

PATIENT INFORMATION LEAFLET

FERROZINC syrup

For oral use.

- **Active substance(s):** Each 5 ml (1 spoon) contains 121 mg ferrous fumarate equivalent to 39.77 mg iron, 66 mg zinc sulfate heptahydrate equivalent to 15 mg zinc, 200 microgram (0.2 mg) folic acid and 50 mg vitamin C.
- **Excipient(s):** Sorbitol (E420), methyl paraben sodium (E219), sodium saccharine, citric acid monohydrate, sodium hydroxide, sodium chloride, sodium acetate, neohesperidin DC 98%, fructose, sodium cyclamate, orange flavor, lemon flavor, tangerine flavor, vanilla flavor and purified water.

Read all of this 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. **What you need to know 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 an opaque white high-density polyethylene (HDPE) bottle closed with a reservoir cap system consisting of an opaque white polyethylene (PE) outer cap, a translucent polyethylene (PE) plug and a polypropylene (PP) plunger (plunger). Each 5 ml syrup contains 121 mg ferrous fumarate equivalent to 39.77 mg iron, 66 mg zinc sulfate heptahydrate equivalent to 15 mg zinc, 200 microgram (0.2 mg) folic acid and 50 mg vitamin C.
- Before use, the powder mixture in the reservoir cap is mixed with the syrup in the bottle containing the mineral mixture (see last page).
- Each box contains 100 ml x 1 bottle and one 5 ml pipette.
- FERROZINC is used in cases of zinc deficiency with iron deficiency.

2. What you need to know before you use FERROZINC?

DO NOT use FERROZINC

If;

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

- You have a kind of anemia called mediterranean anemia (thalassemia) disease
- 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 inflammatory bowel disease
- You have 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)
- Iron is administered via injection (parenteral)
- 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

Warnings and precautions

- 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 undergone surgical removal of part of the stomach (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 iron-containing products in children may cause fatal poisoning. Keep out of reach of children.
- It is not appropriate to use zinc in diarrhea of unknown origin seen in adults.
- It is not used for the treatment of pediatric diarrhea due to the high amount of zinc given at a time in products containing 30 mg of zinc.

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

FERROZINC with food and drink

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

Pregnancy

Consult your doctor or pharmacist before taking this 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.

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

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

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

Driving and using machines

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

Important information about excipients in FERROZINC

Since it contains fructose and sorbitol (E420), if you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicinal product.

Due to methyl paraben sodium (E219) content it may cause allergic reactions (possibly delayed).

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

Other medicines and FERROZINC

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 psychological drugs and antiepileptic drugs used for epilepsy (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 goitre (thyroid) disease (levothyroxine)

- Eltrombopag 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 an antibiotic medicine that contains group of 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 (used in the treatment of thyroid diseases) are taken with FERROZINC, the two drugs should be taken at least 2 hours apart as the absorption of FERROZINC 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 use FERROZINC?

- **Instructions for use and dosage/frequency of administration:**

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

| Age group | Recommended amount of zinc (mg/day) | Maximum tolerated amount of zinc (mg/day) | Scale (Pipette) |
|-------------------|-------------------------------------|---|-----------------|
| 7-12 months | 3 | 5 | 1-1.5 ml |
| 1-3 years | 3 | 7 | 1-2 ml |
| 4-8 years | 5 | 12 | 1.5-4 ml |
| 9-13 years | 8 | 23 | 2.5-7.5 ml |
| 14-18 years | 11 | 34 | 3.5-11 ml |
| 19 years and over | 11 | 40 | 3.5-13 ml |

You should use for the duration which is 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 of administration and method:**

FERROZINC is only for oral use.

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

Before the first use, the powder mixture in the reservoir cap and the syrup in the bottle containing the mineral mixture should be mixed, detailed information is on the last page of the Patient Information Leaflet.

- **Different age groups:**

Use in children:

Zinc should be administered to pediatric patients as indicated in the table above. It should not be used in infants aged 0-6 months, since dose adjustment cannot be made unless recommended otherwise by the doctor.

Use in elderly:

No additional information is available on the use of FERROZINC in elderly patients. The efficacy and safety of zinc in elderly patients has not been studied.

• Special cases of use:**Kidney/Liver failure:**

Do not use FERROZINC in kidney and liver failure.

The efficacy and safety of zinc in patients with kidney and liver failure have not been studied.

If you have impression that the effect of FERROZINC is very strong or weak, tell a doctor or pharmacist.

If you use more FERROZINC than you should:

If you use more FERROZINC than you should, tell your 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. Blood vomiting (hematemesis) 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.

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

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

Zinc sulphate is 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: may be seen at least 1 in 10 patients.

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

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

Rare: may be seen less than 1 in 1.000 patients.

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

Unknown: it cannot 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, it is recommended to 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 listed in this leaflet, please inform your doctor or pharmacist.

5. How to store FERROZINC?

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

Store at room temperature below 25°C

The ready-to-use syrup can be used 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.

Marketing Authorization Holder:

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Türkiye

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/ İstanbul-Türkiye

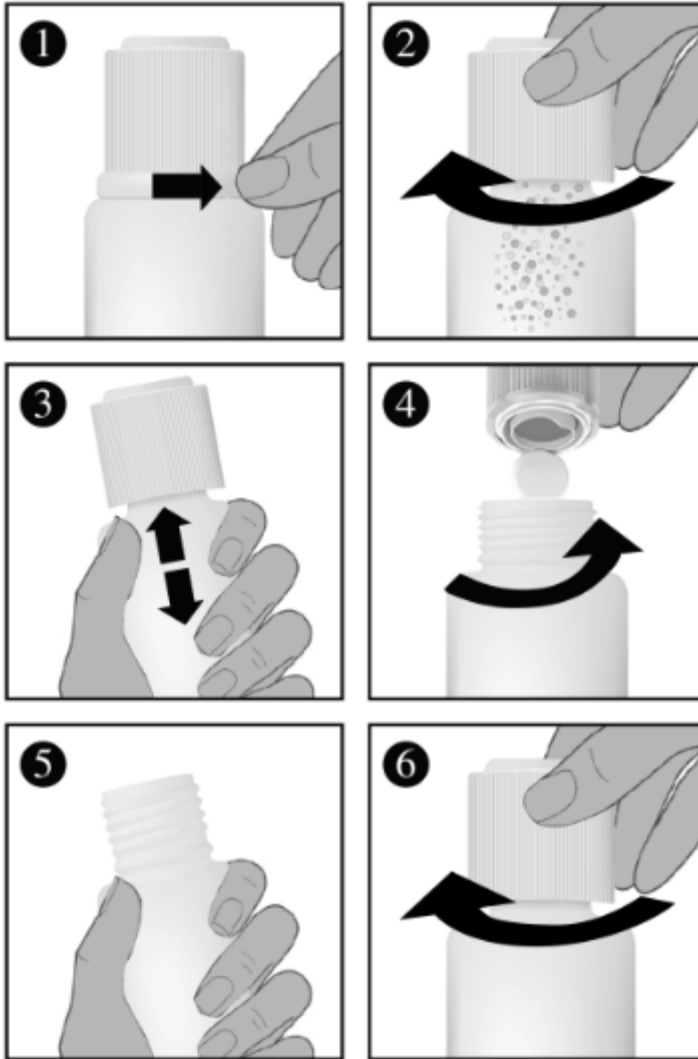
+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

This patient information leaflet was last approved on 18/05/2021.

Preparation of the syrup prior to use:

Before use, the powder mixture in the reservoir cap is mixed with the syrup in the bottle containing the mineral mixture by following the steps below.



1. Open the safety ring by holding the extension of the safety ring at the bottom of the cap and pulling it.
2. Turn the cap clockwise.
3. Shake the bottle well for 1-2 minutes.
4. Open the cap by turning it counterclockwise.
5. Use the appropriate doses of the syrup by pipette.
6. Close the cap by turning it clockwise.

Expiration of the resulting syrup is 20 days.