma

These are all serious side effects. They may require emergency medical treatment.

Serious side effects occur very rarely.

If you notice any of the following immediately inform your doctor:

- Indigestion
- Abdominal discomfort
- Nausea, vomiting
- Heartburn
- Bitter taste in mouth
- Mild abdominal pain
- Itchy bumps, rash, redness on skin
- Headache
- Discoloration of urine and stool

These are mild side effects of FERIFER.

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

5. How to store FERIFER?

Keep FERIFER away from children's sight and reach and in its package.

Keep at room temperature below 25°C.

Use in accordance with the expiry date.

Do not use FERIFER after the expiry date indicated on the package.

Do not use FERIFER if you notice any damage on the product and/or the package

Marketing authorization holder:

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