

## PATIENT INFORMATION LEAFLET

### FERIFER-40 Oral Solution, 40 mg/5 ml

For oral use only.

- **Active substance:** Each spoon contains (5 ml) solution having 117.65 mg iron III hydroxide polymaltose complex equivalent to 40 mg iron.
- **Excipients:** Sorbitol (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. It may harm them, even if their signs of illness are the same as yours.*
- *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. ***Before you take FERIFER-40***
3. ***How to take FERIFER-40?***
4. ***Possible side effects***
5. ***How to store FERIFER-40?***

#### **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 and prophylaxis of iron deficiency anemia; and as an iron supplement in pregnancy, lactation and childhood.

## **2. Before you take FERIFER-40**

### **DO NOT take FERIFER-40:**

**If you have,**

- Hypersensitivity to iron or other excipients
- Iron overload (hemochromatosis, chronic hemolysis)
- Hypersensitivity to iron
- Non-iron deficiency anemia (e.g. hemolytic anemia)
- Disturbances in iron utilization (lead anemia, sideroachrestic anemia)
- Mediterranean anemia, a hereditary blood disease (thalassemia)
- Progressive and chronic joint inflammation
- Conditions requiring regular blood transfusion
- HIV infection and anemia which is not clear to be caused from iron deficiency
- Severe liver and kidney diseases

### **Take special care with FERIFER-40**

- If you are allergic
- If you have stomach ulcers; use this medicine on doctor control.

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 nursing as iron supplement as your doctor advice.

Iron penetrate 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 (E420).

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

Due to the glycerin it contains, it may cause headache, nausea and diarrhea. Because it contains propylene glycol, it may cause symptoms like alcohol.

This medicinal product contains 1.27 mg sodium in each of 5 ml. This should be considered for patients on sodium controlled diet.

**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 used at least 1 month 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:**

**Children:**

Take as described above.

**Elderly:**

Take in elderly is the same as in adults.

- **Special populations**

**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.

In children younger than 6 years of age, taking/swallowing products containing iron may cause fatal poisoning. Therefore, keep these drugs out of the reach of children. In case of overdose, call your doctor or the National Poison Information Centre immediately.

**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; 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.

These very serious side effects occur very rarely.

**If you get any of following side effects, contact your doctor or go to the emergency room of the nearest hospital.**

- Asthma

These all are serious side effects. Urgent medical care may be needed.

These serious side effects occur very rarely.

**If you get any of following side effects, tell your doctor:**

- Indigestion
- Abdominal discomfort
- Nausea, vomiting
- Burning feeling in your stomach
- Bitter taste in your mouth
- Mild abdominal pain
- Itching of the skin, swellings, rash, and redness
- Headache
- Change in color of urine and feces
- Reversible color change of teeth

These are minor side effects of FERIFER-40.

*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.

**Please use in accordance with 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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