

PACKAGE LEAFLET: INFORMATION FOR THE USER

## **FERROGRAD tablets**

Ferrous Sulfate

**Read all of this leaflet carefully before you start taking this medicine.**

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

**In this leaflet:**

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

### **1. What Ferrograd is and what it is used for**

Ferrograd is an iron supplement used to prevent and treat iron-deficiency anaemia. Iron is critical (essential) for your body to produce normal blood red cells. Ferrograd is formulated with an inert porous matrix (Gradumet) to release iron gradually and reduce (limit) the gastro-intestinal irritation occurring with iron supplements.

### **2. Before you take Ferrograd**

**Do not take Ferrograd if you**

- have an intestinal blockage
- have been told by your doctor that you have a disease of the bowels known as diverticular disease
- suffer from a rare inherited problem involving the way your blood cells use iron known as haemochromatosis or haemosiderosis
- are receiving repeated blood transfusions
- are already being treated with iron injections
- are already taking medicines containing iron.

You should check with your doctor or pharmacist if you are not sure.

### **Warnings and precautions**

Talk to your doctor before you take Ferrograd if you:

- Have difficulties swallowing  
If you accidentally choke on a tablet, please contact your doctor as soon as possible. This is because there is a risk of ulcers and narrowing of the bronchus occurring 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.
- Before taking this tablet speak to your doctor if you suffer from bowel strictures (resulting in difficult intestinal transit) as the inert core tablet may not be suitable for you.

- Ferrograd is not recommended for children under 12 years old. Acute iron poisoning is a serious risk in the paediatric population.
- 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.
- 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.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking any of the following medicines, or any medicines bought without a prescription, as Ferrograd may stop these from working properly:

- antibiotics: tetracyclines, quinolones or chloramphenicol
- a penicillamine (for metal poisoning or rheumatoid arthritis)
- indigestion remedies
- zinc - containing preparations
- trientine

If your doctor tells you that you can continue taking Ferrograd with the above medication, please take note of the following advice:

Tetracycline antibiotics	- take these at least 2 hours before OR 3 hours after taking your Ferrograd
Quinolones and penicillamines	- take these at least 2 hours before OR 2 hours after taking your Ferrograd
Indigestion remedies (e.g. antacids), calcium supplements, oxalates or phosphates	- take these at least 1 hour before OR 2 hours after taking your Ferrograd

If you are not sure, please check with your doctor or pharmacist.

### **Taking Ferrograd with food and drink**

Ferrograd tablets may not work as well if they are taken around the same time as the following foods: tea, coffee, eggs, milk or milk products, wholegrain bread and cereals, and any high fibre food. Make sure you take your tablets at least 1 hour before or 2 hours after eating any of these foods.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Ferrograd has no influence on the ability to drive and use machines.

### **Important information about some of the ingredients of Ferrograd**

Ferrograd tablet contains the colouring agent E110, which may cause allergic reactions.

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

### 3. How to take Ferrograd

Always take Ferrograd exactly as your doctor has told you. You should check with your doctor if you are not sure.

**Adults and children over 12 years:** The usual dose is one tablet a day on an empty stomach. Swallow the tablet whole with water. Do not suck, chew or keep the tablet in your mouth.

**Children:** Ferrograd is not recommended for children under 12 years old.

#### If you take more Ferrograd than you should

If you (or someone else) take a lot of tablets at the same time, or if you suspect a child has taken the tablets, you should contact the nearest hospital or tell your doctor immediately. In children iron poisoning is accidental and may be fatal.

Symptoms of an overdose include nausea, vomiting, abdominal pain, diarrhoea and blood loss in the faeces. Low blood pressure (hypotension), nervous system depression (ranging from reduced attention to coma) and liver failure occur later.

#### If you forget to take Ferrograd

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 can cause side effects, although not everybody gets them. You may experience some of the following effects:

- **An allergic reaction ranging from itchy skin rash, to, in rare cases, swelling of the face, tongue or throat, or difficulty in breathing, fainting.**
- Feeling sick
- Vomiting
- Stomach pain
- Diarrhoea
- Constipation
- Blackened stools
- 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 difficulties swallowing may also be at risk of ulceration of the throat or the esophagus (the tube that connects your mouth with your 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.

#### Reporting of side effects

If you get any side effects tell your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Ferrograd

Store in a dry place below 25°C.

Keep out of the reach and sight of children, your medicine could harm them.

Do not use Ferrograd after the expiry date which is stated on the carton and on the edge of the strip of tablets. If the tablets are out of date, return them to your pharmacist and, if necessary, obtain more tablets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Further information**

### **What Ferrograd contains**

- The active substance is Dried Ferrous Sulfate 325mg (equivalent to 105 mg elemental iron) as the active ingredient in a prolonged release Gradumet® form.
- The other ingredients are methylacrylate methylmethacrylate copolymer, lactose, povidone, magnesium stearate, hydroxypropylmethylcellulose, ethylcellulose, sodium saccharin, triethyl citrate, sorbitan monooleate, castor oil, titanium dioxide, dye Red FD&C No.3 (E127), and dye Yellow FD&C No.6 (E110).

### **What Ferrograd looks like and contents of the pack**

Ferrograd prolonged release, film coated tablets are circular, biconvex, red tablets.

Ferrograd is provided in carton pack containing 30 tablets in blister packs.

### **Marketing Authorisation Holder**

TEOFARMA s.r.l.

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### **Manufacturer**

TEOFARMA s.r.l.

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