

PATIENT INFORMATION LEAFLET

FERROZINC Syrup, For oral use.

- **Active substance(s):** Each 5 ml (1 measuring cup) contains 39.77 mg iron equivalent to 121 mg ferrous fumarate, 15 mg zinc equivalent to 66 mg zinc sulfate heptahydrate, 200 mcg folic acid and 50 mg vitamin C.
- **Excipients:** Sorbitol (E420), methyl paraben sodium (E219), sodium saccharine, citric acid monohydrate, sodium hydroxide, sodium chloride, sodium acetate, neohesperidin DC, fructose, sodium cyclamate, orange flavor, lemon flavor, tangerine flavor, vanilla flavor and deionized water.

Read this PATIENT INFORMATION 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 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 FERROZINC is and what it is used for?**
- 2. Before you use FERROZINC**
- 3. How to use FERROZINC?**
- 4. Possible side effects?**
- 5. How to store FERROZINC**

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

- FERROZINC is orally taken syrup which is presented in amber-colored glass bottle closed with pilfer-proof LDPE reservoir screw cap together with self-piston and LDPE/EPE/LDPE membrane. It contains 39.77 mg iron equivalent to 121 mg ferrous fumarate, 15 mg zinc equivalent to 66 mg zinc sulfate heptahydrate, 200 mcg folic acid and 50 mg vitamin C.
- FERROZINC is used in cases of zinc deficiency with iron deficiency.

2. Before you use FERROZINC

Do not use FERROZINC in the following situations

If;

- You have iron absorbance (hemochromatosis) or iron accumulation (hemosiderosis) disorder,
- You have iron utilization disorders (lead anemia, sidero acrestic anemia),

- You have some kind of anemia called the Mediterranean anemia (thalassemia)
- You have anemia not dependent on iron insufficiency (megaloblastic anemia dependent on Vitamin B12 insufficiency, hemolytic anemia),
- You have anemia dependent on failure of iron-bearing structures (hemoglobinopathy),
- You have urethritis (inflammatory) bowel disease,
- You have gut (intestinal) narrowing,
- You have inflammation of the projections in the intestinal wall (diverticulitis),
- You have active gastric ulcer,
- You have regional small bowel inflammation (enteritis),
- You have inflammation of the area covering the inside of the large intestine with the effect of environmental factors (ulcerative colitis),
- Parenteral (by injection) iron is administered,
- Medicine called dimercaprol used in some metal poisonings is to be administered,
- You have copper deficiency,
- You receive regular blood transfusions,
- You are HIV-infected (AIDS disease),
- You have alcohol dependence or liver inflammation (hepatitis)
- Your iron insufficiency is not clinically proven,
- You have allergic (hypersensitivity) to any of active substances and/or other substances in FERROZINC.

TAKE SPECIAL CARE WITH FERROZINC in the following conditions

- If your child have anemia not dependent on iron insufficiency, do not use without consulting your doctor.
- Because iron-containing medicines cause the stool color to darken, it can lead to incorrect results in fecal occult blood tests.
- Darkening may occur in the teeth. Therefore, it is recommended that you rinse your mouth with plenty of water after using FERROZINC.
- Prolonged and excessive use without medical supervision can cause toxic accumulation in children (poisoning).
- If you have surgical removal of part of the stomach, (undergone gastrectomy) the absorption of FERROZINC may be impaired.
- Once the iron deficiency has been treated, do not exceed the treatment period recommended by your doctor.
- If you have vitamin B12 or folic acid deficiency, consult your doctor.
- If you have stomach ulcer, use under supervision of your doctor.
- If you have kidney failure, it can lead to zinc accumulation.
- During pregnancy do not use without consulting your doctor.
- Long term or high dose zinc intake may cause copper deficiency.
- Accidental intake of 60 mg / kg of iron-containing products in children under 6 years causes fatal poisoning. Therefore, these medicines should be kept out of reach of children.

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

Using FERROZINC with food and drink

Do not use together with tea, coffee, milk, cheese, eggs and whole-grain and fiber foods as they decrease iron and zinc absorption. Take FERROZINC at least 1 hour before or 2 hours after the nutrition above.

Pregnancy

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

There is not adequate information about the use of FERROZINC in pregnant women.

Use under your doctor's supervision during pregnancy period, if necessary.

FERROZINC should not be used during pregnancy unless it is necessary.

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

Breastfeeding

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

FERROZINC may be secreted to the milk, therefore use under your doctor's supervision during breastfeeding period, if necessary.

Effects on ability to drive and use machines

It has no negative effect on ability to drive or use machines.

Important information about some of the ingredients of FERROZINC

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FERROZINC as it contains fructose and sorbitol (E420).

FERROZINC contains 5 mg methyl paraben sodium (E219) per each 5 ml. Therefore, allergic reactions (possibly delayed) and extraordinary temporary narrowing of the airways (bronchospasm) may occur.

If you are on a controlled sodium diet, please note that this medicinal product contains 82.3 mg sodium per each 5 ml

Using with other medicines

FERROZINC must be taken carefully with the medicines below;

- Antacids reducing stomach acid (magnesium trisilicate and carbonate),
- Mineral supports (calcium, copper, magnesium and other mineral supports, bicarbonates),
- Some painkillers (salicylates, phenylbutazone and oxyphenbutazone),
- Some anti-inflammatory drugs (tetracycline and sulfonamide, penicillamine, chloramphenicol, fluoroquinolone group antibiotics, nalidixic acid, neomycin),
- Medicines used in the treatment of some rheumatic diseases (gold compounds taken orally),
- Birth control medications can reduce plasma zinc levels,
- Some psycholeptics and anti-epileptics for treatment of falling sickness (barbiturates),
- Some cancer drugs (antineoplastic agents, cytostatics),
- Medicines used in Parkinson's treatment (levodopa, carbidopa, entacapone),
- Some medicines that suppress the immune system (mycophenolate),
- Some stomach medications (proton pump inhibitors),
- Some drugs used in the treatment of thyroid (goitre) disease (levothyroxine),

- Eltrombopag which is a drug that increases the number of platelets that are blood cells that provide blood clotting),
- Bisphosphonate-group drugs used in osteoporosis,
- Vitamin C, drugs containing citric acid,
- Vitamin E,
- Methyldopa used in the treatment of high blood pressure,
- Trientine used in the treatment of Wilson's disease caused by copper accumulation in the body
- Cholestyramine used in the treatment of cholesterol.

If you use a medicine that contains fluoroquinolone (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, sparfloxacin, etc.) and if you have to take syrup twice a day, take FERROZINC at least 3 hours after meals.

When the drugs containing levothyroxine are taken with FERROZINC, the two drugs should be taken at least 4 hours apart as the absorption of FERROZINC is impaired

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

3. How to use FERROZINC?

- **Instructions for appropriate method and dose/frequency of administration:**

Unless recommended otherwise by your doctor, use FERROZINC in children as below:

Age	Daily dose (ml)
6 months – 1 year	1.5 ml with pipette
1 – 3 years	2.0 ml with pipette
4 – 8 years	4 ml with pipette
9 – 13 years	6.0 ml with pipette
14 – 18 years	10 ml (2 spoons)
18 years and above	13 ml with pipette

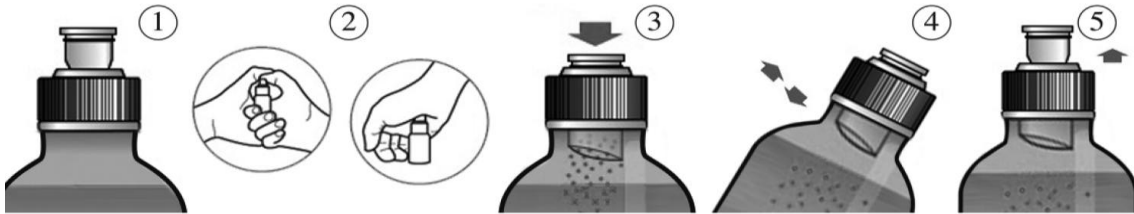
It should be used for the duration recommended by the doctor. It should be used at least two more months to fill depots after the symptoms of iron deficiency have disappeared

- **Route and method of administration:**

FERROZINC is only for oral use.

Take at least 1 hour before or 2 hours after meals with pipette.

- **Preparation of the syrup prior to use**



1. FERROZINC contains 1 bottle, reservoir cap system and 5 ml pipette.
2. Press the piston on the mouth of the bottle down strongly with both your hands to ensure the powder discharge into the bottle.
3. Shake the bottle hardly for 1-2 minutes.
4. Open the reservoir cap system on the mouth of the bottle while using.
5. Use the appropriate doses of the syrup by pipette and then recap.

Expiration of the resulting syrup is 20 days

- **Different age groups:**

- Use in elderly:**

- No additional information is available on the use of FERROZINC in elderly patients.

- **Special conditions:**

- Kidney/Liver failure:**

- Do not use FERROZINC in kidney and liver failure.

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

If you have used more FERROZINC than you should:

If you have used more FERROZINC than you should, talk to a doctor or pharmacist.

If the syrup is taken in overdose, the following symptoms may occur depending on the iron content:

Gastrointestinal poisoning, excessive nausea, vomiting, abdominal pain and diarrhea usually occur in the first stage up to 6 hours after taken orally. Hematemesis (blood vomiting) and rectal bleeding may also occur. Symptoms range from low blood pressure, increase in heart rate (tachycardia), increase in blood acid, increase in blood sugar, weakness and coma (deep unconsciousness that a person cannot react to environment) can be seen. Patients with mild to moderate intoxication usually do not progress to this stage.

Temporary healing may be seen in the second stage after 6 to 24 hours.

Shock, increase in blood acid, seizure (convulsion), coma (deep unconsciousness that a person cannot react to environment), liver damage and jaundice, decrease in blood sugar, blood clotting (coagulation) disorders, reduction in daily urine volume (oliguria) or gastrointestinal toxicity with kidney failure and lung edema occur in the third stage after 12 to 48 hours. In addition, severe fatigue and (impairment of the contraction of the heart (myocardial dysfunction) may occur.

The fourth stage may be seen a few weeks after oral intake and congestion in the digestive tract and possibly late liver damage may occur.

Hemosiderosis (iron storage disorder) occur when taken overdose for a long time. Liver cirrhosis due to iron accumulation and pancreatic fibrosis, a pancreas disease may develop.

Accidental intake of 60 mg/kg (7.5 ml/kg with pipette) in children under 6 years of age results in fatal intoxications. In case of overdose, call your doctor or National Toxic Information Center immediately.

If the syrup is taken in an overdose, the following symptoms may occur depending on the zinc content:

Zinc sulphate is abrasive (corrosive) in case of overdose. The overdose signs are abrasion (corrosion), inflammation of the mucous membrane covering the mouth and the outer layer of the stomach, and perforation following penetration of the stomach ulceration.

No zinc poisoning due to long term use of zinc has been detected in humans.

If you forget to use FERROZINC:

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

Continue to take it again at the recommended dose according to the subsequent normal intake time.

If you stop using FERROZINC:

None.

4. Possible side effects?

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

The specified side effects are classified according to the following frequency:

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1.000$ to $< 1/100$); rare ($\geq 1/10.000$ to $< 1/1.000$); very rare ($< 1/10.000$); not known (can not be estimated from the available data).

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

- Swelling in face, tongue, throat
- Trouble breathing, wheezing
- Excessive drop in blood pressure, dizziness, loss of balance
- Hives and itch, skin rash

These are all very serious side effects. If you have any of them, this means you have serious allergy to FERROZINC. You may need emergency medical care or hospitalization.

These 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:

- Tar colored stool or light colored blood in the stool
- Vomiting along with severe stomachache
- Low blood pressure, irregular heartbeat (arrhythmia)

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

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

Common

- Diarrhea
- Nausea
- Abdominal ache in stomach area
- Burning sensation in the stomach
- Bloating in the stomach, indigestion
- Constipation
- Vomiting
- Darkening of stool color
- Gastritis (stomach inflammation)

Uncommon:

- Change in the complete blood count (neutropenia, leukopenia, anemia)
- Nervousness, numbness, feeling of drowsiness
- Headache, dizziness,
- Darkening of urine color

Very rare:

- Changes in electrocardiographic (electrical activity of the heart) in potassium deficiency

These are mild effects of FERROZINC.

These side effects disappear when the dose is reduced or treatment is discontinued.

These symptoms caused by irritation can be prevented by reducing the dose or taking the medicine after meals. It should not be forgotten that food will prevent iron absorption.

Oral syrup containing iron salts and similar medicines can lead to darkening of teeth. To avoid this, the mouth should rinse with water after use.

Overdose or wrong treatment can lead to hemosiderosis (excess iron).

Zinc may affect copper absorption, lead to reduced copper levels and copper deficiency. The risk of copper deficiency is greater with long-term treatment and / or high zinc doses.

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

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store FERROZINC

Keep in the original package and out of the reach and sight of children.

Store at room temperature below 25°C

The ready-to-use syrup is stable for 20 days when stored at room temperature below 25 ° C

Use in accordance with expiry date.

Do not use FERROZINC after the expiry date which is stated on the label or package.

Do not use FERROZINC if you notice any damage to the product and/or package.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization holder:

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