Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986
This medicine can be sold without a physician's prescription

Ferrocal® Tablets

Composition:
Each tablet contains:
Ferrous Citrate (Monohydrate) 246 mg equivalent to 52 mg iron.
Calcium Citrate 249 mg
Inactive ingredients and allergens in the medicine- See section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
Take this medicine according to the instructions in section 3 "How to use this medicine?" in this leaflet.
Consult the pharmacist if you need additional information.

1. What is the medicine intended for?

This medicine is intended for the prevention and treatment of iron deficiency anaemia.
Therapeutic group: Iron supplements

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to iron salt or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- You suffer from an active stomach ulcer (peptic ulcer).
- You suffer from inflammation which causes abdominal pain or diarrhea (ulcerative colitis) or any other inflammatory condition of the bowels (regional enteritis).
- You suffer from a disorder in which there is excessive absorption and storage of iron, such as hemosiderosis or hemochromatosis.
- You have received or have previously recieved repeated blood transfusions.
- You are receiving iron intravenously.
- You suffer from haemolytic anaemia (anaemia due to destruction of red blood cells).
- You notice blood in your urine.
- You are having dimercaprol injections for treatment of metal poisoning.
- You are already being treated with iron supplements.

Special warnings regarding the use of this medicine
Before using Ferrocal Tablets, tell the doctor if:
• You suffer from a blood disease (haemoglobinopathy).
• You suffer from vitamin deficiency, especially co-existing deficiency of vitamin B12 or folic acid.
• You suffer from diabetes.
• You suffer from inflammatory bowel disease.
• You suffer from diverticular disease (where pouches form in the bowel wall).
• You suffer from intestinal strictures (abnormal narrowing of the bowel often caused by inflammation).
• You suffer from iron overload.
• You have a history of stomach ulcer.
• You had a removal of some or all of your stomach.
• You have difficulty swallowing.
• You are a male, as iron deficiency is less common in men than women, and the causes may need investigating further by the doctor.
• Due to the risk of mouth ulceration and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth but swallowed whole with water. If you cannot follow this instruction or have difficulty swallowing, please contact your doctor.
• If you accidentally choke on a tablet, please contact your doctor as soon as possible, because there is a risk of ulcers and narrowing of the bronchus if the tablet enters the airways. This may result in persistent coughing, coughing up blood and/ or feeling out of breath, even if the choking happened days to months before these symptoms occurred. Therefore you need to be urgently assessed to make sure that the tablet doesn't damage your airways.
Children and adolescents:
This medicine is intended for adults and children above the age of six year old. **This medicine is not intended for infants and children under 6 years of age.**
Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
• Levodopa, carbidopa, entacapone (for Parkinson's disease).
• Methyldopa (to treat high blood pressure).
• Penicillamine (for rheumatoid arthritis).
• Zinc or ascorbic acid (vitamin C) supplements.
• Cholestyramine (to treat high blood cholesterol).
• Dimercaprol (for metal poisoning).
• Mycophenolate mofetil (to suppress the immune system and stop organ rejection after transplant).
It is important not to take the following medicines for two hours before or after taking **Ferrocal Tablets:**
• Medicines to treat infections (e.g. tetracyclines, ciprofloxacin, levofloxacin, ofloxacin, norfloxacin, chloramphenicol, quinolones).
• Medicines used to treat bone problems e.g. bisphosphonates.
• Medicines used to treat indigestion (antacids and mineral supplements containing calcium, magnesium, bicarbonates, carbonates, oxalates and phosphates).
• Levothyroxine (for under-active thyroid glands).
• Trientine (for Wilson's disease).
Use of this medicine and food
Ferrocal Tablets should not be taken within one hour before or two hours after eating or drinking the following products: tea, 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 **Ferrocal Tablets** with any of the food or drink listed, and about which of them should be avoided in combination with the medicine. See further information in section 3 "Method of administration".
Pregnancy, breastfeeding and fertility:
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.
During the first 12 weeks of pregnancy, only take this medicine if your doctor has specifically recommended it. For the remainder of the pregnancy **Ferrocal Tablets** can be taken to prevent iron deficiency.
Driving and using machines:
This medicine does not affect your ability to drive or use machines.
Important information about some of the ingredients of this medicine
This medicine contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The usual dosage is generally:
Adults and children over 12 years of age:
Treatment of iron deficiency: 1 tablet, 3-4 times daily.
Prevention treatment: 1 tablet a day.
Children 6 to 12 years of age:
1/2-1 tablet, 3 times daily (in accordance with body weight).
Prevention treatment: 1 tablet a day.
This medicine is not intended for infants and children under 6 years of age.
Use of this medicine in children should be under medical supervision. Prolonged use in children may lead to toxic accumulation of iron and need to be carefully controlled by the doctor.
Do not exceed the recommended dose.
Duration of treatment
Treatment should not normally carry on for more than 3 months after the iron deficiency has been corrected. Your doctor will advise you when to stop using the medicine.
Method of administration:
It is advisable to take the tablet whole, without food, with water or fruit juice.
Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side effects.
Do not suck, chew, crush or keep the tablet in your mouth.
If necessary to ease swallowing, the tablet can be halved for immediate use. Both halves should be swallowed together immediately after halving.
If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.
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 forgot to take the medicine

If you forgot to take this medicine at the designated time, take the dose as soon as you remember. Then, take the next dose at the scheduled time. Do not take a double dose to make up for a forgotten dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Ferrocal Tablets** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking this medicine and refer to the doctor or to a hospital emergency room immediately with the appearance of one or more of the following serious side effects:

Allergic reactions which cause difficulty in breathing or swallowing, fever, swelling of the face, mouth, throat or tongue, lips or skin, severe rashes, itching or stomach pain.

Additional side effects:

Side effects of unknown frequency (effects for which a frequency has not yet been determined):

- Loss of appetite, nausea and vomiting, abdominal discomfort, constipation, diarrhoea, abdominal pain, accumulation of iron in the body cells.
- Darkening of the stools/ black stools (change in the colour of your stools is a normal effect, caused by using medicines containing iron).
- Irritation and ulceration of the esophagus can occur if the tablets become stuck, so take with water.
- Increased risk of tooth decay and infections (during prolonged use).
- Mouth ulceration (in case of incorrect use, when tablets are chewed, sucked or left in the mouth).
- All patients, but especially elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat and esophagus (the tube that connects the mouth with the stomach). If the tablet enters the airways, there may be a risk of ulceration of the bronchus (the major air passages of the lungs), resulting in bronchial narrowing.
- Constipation may appear more in the elderly.
- Diarrhoea may appear more in patients with inflammatory bowel disease (such as irritable bowel syndrome, colitis or diverticulitis).

If you notice any of these side effects, which are usually mild, contact your doctor or pharmacist.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information:

In addition to the active ingredients, this medicine also contains:

Lactose Monohydrate, Methylcellulose 400, Magnesium Stearate, Starch, Microcrystalline Cellulose (Avicel PH 101), Colloidal Silicon Dioxide (Aerosil), Gelatin, Povidone (PVP K-30).

What the medicine looks like and what the package contains:

Greyish-white tablet, scored in half on one side and plain on the other.

Approved package sizes:

30 and 50 tablets. Not all package sizes may be marketed.

Manufacturer and registration Holder:

Rekah Pharmaceutical Industry Ltd.,
30 Hamelacha St., Holon, Israel.

Revised in September 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

137-54-25091-01