

PACKAGE LEAFLET: INFORMATION FOR THE USER

FERROGRAD 325 mg

PROLONGED-RELEASE TABLETS

Dried Ferrous Sulphate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- This medicine is available without prescription. However, you still need to take Ferrograd Tablets carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 4 weeks.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Ferrograd Tablets are and what they are used for
2. Before you take Ferrograd Tablets
3. How to take Ferrograd Tablets
4. Possible side effects
5. How to store Ferrograd Tablets
6. Further information

1. WHAT FERROGRAD TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your tablets is Ferrograd Prolonged-Release Tablets. Ferrograd are prolonged release, film coated tablets which contain the active ingredient dried Ferrous Sulphate.

Ferrograd is an iron supplement. Its use is described below.

What is Ferrograd used for?

Ferrograd is an iron supplement used to prevent and treat iron-deficiency anaemia. Ferrograd should only be used for the prevention and treatment of iron-deficiency anaemia diagnosed by laboratory testing under the supervision of a medical doctor. Ferrograd can be used by pregnant women, but only after the first thirteen weeks of pregnancy. A controlled-release system in the tablet allows release of the iron over several hours and reduces the likelihood of stomach irritation. The controlled-release system consists of a harmless plastic honeycomb with thousands of narrow passages containing iron. As the tablet passes through the stomach and gut the iron is released and the empty honeycomb is passed out in the stools.

2. BEFORE YOU TAKE FERROGRAD TABLETS

Do not take FERROGRAD Tablets

- If you are allergic to Ferrous Sulphate or any of the other ingredients of this medicine (See Section 6)
- If you are under 12 years of age
- If you have been told that you have an intestinal blockage or diverticular disease of the intestine or if you are already taking medicines containing iron
- If you have problems dealing with iron (haemochromatosis, haemosiderosis, iron overload syndromes).

Take special care with FERROGRAD Tablets

Before taking Ferrograd, consult your doctor

- If you have a family history of problems dealing with iron (haemochromatosis, haemosiderosis, iron overload syndromes)

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.

If you are taking any of the following medicines please contact your doctor before taking Ferrograd;

- Antibiotics for infections such as tetracycline antibiotics
- Indigestion remedies such as antacids and preparations of calcium, zinc and phosphorous
- Quinolone anti-infective agents such as ciprofloxacin, norfloxacin and ofloxacin
- Levothyroxine as a thyroid hormone medication
- Methyldopa for high blood pressure
- Levodopa for Parkinson's disease
- Penicillamine for arthritis
- Ascorbic or citric acids as these increase absorption of iron

If your doctor tells you that you can continue taking Ferrograd with any of the above medications please allow 2 – 3 hours between taking Ferrograd C and the other medications (or 4 hours for the quinolone anti-infective agents)

The absorption of Ferrograd may be decreased when taken with tea, coffee, milk, eggs, wholegrain cereals and dietary fibre, therefore, Ferrograd should be taken at least 1 hour before or 2 hours after ingestion of these products.

Warnings and Precautions

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.

Pregnancy and Breast Feeding

Do not take Ferrograd Tablets during the first thirteen weeks of pregnancy.

After the first thirteen weeks of pregnancy consult your doctor before taking Ferrograd as you may require a different iron supplement containing also folic acid.

Ask your doctor or pharmacist for advice before taking any medicine if you intend breast feeding.

Driving and Using Machines

Ferrograd has no influence on the ability to drive or use machinery.

Important information about some of the ingredients of FERROGRAD Tablets

If you have been told by your doctor that you have an intolerance to some sugars (lactose), contact your doctor before taking this medicinal product.

This product contains the colour Sunset yellow FCF (E110), which may cause allergic reactions including asthma; allergy is more common in those people who are allergic to aspirin.

3. HOW TO TAKE FERROGRAD TABLETS

Take one tablet daily before a meal. Although iron preparations are best absorbed on an empty stomach, they may also be taken with food to reduce gastrointestinal side effects. Swallow the tablet whole with water. Do not suck, chew or keep the tablet in your mouth. Ferrograd should not be given to children under 12 years old.

If your symptoms do not improve after 4 weeks of taking Ferrograd, consult your doctor for further advice.

If you take more Ferrograd Tablets than you should

If you accidentally take more than one tablet in one day or if a child has taken the tablets, you should seek medical advice urgently.

If you forget to take Ferrograd Tablets

If you forget to take a tablet for one or more days, carry on taking one each day. Do not take more than one tablet a day.

4. POSSIBLE SIDE EFFECTS

Like all medicines Ferrograd Tablets can cause side effects, although not everybody gets them.

You may experience some of the following effects:

- Your stools may turn black whilst taking Ferrograd. If you have a test for the detection of blood in your stools, tell your doctor you are taking Ferrograd as black stools may cause an incorrect result to the test
- Allergic reaction (itchy skin and in rare cases swelling of the face and oral mucosa and difficulty in breathing or fainting). If you develop any of these symptoms stop taking the tablets and contact your doctor
- Feeling sick
- Vomiting
- Stomach Pain
- Diarrhoea
- Constipation
- Haematemesis (blood in vomiting) and ileus

(intestinal obstruction) have been reported.

Not known (Frequency cannot be estimated from the available data)

- Mouth ulceration (in case of incorrect use, when tablets are chewed, sucked or left in the mouth)
- Elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (the tube that connects your mouth with your stomach) or bronchus (the major air passages of the lungs) if the tablet enters the airways.

The honeycomb part of the tablet may cause problems in the elderly or in people with constipation. Consult your doctor if you think this may be a problem for you.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FERROGRAD TABLETS

Keep out of the reach and sight of children, as overdose may be fatal.

Do not use these tablets after their use-by (expiry) date, which is printed on the box and on the edge of the strip of tablets. The expiry date refers to the last day of that month. If the tablets are out of date, return them to your pharmacist

and, if necessary, obtain some more tablets.

Do not store above 25°C. Store in the original package.

IMPORTANT WARNING - contains iron.

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 FERROGRAD Tablets contain

Each Ferrograd tablet contains Dried Ferrous Sulphate 325 mg (equivalent to 105 mg elemental iron) as the active ingredient in a controlled-release Gradumet form.

Other ingredients are: methylacrylate methylmethacrylate copolymer (1:1), lactose monohydrate (see section 2), povidone, magnesium stearate, hypromellose, ethylcellulose, sodium saccharin, triethyl citrate, sorbitan oleate, castor oil virgin, titanium dioxide (E171), Erythrosine (E127), and Sunset yellow FCF (E110) (See Section 2).

What FERROGRAD Tablets look like and contents of the pack

Ferrograd is available in cartons of thirty tablets containing (3x10) tablets in an AL/PVC blister.

Appearance of tablets: circular, biconvex, red tablets

Marketing Authorisation Holder's Name and Address

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Manufacturer's Name and Address:

TEOFARMA S.r.l. - Viale Certosa, 8/A - 27100 Pavia - Italy

Remember:

This leaflet provides a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet applies only to Ferrograd tablets and was revised in June 2017