

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**FERROGRAD FOLIC 325 mg/0.35 mg**

**PROLONGED-RELEASE TABLETS**

**Dried Ferrous Sulphate/Folic Acid**

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

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

The name of your tablets is Ferrograd Folic Prolonged-Release Tablets. Ferrograd Folic are prolonged release, film coated tablets. The active ingredients in Ferrograd Folic are: Dried Ferrous Sulphate and Folic Acid. Ferrograd Folic is a combined iron and folic acid supplement. Its use is described below.

**What is Ferrograd Folic used for?**

Ferrograd Folic is an iron and folic acid supplement used to prevent and treat iron-deficiency anaemia and to prevent anaemia due to folic acid deficiency. Ferrograd Folic 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 Folic 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 a number of 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 FOLIC TABLETS**

**Do not take FERROGRAD FOLIC Tablets**

- If you are allergic to Ferrous Sulphate, Folic Acid or any of the other ingredients of this medicine (See Section 6)
- If you are under 12 years of age
- If you have problems dealing with iron (haemochromatosis, haemosiderosis, iron overload syndromes).
- If you know you have anaemia due to a vitamin B12 deficiency, as this requires a different treatment
- If you have been told that you have an intestinal blockage or diverticular disease of the intestine
- If you are already taking medicines containing iron.

**Warnings and Precautions**

Talk to your doctor before you take Ferrograd Folic if you:

- Have a family history of problems dealing with iron (haemochromatosis, haemosiderosis, iron overload syndromes).
- Have difficulties swallowing. 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 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.

**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 Folic;

- 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
- Anticonvulsant agents such as phenobarbitol, phenytoin or primidone
- Sulfasalazine for some bowel diseases and rheumatoid arthritis

If your doctor tells you that you can continue taking Ferrograd Folic 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 Folic may be decreased when taken with tea, coffee, milk, eggs, wholegrain cereals and dietary fibre, therefore, Ferrograd Folic should be taken at least 1 hour before or 2 hours after ingestion of these products.

#### **Pregnancy and Breast Feeding**

Do not take these tablets during the first thirteen weeks of pregnancy unless instructed to do so by your doctor. Ferrograd Folic may be taken after the first 13 weeks of pregnancy in consultation with your doctor. Ask your doctor or pharmacist for advice before taking any medicine if you intend breast feeding.

#### **Driving and Using Machines**

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

#### **Important information about some of the ingredients of FERROGRAD FOLIC Tablets**

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

This product contains the colour Ponceau 4R red (E124), which may cause allergic reactions including asthma; allergy is more common in those people who are allergic to aspirin.

### **3. HOW TO TAKE FERROGRAD FOLIC TABLETS**

Take one tablet daily before a meal from the 13th week of pregnancy and for one month after delivery. 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 Folic should not be given to children under 12 years old.

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

#### **If you take more Ferrograd Folic 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 Folic Tablets**

If you forgot 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 Folic 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 Folic. If you have a test for the detection of blood in your stools, tell your doctor you are taking Ferrograd Folic 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)

- Severe allergic reaction (anaphylactic reaction)
- Mouth ulceration (in case of incorrect use, when tablets are chewed, sucked or left in the mouth)

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.

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, 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](http://www.hpra.ie); E-mail:[medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE FERROGRAD FOLIC 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 in order to protect from light.

**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 FOLIC Tablets contain**

The active ingredients in Ferrograd Folic are: Dried Ferrous Sulphate 325 mg (equivalent to 105 mg elemental iron) in a controlled-release Gradumet form and Folic Acid 0.35 mg (corresponding 350 micrograms).

Other ingredients are:methylacrylate methylmethacrylate copolymer (1:1), magnesium stearate, povidone, macrogol 8000, Colloidal Anhydrous Silica, lactose monohydrate (see section 2), sucrose (see section 2), acacia powder, maize starch, cellacefate, sorbitan oleate, castor oil virgin, titanium dioxide (E171) and dye Red Ponceau 4R (E124) (See Section 2).

##### **What Ferrograd Folic Tablets Look Like and Contents of the Pack**

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

Appearance of tablets: circular, biconvex, 2 layered, red and yellow tablets.

##### **Marketing Authorisation Holder's Name and Address**

TEOFARMA S.r.l. - Via F.lli Cervi, 8 - 27010 Valle Salimbene (PV) - Italy e-mail:[servizioclienti@teofarma.it](mailto:servizioclienti@teofarma.it)

##### **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 Folic tablets and was revised in August 2018