

PATIENT INFORMATION LEAFLET

FERIFER 100 mg/5 ml oral solution in a spoon

For oral use.

- **Active substance:** In each spoonful (5 ml) of solution contains 294.12 mg iron III hydroxide polymaltose complex equivalent to 100 mg iron.
- **Excipients:** Sorbitol (E420), methyl paraben sodium (E219), propyl paraben sodium (E217), citric acid monohydrate, vanilla aroma, glycerin, propylene glycol and deionized water.

Read all of THIS LEAFLET carefully before you start taking 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, 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, tell it to your doctor.*
- *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. ***Before you take FERIFER***
3. ***How to take FERIFER***
4. ***Possible side effects***
5. ***How to store FERIFER***

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

- FERIFER is an oral solution containing 294.12 mg iron III hydroxide polymaltose complex equivalent to 100 mg iron in each spoon (5 ml), which is made of PET, and covered by aluminum.
- Each box is contained 10, 20, 28 or 30 disposable spoons of 5 ml. Each spoon presentation forms is also packaged in PVC separator.
- In treatment and prophylaxis of iron deficiency, which is originated from various causes, and iron deficiency anemia; it is used in iron supplementation treatment in pregnancy, lactation, and in children.
- All iron deficiencies of different origins and prevention (prophylaxis) and treatment of anemia due to iron deficiency.
- During pregnancy, folic acid supplementation should also be considered with iron supplementation.

2 – What you need to know before you take FERIFER

DO NOT take FERIFER if:

- you have high iron loads (hemochromatosis, hemosiderosis)
- you have hypersensitivity against iron
- you have an iron metabolism disorder (lead anemia, sideroachrestic anemia) and “Mediterranean Anemia” (thalassemia) disease,
- you have anemia other than iron deficiency (hemolytic anemia),

Use FERIFER with CAUTION if:

- you have an allergic condition,

“If the abovementioned warnings apply to you even in the past, please consult your doctor.”

FERIFER with food and drink:

No interaction with foods and drinks.

Pregnancy:

Consult your doctor or pharmacist before taking this medicine.

FERIFER can be used as iron supplementation during the pregnancy.

Contact your doctor or pharmacist immediately if you realize that you are pregnant during your treatment.

Breastfeeding

Consult your doctor or pharmacist before taking this medicine.

FERIFER can be used during breastfeeding.

Ability to drive and use of machines

No effect on ability to drive or use of machines.

Important information about some excipients contained in FERIFER

As this medicine contains sorbitol and sucrose, if you have been previously told by your doctor that you have intolerance to some sugars, contact to your doctor before taking FERIFER.

It may cause allergic reactions (possibly delayed type) because it contains methyl paraben sodium and propyl paraben sodium.

This medicinal product contains 1.27 mg of sodium per 5 ml. This should be considered for patients on a controlled sodium diet. Due to the glycerin it contains, it can cause headache, nausea and diarrhea. Because it contains propylene glycol, it can cause alcohol-like symptoms.

Using with other medicines

Iron (III) Hydroxide Polymaltose Complex does not have an ionic interaction with foods and concomitant drugs (tetracyclines, antacids).

It is known that vitamin C increases the iron absorption.

When levothyroxine-containing drugs used in the treatment of thyroid diseases are taken together with FERIFER, the absorption is impaired, therefore two drugs should be interrupted for at least 4 hours.

Tell your doctor or pharmacist if you are taking or have recently taken any medicine with or without prescription.

3 - How to take FERIFER?

- **Instructions for appropriate use and dosage/frequency:**

FERIFER is always taken as recommended by your doctor accurately. If you are not sure, check with your doctor or pharmacist. This drug is prescribed for you. Don't give somebody else. It can be harmful, even if the symptoms are the same as yours.

Latent iron deficiency: 1/2 or 1 spoon a day (50 mg or 100 mg).

Severe iron deficiency: 1 spoon twice or three times a day (200 mg – 300 mg).

The duration of treatment depends on degrees of anemia and becoming normal level of erythrocyte. Average 3-5 months are needed to achieve normal blood levels for treatment on significant iron deficiency.

The duration of treatment for latent iron deficiency is for 1 – 2 months.

Treatment should be continued at least for 2 – 3 months with a spoon a day more after iron deficiency symptoms are disappeared for the body reserves to be filled up.

Route and method of administration:

FERIFER is for oral use.

FERIFER is taken directly from the spoon.

- **Various age groups:**

Use in children:

There is no sufficient data to advice a dosage in use children under 12 years-old for routine usage.

Use in elderly people:

Use in elderly people is the same as the use in adults.

- **Special conditions for use**

Kidney/Liver failure:

It shouldn't be used in individuals with severe kidney and liver failure.

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

If you take more FERIFER than you should:

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

If you take more FERIFER than you should take, nausea, vomiting, abdominal pain, and diarrhea may be observed. Light headedness, paleness, or the grey-blue discoloration of the skin (cyanosis), even shock may be developed. Patient needs to be forced to vomit and/or gastric lavage may be needed. If some time is passed since the intoxication, then a drug like desferrioxamine can be used to chelate iron excess in the body.

In children younger than 6 years old, intake/swallowing of 60 mg/kg (3/5 spoon /kg) of iron containing products cause fatal toxicity outcomes. Therefore these drugs should keep out of reach of children. In cases of overdose, immediately contact your doctor or the National Poison Information Centre immediately.

If you forget to take FERIFER:

Do not take a double dose to make up for the missed dose of FERIFER.

Omit the missed dose, and take the next dose at the planned dose time.

Effects that may occur if you stop treatment with FERIFER:

None.

4 – Possible side effects?

Like all medicines, FERIFER can cause side effects in individuals sensitive to ingredients.

IMMEDIATELY contact your doctor or apply to the emergency service of the nearest hospital, if you experience any of the following symptoms after FERIFER:

- Swelling in hands, feet, wrists, face, lips or especially in mouth or throat, which may cause difficulty in swallowing or breathing
- Severe skin rash

All of these are very serious side effects.

If you have any one of these side effects, then it indicates that you have serious allergy against FERIFER. You may require medical intervention or you should be hospitalized.

All of these very severe side effects are observed quite rare.

IMMEDIATELY contact your doctor or apply to the emergency service of the nearest hospital, if you experience any of the following symptoms:

- Pain in the chest or throat (especially while swallowing)
- Blood in the stool (red or black in color)

All of these are serious side effects, and they may require emergent medical interventions.

Severe side effects are observed very rarely.

Contact your doctor if you realize any of the complaints below:

- Nausea
- Diarrhea
- Vomiting
- Constipation

These are mild side effects of FERIFER.

These side effects recover when the dose is decreased or the treatment is discontinued.

If you get any side effects not mentioned in this leaflet, talk to your doctor or pharmacist.

5 – How to store FERIFER

Keep FERIFER out of the sight and reach of children and in its package.

Keep at the room temperature below 25°C.

Use according to the expiry date

Use FERIFER before the expiry date indicated on the spoon or the carton.

If you realize any damage in the product and/or package, do not use that FERIFER product.

Marketing authorization holder:

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