

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is marketed without prescription of doctor

Ferrocal® Tablets

Composition:

Each tablet contains:

Ferrous Citrate	246 mg
Calcium Citrate	249 mg
(= 52 mg Bivalent Iron)	

For the list of inactive ingredients in the preparation- See section 6 "Further information"

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have further questions, refer to the doctor or pharmacist. This medicine is intended for adults and children below the age of six years old. **This medicine is not intended for infants and children in children under 6 years of age.**

Use, swallow the medicine correctly. Consult a pharmacist if you have need further information.

This medicine was prescribed to treat your illness. Do not forward it to others. It may harm them even if you think that a similar medical condition.

1. What is this medicine intended for?

This medicine is intended for the prevention and treatment of iron deficiency anaemia.

Groups therapeutic: Iron supplements

2. Before using this medicine:

Do not use this medicine:

- Do not use this medicine if you are sensitive to iron salt or to any of ingredients of medicine.
- Problems with iron in the blood (including problems with red blood cells)
- If you suffer from stomach ulcers or intestinal problems.
- If you are suffering from hemochromatosis (excessive absorption and accumulation of iron in organs of the body), intestinal obstruction.
- Avoid use of the preparation in people who are receiving repeated blood transfusions.
- If you receive iron injections intravenously.
- Other anemia who does not accompanied from iron deficiency such as hemolytic anemia.
- If you receive dimercaprol injections from treatment of metal poisoning.

Do not take this medicine without consulting a doctor before starting treatment:

- If you are pregnant or breastfeeding.
- If you have haemolytic anaemia.
- If you have blood disease (haemoglobinopathy)
- If you are suffering from diseases concerning storage or absorption iron.
- If you suffer or you had history from gastrointestinal diseases (such as peptic ulcer or inflammatory bowel disease)
- If you have exclusion of some / all of your stomach.
- If you are a man, as iron deficiency is less common in men than women, and the cause may need investigating further by the doctor.

Special warnings concerning use of the medicine:

- Do not use this medicine frequently, or for a long period, without consulting a doctor.
- During treatment with this medicine, blood tests should be performed.
- If you need to perform a stool test, tell to your doctor or nurse that you are taking this medicine because it may make your stool colour black and influence the test results.
- Keep this medicine out of the reach of children in order to avoid a risk of poisoning due to iron overdose. Poisoning in children under 6 years of age in particularly serious. In case a child has swallowed iron tablets proceed to a hospital without delay.
- If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

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- Keep this medicine out of the reach of children in order to avoid a risk of poisoning due to iron overdose. Poisoning in children less than 6 years of age in particularly serious. In case a child has swallowed iron tablets proceed to a hospital without delay.
- If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

If you are taking or if you have just finished treatment with another medicine including medicine over the counter, dietary supplement, inform the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

- Antibiotic: fluoroquinolones groups (ciprofloxacin, norfloxacin, ofloxacin), tetracyclines (e.g. oxytetracycline): a lapse of at least two hours between taking this medicine and taking Tetracycline or fluoroquinolone.
- Antacids (containing magnesium or aluminum): a lapse of at least two hours between taking this medicine and antacids.
- Levodopa, carbidopa, entacapone (for Parkinson's disease)
- Methyldopa (to treat high blood pressure)
- Penicillamine (for rheumatoid arthritis)
- Vitamin C
- Cholestyramine (reduce cholesterol level in blood)
- Trientine (for Wilson's disease)
- Medicines to treat indigestion, antacids, calcium and zinc supplements.
- Neomycin and chloramphenicol (antibiotics)
- Levothyroxine (medicine for the treatment of under active thyroid)
- Bisphosphonates (for the treatment of osteoporosis)

Use of this medicine and food: it is advisable to take the medicine without food, with water or fruit juice.

Although iron preparations are more absorbed on an empty stomach, in the case of gastrointestinal side effects can be taken with/ after dinner. Some of the foods such as tea, eggs and milk can lower the amount of iron absorbed by the body. Iron should be taken one hour before or two hours after eating or drinking of tea, coffee, milk, eggs and whole grains. Meat and products containing vitamin C can increase the absorption of iron. Check with your doctor or pharmacist which foods should be avoided

Pregnancy and breast-feeding: Do not use this medicine without consulting a doctor if you are pregnant, might be pregnant or breastfeeding.

Driving and using machinery: This medicine do not influence the capacity of driving and using machinery.

Important information about some of the ingredients in

Ferrocal: This medicine contains lactose (each tablet contains 39.39 mg of lactose) and may be caused allergy in you have intolerance to lactose. So consult your doctor before taking this medicine.

3. How should you use this medicine?

If you are unsure how as to how use this medicine, consult your doctor or your pharmacist.

Usually the treatment with medicine should not normally carry on for more than 3 months after the discovery of the iron deficiency. Your doctor will advise you when to stop the use of the medicine.

Recommended dosage unless otherwise prescribed by your doctor:

Adults and children over 12 years of age:

Treatment of iron deficiency: 1 tablet, 3-4 times daily.

As a prophylactic treatment: 1 tablet daily.

Children: from 6 to 12 years of age:

1/2-1 tablet, 3 times daily (in accordance with body weight).

As a prophylactic treatment: Once daily.

This medicine is not intended for infants and children below 6 years of age.

Use of this medicine in children should also 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 dosage.

If you forget to take this medicine at the specified time, take the dose as soon as you remember, but never take a double dose!

If you forget to take this medicine at the specified time, take the dose as soon as you remember it and then take the next dose at the right time.

If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you.

Symptoms of an overdose include:

Up to 24 hours: stomach and intestinal poisoning including vomiting and diarrhea, 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 (hyperglycemia), 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 have further questions regarding the use of this medicine, check with your doctor or pharmacist

Attention: Allow a lapse of at least two hours between taking this medicine and taking antacids, tetracycline and quinolone antibiotics group, tea, coffee, milk and dairy products, eggs, and calcium supplement. Ferrocal tablets should 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 doctor when taking Ferrocal tablets with any of the food or drink listed.

Directions for use: it is advisable to take the medicine without food, with water or fruit juice.

Although iron preparations are absorbed best on an empty stomach in the case of gastrointestinal side effects can be taken with/ after dinner.

The tablet may be halved/ crushed.

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 any further questions regarding use of the medicine, consult a doctor or pharmacist.

4. Side effects:

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

- This medicine may cause a change in the color of stools; this change does not have to worry about.
- Stop using this medicine and contact your doctor as soon as possible if you are allergic reactions such as severe rash and itching, abdominal pain, swelling of the face, lips, tongue, throat, skin, difficulty breathing or swallowing and fever.

Other side effects are:

- Loss of appetite, nausea and vomiting, abdominal discomfort, constipation, diarrhea, abdominal pain, black stools, or accumulation of iron in the body cells or black stools.
- Constipation may be more pronounced in the elderly
- Diarrhea may be more pronounced in patient 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.

Adverse reactions and drug interactions in children:

Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child. **Signs of Overdose** See "3. How do you use this medicine?" (Especially in children): severe abdominal pain, rectal bleeding or diarrhoea, with black stool, **low blood pressure and loss of consciousness** **Take the victim to a hospital as quickly as possible.**

If any of the side effects worsen, or if you suffer from side effects not mentioned in this leaflet, consult immediately your doctor.

5. How should the medicine be stored?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!

- Do not use this medicine after the expiry date stated on the label/carton/bottle.
- The expiry date refers to the last day of that month.
- Store the medicine at a temperature below 25°C and a dry place.

6. Further information:

In addition of active ingredient (substance) this medicine contains also: Lactose monohydrate, Methylcellulose 400, Magnesium Stearate, Starch, Microcrystalline cellulose (Avicel PH 101), Colloidal Silicon dioxide (Aerosil), Gelatin, Povidone (pvp k30)

What does the medicine look like and what is the content of the package: Greyish-white tablet scored in half on one side, plain on the other packaged in box of 30-50 tablets.

Manufacturer and Holder:

Rekah Pharmaceutical Prod. Ltd., 30 Hamelacha St., Holon, Israel
This leaflet was checked and approved it in November 2014

Drug registration number: 137-54-25091-01

For simplicity and easier to read, this leaflet is formulated male, however, the medicines is intended for members of both sex.