

PATIENT INFORMATION LEAFLET

FERLOS® 20 mg/mL Oral Solution

For oral use

- **Active substance:** Each ml contains 64,516 mg of ferric III hydroxide polymaltose complex equivalent to 20 mg of elemental iron.
- **Excipients:** Sugar, sorbitol 70% non-crystallized (E420), sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), cream flavor, caramel flavor, hydrochloric acid or sodium hydroxide, 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. Do not pass it on to others.*
- *It may harm them, even if their symptoms are the same as yours.*
- *Please tell your doctor that you are taking this medicine if you seek medical assistance during the use of this medicine.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended*

What is in this leaflet:

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

1. What FERLOS® is and what it is used for.

FERLOS® is a solution for oral use that contains iron III hydroxide polymaltose complex. Each vial of FERLOS® for oral use (5 ml) contains iron III hydroxide polymaltose complex equivalent to 100 mg of elemental iron.

Each box of FERLOS® contains 10 or 20 vials (5 ml) for single use.

FERLOS® is used for the treatment of anemia caused by reduced iron content in red blood cells.

A complex molecule is formed by the combination iron hydroxide and polymaltose molecules found in FERLOS®. FERLOS® is used for the treatment and prophylaxis of all the iron deficiencies due to various causes, and iron deficiency anemia.

2. What you need to know before you use FERLOS®

DO NOT USE FERLOS® if you have the following conditions:

- Iron overload (hemochromatosis, hemosiderosis)
- Hypersensitivity to iron or any of the other excipients
- Disorders of iron utilization (lead anemia, sidero-achrestic anemia) or thalassemia
- Severe hepatic or renal impairment
- Progressive and chronic inflammation of the joints
- Requirement for regular and continuous blood transfusions
- HIV infection without clinically confirmed iron deficiency anemia
- Anemia not caused by iron deficiency (hemolytic anemia).

FERLOS® should be used WITH CAUTION in following conditions:

- Requirement for regular blood transfusions
- Gastric ulcer; your doctor will decide whether you will use FERLOS® or not
- Stools may darken during treatment with oral iron preparations; this is normal, requiring no precautions.
- This medicine does not affect occult blood test in the stool. Therefore, there is no need to discontinue treatment during such tests.
- Should be used with caution in alcoholism and disorders impairing intestinal iron absorption.
- In certain disorders or anemia due to cancer, ingested iron is stored in the liver, and is utilized following the treatment of such disorders or cancer.

Please consult your doctor if these warnings apply to you even at any time in the past.

Effects of food and drinks on FERLOS®

FERLOS® should be taken together or after a meal.

It should not be taken with calcium-containing medications. A 2-hour time interval is recommended between these two preparations. Similarly, simultaneous ingestion with milk and dairy products is not recommended.

Pregnancy

Tell your doctor or pharmacist before using this medicine

FERLOS® may be used for iron supplementation during pregnancy.

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

Breastfeeding.

Tell your doctor or pharmacist before using this medicine

FERLOS® can be used during breastfeeding.

Ability to drive and use machinery

This medicine does not affect the ability to drive or use machinery.

Important information on some of the excipients of FERLOS®

FERLOS® contains sorbitol (E420) and sugar. If you have been previously told by your doctor that you have intolerance to certain sugars, ask advice from your doctor before using FERLOS®. This only applies to chronic use (e.g 2 weeks or more) of the medicinal product.

This product may lead to allergic reactions (probably delayed) due to methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217) content.

This product contains less than 1 mmol (23 mg) of sodium; therefore, it is essentially sodium-free.

Concurrent use with other medicines

Iron III hydroxide polymaltose complex does not enter an ionic interaction with food and medicines (tetracyclines, antacids) taken concurrently.

Vitamin C is known to increase iron absorption.

Since concomitant intake of iron and medicines containing levothyroxine may impair the absorption of levothyroxine, these two medicines should be taken at least 4 hours apart.

If you are taking or have recently taken any prescribed or non-prescribed medications, tell this to your doctor or pharmacist.

3. How to use FERLOS®

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

Always use FERLOS® as exactly prescribed by your doctor. If you are not sure, ask your doctor or pharmacist. This medicine has been prescribed only for you. Do not pass it onto others. It may harm them even if they have similar symptoms.

Occult iron deficiency: half or 1 vial of FERLOS® daily (50-100 mg)

Overt iron deficiency: 2-3 vials of FERLOS® daily (200-300 mg)

The duration of treatment depends on the severity of anemia and on the normalization of the red blood cell count. In overt iron deficiency, normal blood levels can be restored within 3 to 5 months on average. For occult iron deficiency, the average duration of treatment is 1 to 2 months.

In order to replete the iron stores, treatment should be continued for 1 more month after normalization of blood parameters (Hb, Hct, RBC count).

• Method and route of administration:

FERLOS® is only for oral use.

• Age groups

Pediatric patients:

Currently, there is no sufficient data to recommend routine use of FERLOS® in children under 12 years of age.

Elderly:

The adult dose is administered.

• Special precautions for use:**Hepatic/renal failure:**

Do not use FERLOS® in sever hepatic or renal disease.

If you have an impression that the effect of FERLOS® is much stronger or weaker than expected, ask advice from your doctor or pharmacist.

If you have taken more FERLOS® than you should:

Inadvertent intake/ingestion of iron preparations in children under 6 years of age may lead to fatal poisoning. Therefore, keep medicines out of the reach of children. In case of overdose, immediately contact with your doctor or the National Poison Control Center.

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

If you forget to take FERLOS®

Do not take double doses to make up for the missing dose.

Skip the missing dose, and take the next dose as prescribed.

Effects that may occur when the treatment with FERLOS® is stopped.

None.

4. Potential side effects

As with all medicines, FERLOS® may cause side effects in subjects sensitive to its ingredients.

Stop taking FERLOS® and seek for IMMEDIATE medical assistance or call your doctor if you experience any of the following:

- Swelling in hands, arms, wrists, face, or lips; or particularly, the swelling of the mouth or throat making swallowing or breathing more difficult.
- Severe rash

All these represent severe side effects.

Presence of these symptoms shows that you have severe allergy to FERLOS®.

You may need urgent medical assistance or hospitalization.

These very severe side effects occur rarely.

Seek for immediate medical assistance or call your doctor if you experience any of the following:

- Pain in the chest or throat (particularly when swallowing)
- Bloody stools (red or black colored stools)

All of these represent severe side effects. They may require immediate medical treatment.

Severe side effects occur very rarely.

Talk to your doctor if you notice any of the following:

- Nausea
- Diarrhea
- Vomiting
- Constipation
- Abdominal discomfort
- Heartburn
- Indigestion
- Change in the color of stools or urine
- Mild abdominal pain
- Headache

These represent mild side effects of Ferlos.

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

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also, you can report the side effects to TÜFAM (Turkish Pharmacovigilance Center) by clicking the “Reporting of Drug Side Effects” button at www.titck.gov.tr or by calling at 0 800 314 00 08. By reporting side effects, you will help us collect more data on the safety of the medicine you are using.

5. How to store FERLOS®

Keep FERLOS® out of the reach and sight of children in its original box.

Store in room temperature under 30°C.

Use in accordance with the expiry date.

Do not use FERLOS® after the expiry date printed on the package.

If you notice any compromise in the integrity of the product and/or its packing, do not use FERLOS®.

Do not throw unused or expired medicines into common household waste! Discard them through the collection system organized by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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This leaflet has been approved <{DD month YYYY}>.

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