

PATIENT INFORMATION LEAFLET

FERROZINC-G 40 mg/15 mg syrup

For oral use

Active substance(s): Each 5 ml (1 spoon) syrup contains 344 mg iron II gluconate equivalent to 40 mg iron and 105 mg zinc gluconate equivalent to 15 mg zinc.

Excipient(s): Citric acid, sorbitol (70%) (E420), glycerin, sodium benzoate (E211), fructose, neohesperidin DC, sodium cyclamate, sodium chloride, sodium hydroxide, sodium acetate, raspberry aroma, and deionized water.

Read all of 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-G is and what it is used for?**
- 2. What you need to know before you use FERROZINC-G?**
- 3. How to use FERROZINC-G?**
- 4. Possible side effects**
- 5. How to store FERROZINC-G?**

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

- FERROZINC-G is a syrup containing 344 mg iron II gluconate equivalent to 40 mg iron and 105 mg zinc gluconate equivalent to 15 mg zinc per each 5 ml and presented in a 100 ml amber colored glass bottle.
- FERROZINC-G is used in cases of zinc deficiency with iron deficiency.

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

Do not use FERROZINC-G

If;

- You have iron absorbance (hemochromatosis) or iron accumulation (hemosiderosis) disorder
- You have disturbances in utilization of iron (lead anemia, sidero-achrestic anemia or mediterranean anemia)
- You have anemia not dependent on iron deficiency (megaloblastic anemia dependent on Vitamin B12 deficiency, hemolytic anemia)
- You have presence of hemoglobin in urine (hemoglobinuria)
- You have anemia due to impairment of iron bearing structures (hemoglobinopathy)
- You receive regular blood transfusions or iron treatment via injection (parenteral)
- You are HIV-infected (AIDS)

- You have alcoholism or hepatitis
- You have inflammatory bowel disease
- You have intestinal obstruction
- You have diverticular disease (formation of vesicles toward the outside in the intestinal wall)
- You have active gastric ulcer
- You have inflammation of the regional small intestine (enteritis)
- You have ulcerative colitis (Inflammation of the area covering the inner surface of the large intestine by the effect of environmental factors)
- You use a medicine called dimercaprol which is used in some metal poisoning
- You have copper deficiency
- Your iron deficiency is not clinically confirmed
- You have hypersensitivity to any active substances and/or other ingredients in the product

Warnings and precautions

- If you had anemia not dependent on iron deficiency in your child, do not use without consulting your doctor
- Because iron-containing medicines cause blackening in the stool color, fecal occult blood test may give incorrect results
- Tooth discoloration can be seen. Therefore, it is recommended that you rinse your mouth with plenty of water after using FERROZINC-G
- It can cause poisoning (toxic accumulation) in children in case of excessive use without medical advice
- If you have undergone gastrectomy (a medical procedure that involves surgically removing all or part of the stomach, the absorption of FERROZINC-G may be impaired)
- Do not exceed the duration of treatment recommended by your doctor after treatment of iron deficiency
- If you have vitamin B12 or folic acid deficiency, consult your doctor
- If you have a stomach ulcer, use it under doctor supervision
- If you have impaired iron absorption, consult your doctor
- If you are older, use carefully
- 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 use of zinc may cause copper deficiency

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

FERROZINC-G with food and drink

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

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Use under the supervision of your doctor during pregnancy, if necessary.

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

Breastfeeding

Consult your doctor or pharmacist before taking this medicine.

As FERROZINC-G can pass into breast milk, use under the supervision of your doctor if necessary during breastfeeding.

Driving and using machines

There is no negative effect on ability to drive and use machines.

Important information about some of the excipients of FERROZINC-G

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FERROZINC-G. Because this medicinal product contains fructose and sorbitol (70%) (E420).

If you are on a controlled sodium diet, please note that this medicinal product contains 66.34 mg sodium per each 5 ml.

Other medicines and FERROZINC-G

FERROZINC should be taken carefully with the following medicines;

- Acetohydroxamic acid used in the treatment of kidney stones
- Dimercaprol used in heavy metal poisoning
- Antacids reducing stomach acid (magnesium trisilicate and carbonate)
- Mineral supplements, other drugs containing bicarbonate, carbonate, oxalate or phosphate
- Certain painkillers (salicylates, phenylbutazone and oxyphenbutazone)
- Certain anti-inflammatory medicines (tetracycline, penicillamine, chloramphenicol, nalidixic acid, neomycin, fluoroquinolone group antibiotics)
- Medicines used in the treatment of certain rheumatic diseases (oral gold compounds taken orally)
- Birth control medications can reduce plasma zinc levels
- Drugs used in the treatment of some psychological diseases (psycholeptic) and antiepileptic drugs (barbiturates) used for epilepsy
- Some cancer medicines (antineoplastic drugs, cytostatics)
- Drugs used in Parkinson's treatment (levodopa, carbidopa, entacapone)
- Some drugs that suppress the immune system (mycophenolate)
- Some stomach medications (proton pump inhibitors)
- Some drugs used in the treatment of goitre (thyroid) disease (levothyroxine)
- A drug called eltrombopag which increases the number of platelets that provide blood clotting
- Bisphosphonate group drugs used in osteoporosis
- Vitamin C, drugs containing citric acid
- Vitamin E
- Calcium, aluminum and zinc salts
- Methyldopa, a drug used in high blood pressure treatment
- Trientine, a drug used in the treatment of Wilson's disease caused by copper accumulation in the body
- Cholestyramine, a drug used in the treatment of cholesterol

If you are taking antibiotics in the fluoroquinolone group (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, sparfloxacin, etc.) and you need to use syrup twice daily, use FERROZINC-G at least 3 hours after meals.

Since the absorption of FERROZINC-G is impaired when drugs containing levothyroxine (used in the treatment of thyroid diseases) are taken with FERROZINC-G, these two drugs should be taken at least 2 hours apart.

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-G?

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

Unless recommended otherwise by your doctor, divide FERROZINC-G into 2-3 doses in children and use as follows.

Age	Daily dose (ml)	Daily dose (mg)
6 months – 1 year	1.5 ml with pipette	12 mg iron, 4.5 mg zinc
1 – 3 years	2.0 ml with pipette	16 mg iron , 6 mg zinc
4 – 8 years	4 ml with pipette	32 mg iron , 12 mg zinc
9 – 13 years	6.0 ml with pipette	48 mg iron , 18 mg zinc
14 – 18 years	10 ml (2 spoons)	80 mg iron , 30 mg zinc
18 years and older	13 ml with pipette	104 mg iron , 39 mg zinc

It should be used for the period of time recommended by the doctor. Treatment should be continued for at least two months to fill iron stores after iron deficiency symptoms resolve

- **Route of administration and method:**

FERROZINC-G is only for oral use.

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

- **Different age groups:**

Use in children:

There is no additional information regarding the use of FERROZINC-G in children.

Use in elderly:

There is no additional information regarding the use of FERROZINC-G in elderly patients.

- **Special cases of use:**

Kidney/Liver failure:

Do not use FERROZINC-G in case of kidney and liver failure.

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

If you use more FERROZINC-G than you should:

High iron (II) gluconate intake can be fatal in children.

In case of overdose of syrup, the following symptoms may be seen depending on the iron content:

Gastrointestinal poisoning, excessive nausea, vomiting, abdominal pain and diarrhea usually occur in the first 6 hours after ingestion. In addition, blood vomiting (hematemesis) and rectal bleeding may occur. Symptoms can range from low blood pressure, increased heart rate (tachycardia), increased acid in blood, elevated blood sugar, fatigue to coma with deep unconsciousness in which people can not respond to the environment. Patients experiencing mild to moderate poisoning usually do not progress to this stage.

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

Shock, worsening of acidity, increased acid in blood, seizures (convulsions), coma with deep unconsciousness in which people can not respond to the environment, liver damage and jaundice, decreased blood sugar, coagulation disorders, decreased daily urine volume (oliguria) or gastrointestinal toxicity with pulmonary edema and kidney failure may re-occur in third stage between 12 and 48 hours. In addition, severe fatigue and myocardial dysfunction can be seen.

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

Long term or high dose use may cause iron storage disorder (hemosiderosis). Iron accumulation-associated liver cirrhosis and pancreatic fibrosis, a form of pancreatic disease may develop.

In case of overdose of syrup, the following symptoms may be seen depending on the zinc content:

Zinc sulphate is corrosive in overdose. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur.

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

Accidental intake of iron-containing products at a dose of 60 mg / kg (7.5 ml/kg with a pipette) in children under 6 years of age results in fatal intoxications. Therefore keep these medicines out of reach of children. In cases of toxication, immediately contact your doctor or the National Toxicity Information Center (UZEM).

If you take more FERROZINC-G than you should, tell your doctor or pharmacist.

If you forget to use FERROZINC-G:

Continue to take the recommended dose again according to the subsequent normal intake time.
Do not use a double dose to make up for a forgotten dose.

If you stop using FERROZINC-G:

None.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

If you notice any of the followings stop using FERROZINC-G and IMMEDIATELY inform your doctor or go to the nearest emergency department:

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

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

All of these very serious side effects occur very rarely.

Common

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

Uncommon:

- Changes in blood panel (neutropenia, leukopenia, anemia)
- Nervousness, numbness, drowsiness
- Headache, dizziness
- Darkening of the urine color

Rare:

- Light colored blood in the stool

Very rare:

- Low blood pressure, irregular heartbeat (arrhythmia)
- Changes in cardiac electrical activity (electrocardiographic) in case of potassium deficiency

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

These symptoms caused by irritation can be prevented by dose reduction or by taking the drug after meals. Please note that foods will prevent iron absorption.

Oral syrup containing iron salts and similar medicines may darken the tooth color. To prevent this, the mouth should be rinsed with water after use.

Excessive intake or incorrect treatment can lead to iron overload (hemosiderosis).

Zinc can affect copper absorption and cause 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store FERROZINC-G

*Keep this medicine out of the sight and reach of children in the original package.
Store at room temperature below 25°C.*

Use in accordance with expiry date.

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

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

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

Marketing authorization holder:

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