

FEROMIN®

Ferrous Sulphate

190 mg Film Coated Tablets
125 mg / 1 ml Oral Drops

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your 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.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Ferromin belong to a group of medicines called iron supplements. These medicines work by replacing body iron. Iron is a mineral that the body needs to produce red blood cells. When the body does not get enough iron, it cannot produce the number of normal red blood cells needed to keep you in good health. This condition is called iron-deficiency anaemia.

Ferromin are used for the prevention and treatment of iron-deficiency anaemia.

2. Before you take FEROMIN

Do not take FEROMIN tablets/oral drops and tell your doctor if you:

- Are allergic (hypersensitive) to FEROMIN or any of the other ingredients in FEROMIN tablets/oral drops (see section 6).
- Are receiving repeated blood transfusions.
- Are receiving iron intravenously.
- Have a disorder in which there is excessive absorption and storage of iron such as haemochromatosis.

Check with your doctor or pharmacist before taking FEROMIN if you have:

- haemolytic anaemia
- a blood disease (haemoglobinopathy)
- an iron storage or absorption disease
- gastrointestinal disease

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- tetracyclines (to treat infections)
- ciprofloxacin, norfloxacin, ofloxacin (to treat infections)
- colestyramine
- antacids (containing magnesium or aluminium)
- medicines containing zinc, calcium, phosphorus or trientine
- methyldopa (to treat high blood pressure)
- penicillamine (for rheumatoid arthritis)
- levodopa (for Parkinson's disease)
- ascorbic acid (vitamin C)

3. How to take FEROMIN?

Always take FEROMIN tablets/oral drops exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Food and drink

FEROMIN tablets/oral drops should not be taken within one hour before or two hours after eating or drinking the following products: tea, coffee, milk, eggs and whole grains. These products can reduce the absorption of iron. Meat and products containing vitamin C can increase the absorption of iron. Follow the advice of your dietician or doctor when taking FEROMIN tablets/oral drops with any of the food or drink listed.

Swallow the tablets whole with water. Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side effects.

Doses:

Tablets:

Adults and the elderly

Treatment: 2-3 tablets/oral drops a day in divided doses.

Prevention: 1 tablet a day.

Children 6-12 years

Treatment:

- Children weighing over 22kg: one tablet a day.
- Children weighing over 44kg: one tablet twice a day.
- Children weighing over 66kg: one tablet three times a day.

Oral drops:

Prophylactic Dosage:

- Infants 4 – 6 weeks to mixed feeding: 0.2 ml per day (5.0 mg Elemental Iron). Higher doses of up to 0.08 ml per kg body weight (2.0 mg Elemental Iron per kg) might be needed to cover the needs of growing, exclusively breastfed, infants.
- Older infants and children to 6 years: 0.5 to 1.2 ml per day (12.5 – 30 mg Elemental Iron).
- Older children: 2.4 ml per day (60 mg Elemental Iron).
- Adults and Elderly: 2.4 to 4.8 ml per day (60 – 120 mg Elemental Iron).

Therapeutic Dosage:

• Paediatric:

0.12 ml to 0.24 ml (3 – 6 mg Elemental Iron) per kg body weight, up to a maximum of 8 ml (200 mg Elemental Iron) given daily in two or three divided doses.

• Adults:

4.0 ml once or twice per day (100 – 200 mg Elemental Iron).

If you take more than you should

If you (or someone else) swallow a lot of tablets/oral drops at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include:

- Up to 24 hours: stomach and intestinal poisoning including being sick and diarrhoea, heart disorders such as low blood pressure (hypotension) and a racing heart (tachycardia), metabolic changes such as too much acid in the body (acidosis) and high blood sugar (hyperglycaemia), nervous system depression ranging from tiredness to coma, temporary relief of symptoms may occur.

- After 24 hours: stomach and intestinal poisoning and obstruction, shock, too much acid in the body (acidosis), fits, coma, liver failure, jaundice (yellowing of the skin or whites of the eyes), low blood sugar, problems with blood clotting, low production of urine, kidney failure, fluid in the lungs.

If you forget to take the tablets/oral drops

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

4. Possible side effects

Like all medicines, FEROMIN tablets/oral drops can cause side effects, although not everybody gets them.

Contact your doctor at once if you have an allergic reaction e.g. itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects:

- constipation occasionally causing faecal impaction, diarrhoea, stomach pain, feeling sick and blackened stools.

Please tell your doctor or pharmacist if you notice any of the following effects, they get worse or if you notice any not listed.

5. How to store FEROMIN?

Keep out of the reach and sight of children.

Store below 30°C.

Keep in the original pack to protect from light & moisture.

In use instructions (for oral drops): use during one month after first opening.

Do not use FEROMIN tablets/oral drops after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What FEROMIN tablets contain?

The active substance dried ferrous sulphate; each tablet contains dried ferrous sulphate (BP) 190 mg equivalent to elemental iron 80 mg.

- The other ingredients are Microcryst Cellulose PH 102, Colloidal Anhydrous Silica, Cross Povidone, Purified Talc, and Magnesium Stearate.
- Coating material: Opadry red.

What FEROMIN tablets looks like and contents of the pack?

Dark red colored, biconvex, circular film coated tablets with RP 32 engraved on one side and plain on the other side.

FEROMIN tablets pack contains (30) film coated tablets in Polypropylene tracer cap with HDPE cap.

Hospital packs of FEROMIN film coated tablets.

What FEROMIN oral drops contain?

- The active substance ferrous sulphate; each 1 ml contains ferrous sulphate (BP) 125 mg equivalent to elemental iron 25 mg.
- The other ingredients are Ascorbic Acid, Citric Acid Monohydrate, Propylene Glycol, Glycerol, Sorbitol Solution 70%, Benzoic Acid, Ethanol 96%, Cherry Flavour, and Purified Water.

What FEROMIN oral drops looks like and contents of the pack?

- Clear light green/yellow to dark brown solution with cherry odour free from particles

FEROMIN oral drops pack contains 30 ml of FEROMIN solution in amber glass bottle with child resistance cap & measuring pipette with cap.

Marketing Authorisation Holder and Manufacturer

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Marketing department Riyadh

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7. To report any side effects

- Kingdom of Saudi Arabia

-National Pharmacovigilance and Drug Safety Center (NPC)

- Fax: +966-11-205-7662
- To call the executive management of the vigilance & crisis management, Tel.: +966-11-2038222 ext.: 2353 - 2356 - 2317 - 2354 - 2334 - 2340
- Toll-free: 8002490000
- E-mail: npc.drug@sfdca.gov.sa
- Website: www.sfdca.gov.sa/npc

This is a medication

- A medication is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medications out of the reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists

RIYADH PHARMA

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