

## PATIENT INFORMATION LEAFLET

### FERROZINC Capsules

#### For oral use.

- **Active substance(s):** Each 1 capsule contains; 261.29 mg ferrous fumarate equivalent to 79.87 mg iron, 68.7 mg zinc sulfate monohydrate equivalent to 25 mg zinc, 0.4 mg folic acid, and 25 mg vitamin C.
- **Excipients:** Contains; lactose monohydrate (obtained from cow milk), corn starch, colloidal silica dioxide, talc, magnesium stearate, gelatin (bovine gelatin), azorubine (carmoisine, E 122), titanium dioxide (E 171) and polyethylene glycol.

**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 during the use of this medicine, inform your doctor about this.*
- *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 is it 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 is it used for?**

- FERROZINC is a capsule taken orally that contains ferrous fumarate, zinc sulfate monohydrate, folic acid and vitamin C.
- Each box contains 2 blisters with 20 capsules.
- 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 a kind of anemia called mediterranean anemia (thalassaemia) disease
- You have anemia not dependent on iron insufficiency (megaloblastic anemia dependent on Vitamin B<sub>12</sub> 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)
- 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;

- You 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 gastrectomy (partial or total surgical removal of the stomach), 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
- 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, keep these medicines 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, egg 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 lactose.

Due to azorubine (carmoisine, E122) in its contents, it can cause allergic reactions.

### **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, 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 a antibiotic medicine that contains group of fluoroquinolone (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, sparfloxacin, etc.) and if you have to take capsules 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, take the two drugs 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 as below:

- Take 1 capsule once daily.
- Take same dosage until your doctor tells you that your blood levels returned to normal in the blood analyses.
- Take specified dosage unless recommended otherwise by your doctor.

- **Route and method of administration:**

FERROZINC is only for oral use.

- You can take at least 1 hour before or 2 hours after meals.

- **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 capsule 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 may occur (myocardial dysfunction).

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.

Accidental intake of 60 mg/kg (3/4 capsules / kg) in children under 6 years of age results in fatal intoxications. Therefore keep these medicines out of reach of children. In case of overdose, call your doctor or National Toxic Information Center immediately.

If the capsule 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.

Side effects are listed according to the category given below:

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

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

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

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,

**Unknown**

- Dark coloring of the teeth

These are mild effects of FERROZINC.

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

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

**5. How to store FERROZINC**

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

Store in room temperature under 25°C.

**Use in accordance with expiry date.**

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

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

***Marketing authorization holder:***

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