

PATIENT INFORMATION LEAFLET

FERIFER-40 Oral Solution

For oral use only.

- **Active substance:** Each spoon contains (5 ml) solution contains 117.65 mg iron III hydroxide polymaltose complex equivalent to 40 mg iron.
- **Excipients:** Sorbitol (70%) (E420), methyl paraben sodium (E219), propyl paraben sodium (E217), citric acid monohydrate, vanilla flavor, glycerin, propylene glycol and deionized water.

Read this PATIENT INFORMATION 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.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *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-40 is and what it is used for?*
- 2. What you need to know before you take FERIFER-40?*
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1. What FERIFER-40 is and what it is used for?

- FERIFER-40 is an oral solution presented in PET spoons sealed with aluminum; each spoon (5 ml) contains 117.65 mg iron III hydroxide polymaltose complex equivalent to 40 mg iron.
- Each box contains 10 or 28 disposable spoons of 5 ml. These presentations of 10 and 28 spoons are also packaged in a PVC separator.
- FERIFER-40 is used for iron deficiency for different causes; for the treatment of iron deficiency anemia and protection from such anemia; and treatment of iron deficiency in pregnancy, lactation and childhood.

2. What you need to know before you take FERIFER-40?

DO NOT take FERIFER-40

If;

- You have hypersensitivity to iron or other excipients
- You have iron overload (hemochromatosis, chronic hemolysis)
- You have non-iron deficiency anemia (e.g. hemolytic anemia)
- You have disturbances in iron utilization (lead anemia, sideroachrestic anemia)
- You have mediterranean anemia, a hereditary blood disease (thalassemia)
- You have progressive and chronic joint inflammation
- You have conditions requiring regular blood transfusion
- You have HIV infection and anemia which is not clear to be caused from iron deficiency
- You have severe liver and kidney diseases

Take FERIFER-40 with CAUTION

- If you are allergic
- If you have stomach ulcers; use this medicine under doctor control.
- Accidental ingestion of iron-containing products in children can lead to fatal poisoning. Keep out of reach of children.

The color of the stool may become darker during the use of oral iron preparations, this is a normal reaction and it does not require any action.

It does not cause test errors during the fecal occult blood tests. Therefore there is no need to discontinue the treatment during this test.

It should be used with caution in case of alcoholism and diseases which disturb the iron absorption from the intestine.

In the anemia of different diseases and cancer iron stored in the liver and it is used by mobilizing following the cancer treatment.

If any of them apply to you even if in the past please consult your doctor.

Taking FERIFER-40 with food and drink

You should take FERIFER-40 with food or after meals.

You should not take with milk. You should not take with calcium-containing products and pharmaceuticals. It should be at least 2 hours between them.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

You may use FERIFER-40 during pregnancy as iron supplement as your doctor advice.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

You may use FERIFER-40 during breast-feeding as iron supplement as your doctor advice.

Iron pass into breast milk. Amount of iron in breast milk is not affected by current iron levels or iron taken with food. Therefore, administration of an iron preparation to nursing mother does not cause the iron intoxication or treatment of iron deficiency in infant.

Driving and using machines

There is no effect on driving or using machines.

Important information about some of the excipients of FERIFER-40

If you have been previously told by your doctor that you have an intolerance to some sugars, contact with your doctor before taking this medicinal product, because FERIFER-40 contains sorbitol (70%) (E420).

It contains methyl paraben sodium (E219) and sodium propyl paraben (E217) which may cause (probably delayed) allergic reactions.

Taking with other medicines

There is no interaction between FERIFER-40 and the other medicines except for the following drugs.

It is known that vitamin C increases iron absorption.

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

Drugs containing levothyroxine (used in the treatment of thyroid diseases) should be taken with FERIFER-40 for at least 4 hours after taking the medicines, because their absorption is impaired.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to take FERIFER-40?

• **Instructions for proper use and dosage/administration frequency:**

Take FERIFER-40 with or after meals as described below unless your doctor recommended otherwise.

- *Children:* 1 spoon (5 ml) 1-2 times daily
- *Adults:* 1 spoon (5 ml) 2-3 times daily

FERIFER-40 should be used as long as doctor recommends. For iron storage, it should be continued to treatment after the signs of iron deficiency disappear.

• **Route and method of administration:**

FERIFER-40 is only for oral use.

FERIFER-40 spoon content is taken directly through oral route.

It can be taken with fruit or vegetable juice.

• **Various age groups:**

Use in children:

Take as described above.

Use in elderly:

Take in elderly is the same as in adults.

• **Special usage conditions:**

Kidney/Liver insufficiency:

Do not use FERIFER-40 in case of serious liver and kidney diseases.

If you have any impression that effect of FERIFER-40 is extremely strong or weak, tell your doctor or pharmacist.

If you take more FERIFER-40 than you should:

If you take more FERIFER-40 than you should, talk to your doctor or pharmacist.

In case of taking more than you should, diarrhea, stomach pain and vomiting may occur and in advanced cases, metabolic acidosis, severe muscle spasms and coma may be observed.

If you forget to take FERIFER-40:

Do not take double dose to balance the missed doses.

Skip the missed dose and use the next dose on time.

If you stop taking FERIFER-40:

Nonnotification

4. Possible side effects

Like all medicines, FERIFER-40 can cause side effects, although not everybody gets them.

If you get any of following side effects, stop taking FERIFER-40 and contact your doctor immediately or go to the emergency room of the nearest hospital.

- Shortness of breath; swelling of face, lips, tongue or throat; sudden decrease in blood pressure; generalized and severe redness; itching (allergic reactions)
- Hives (urticaria)

These all are very serious side effects.

If one of them happens to you, it means that you are allergic to FERIFER-40. Urgent medical care and hospitalization may be needed.

Side effects are classified according to frequency of occurrence as follows:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but more than 1 or 1 in 100 patients

Uncommon: may be seen less than 1 in 100 patients but more than 1 or 1 in 1.000 patients

Rare: may be seen less than 1 in 1.000 patients but more than 1 or 1 in 10.000 patients

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: It cannot be estimated from the available data.

Uncommon

- Headache
- Feeling of satiety
- Weight sensation in stomach (epigastric weight sensation)
- Nausea
- Constipation
- Diarrhea
- Abdominal pain
- Vomiting

- Reversible discoloration of teeth
- Skin rash
- Exanthema (a skin reaction of pink-red color, usually with itchy skin rashes and spread to other parts of the body)
- Itching

Rare

- Change in urine color

Very rare

- Asthma
- Regional skin reactions

Color change can often be seen in the stool due to iron.

If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store FERIFER-40?

Keep FERIFER-40 out of sight and reach of children and store in the original package.

Store below 25°C at room temperature.

Each spoon is for single use only. Unused solution should be disposed.

Use in accordance with the expiry date.

Do not use FERIFER-40 after expiry date which is stated on spoon or package.

Do not use FERIFER-40 if you notice any damage in product and/or package.

Marketing Authorization Holder:

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