

PACKAGE LEAFLET: INFORMATION FOR THE USER
FERROGRAD FOLIC tablets
Ferrous Sulfate and Folic Acid

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

1. What Ferrograd Folic is and what it is used for

Ferrograd Folic is an iron supplement used to prevent and treat iron-deficiency anaemia in pregnant women and to prevent anaemia due to folic acid deficiency during pregnancy.

2. What you need to know before you take Ferrograd Folic

Do not take Ferrograd Folic if you

- know you are allergic to folic acid
- know you have anaemia due to a vitamin B12 deficiency as this requires a different treatment
- 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 Folic 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 are elderly or suffering from any bowel problem as the plastic coating of the tablet may not be suitable.
- Ferrograd is not recommended for children under 12 years old. Acute iron poisoning is a serious risk in the paediatric population.
- 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.
- 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.

Before taking Ferrograd Folic consult your doctor

- if you are diabetic as Ferrograd Folic may stop your urine sugar test sticks from working properly.

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

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

Taking Ferrograd Folic with food and drink

Ferrograd Folic 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

Folic acid is excreted in breast milk so ask your doctor for advice if you intend breastfeeding.

Driving and using machines

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

Important information about some of the ingredients of Ferrograd Folic

This product contains the colour E124, which can cause allergic type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

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 Folic

Always take Ferrograd Folic 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 throughout pregnancy and for one month after delivery.

Swallow the tablet whole with water. Do not suck, chew or keep the tablet in your mouth.

Children: Ferrograd Folic should not be given to children under 12 years old.

If you take more Ferrograd Folic 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. In children overdose may be fatal.

If you forget to take Ferrograd Folic

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 Folic can cause side effects, although not everybody gets them.

You may experience some of the following effects:

- **Allergic reactions have been reported with Ferrograd Folic ranging from rashes to, in rare cases, difficulty in breathing, fainting and swelling of the face and throat which may need emergency treatment.**
- Nausea
- Vomiting
- Abdominal pain or discomfort
- Blackening of stools
- Diarrhoea

- Constipation

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). 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 side effects:

If you get any side effects, talk to 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 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 Folic

Store in a dry place below 25°C.

Keep this medicine out of the sight and reach of children. It could harm them.

Do not use Ferrograd Folic 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. Contents of the pack and other information

What Ferrograd Folic contains

- The active substance is Dried Ferrous Sulfate 325 mg (equivalent to 105 mg elemental iron) as the active ingredient in a prolonged release Gradumet® form and Folic Acid BP 350 micrograms.
- The other ingredients are methylacrylate methylmethacrylate copolymer, lactose, povidone, polyethylene glycol 8000, magnesium stearate, colloidal silicon dioxide, sucrose, acacia powder, cellulose acetate phthalate, propylene glycol, sorbitan monooleate, castor oil, maize starch, titanium dioxide and dye Red Ponceau 4R Lake (E124).

What Ferrograd Folic looks like and contents of the pack

Ferrograd Folic prolonged release film coated tablets are circular, biconvex, two layered, red and yellow tablets.

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

Marketing Authorisation Holder

TEOFARMA s.r.l.

Via F.lli Cervi n° 8 - I-27010 Valle Salimbene (PV) - Italy

Fax: 0039 0382 525845

e-mail: servizioclienti@teofarma.it

Manufacturer

TEOFARMA s.r.l.

Viale Certosa n° 8/A - I-27100 - Pavia - Italy

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