

Reporting of suspected adverse reactions - Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: med.safety@hpra.ie.

4.9 Overdose - Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding. However, following a massive overdose, these initial symptoms may be absent due to the sustained release formulation. Therefore, if overdose is suspected, treatment should not be delayed by the absence of symptoms. A latent phase, followed by a relapse 24-48 hours after ingestion manifested by hypotension, coma and hepatocellular necrosis may occur.

Treatment: The ingested Gradumet matrix cannot be readily aspirated through a stomach tube and there is no known chemical that will dissolve the gradumet without harming gastric mucosa. Accordingly when overdosage is discovered early, the following procedure is recommended.

1. Administer an emetic by stomach tube.
2. Withdraw the stomach tube and wait for the patient to vomit.
3. Keep the patient under constant surveillance to detect possible aspiration of vomitus; maintain suction apparatus and standby emergency oxygen in case of need.
4. Examine the vomitus for returned Gradumet tablets.
5. Administer a saline purgative. By the time toxic signs have appeared Gradumet tablets are in most cases past the pylorus so that emesis is of no value. Gastric lavage may be considered to remove amounts of the drug already released in the stomach. A saline purgative should then be given to speed the Gradumet tablets along the alimentary canal so as to minimise or prevent further absorption of the medication.
6. The use of an iron-chelating agent such as oral desferrioxamine should be considered. In severe cases parenteral desferrioxamine may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties - Iron provided by Ferrograd aids haemoglobin regeneration. Once haemoglobin returns to normal, continuing with iron supplementation for 3 months will help replenish the iron stores within the body.

5.2 Pharmacokinetic properties - The Gradumet device allows controlled release of ferrous sulphate over a number of hours, which increases iron utilisation and reduces gastro-intestinal intolerance. The device consists of an inert plastic matrix, honeycombed by thousands of narrow passages which contain ferrous sulphate together with a water soluble channelling agent. As the tablet passes down the gastro-intestinal tract the iron is leached out. The spent matrix is finally excreted in the stools. Oral iron is absorbed better when administered between meals. However, conventional iron preparations often cause gastric irritation when taken on an empty stomach. Studies with Gradumet iron have indicated that relatively little of the iron is released into the stomach, the major proportion being released in the upper intestinal tract. Thus the possibility of gastric irritation is minimised when iron is administered in the Gradumet form in comparison with conventional oral iron preparations. Controlled release iron, therefore, is beneficial to patients who have a demonstrated intolerance to oral iron preparations.

5.3 Preclinical safety data - There are no pre-clinical data of relevance to the prescriber which are additional to information contained in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients: Core - Methylacrylate methylmethacrylate copolymer - Lactose Monohydrate - Povidone - Magnesium stearate - Film coating - Hypromellose Ethylcellulose Sodium saccharin Triethyl citrate Sorbitan Oleate Castor oil, virgin - Titanium dioxide (E171) Erythrosine (E127) - Sunset Yellow FCF (E110)

6.2 Incompatibilities - Not applicable.

6.3 Shelf life - 5 years.

6.4 Special precautions for storage - Do not store above 25°C. Store in the original package. Keep out of the reach and sight of children.

6.5 Nature and contents of container - Carton containing 30 (3 x 10) tablets in an AL/PVC blister.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product - No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teofarma S.R.L - Valle Salimbene (PV) - Via F.lli Cervi, 8 - CAP 27010 - Italy

8 MARKETING AUTHORISATION NUMBER

PA 1235/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

June 2015

TEOFARMA S.r.l. - Fax 0039/0382/525845 - e-mail: regulatory-medical@teofarma.it - www.teofarma.it

Ferrograd® 325 mg tablets

Dried Ferrous Sulphate



Ferrograd IE - Rev. 2 of 09/11/2016

Therapeutic indications
For the prevention
and treatment of iron
deficiency anaemias.

Classification for the supply:
medicine available without prescription

Ferrograd® 325 mg tablets

Dried Ferrous Sulphate



Efficacy of slow-release preparations based on ferrous sulphate

“Oral iron supplementation is the standard treatment for patients with iron deficiency. Ferrous salts and in particular prolonged release FS preparations are the treatment of choice given their high effectiveness, acceptable tolerability, and low cost.” (1)

References:

1. Santiago P - Review Article - Ferrous versus Ferric Oral Iron Formulations for the Treatment of Iron Deficiency: A Clinical Overview - The Scientific World Journal Volume 2012, Article ID 846824, 5 pages doi:10.1100/2012/846824

Ferrograd® 325 mg tablets

Dried Ferrous Sulphate

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferrograd 325mg Prolonged release Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Dried Ferrous Sulphate 325mg (elemental iron 105mg) Excipients with known effect: Each tablet contains 19.4mg lactose monohydrate and sunset yellow FCF (E110). For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet.
Circular, biconvex, red film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications - For the prevention and treatment of iron deficiency anaemias.

4.2 Posology and method of administration

Adults: The recommended dosage is one tablet daily before food.

Children: Not recommended for children under 12 years. Above this age, as for adults.

Elderly: As for adults. The sustained release tablet and its plastic inert matrix may cause a safety hazard in some elderly or other patients suffering from delayed intestinal transit.

Tablets should be swallowed whole.

4.3 Contraindications - Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Use in patients with intestinal diverticular disease or any intestinal obstruction.

Use in patients with haemochromatosis and iron overload syndromes.

Use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

4.4 Special warnings and precautions for use - The label will state “Important warning: Contains iron. Keep out of reach and sight of children, as overdose may be fatal”. This will appear on the front of the pack within a rectangle in which there is no other information.

As with all iron preparations, this product should be used with caution in patients with haemochromatosis, haemolytic anaemia or haemoglobinopathies. The sustained release tablet and its inert plastic matrix may cause a safety hazard in patients suffering from delayed intestinal transit. There may also be a further delay in release of the iron.

Caution is advised in individuals with a family history of haemochromatosis or iron overload syndromes. It should be noted these conditions may be underdiagnosed. Overdose may be fatal.

Ferrograd contains the colour E110, which may cause allergic type reactions including asthma; allergy is more common in those people who are allergic to aspirin.

This product should only be used for the prevention and treatment of iron deficiency anaemia diagnosed by laboratory testing under the supervision of a medical doctor.

4.5 Interaction with other medicinal products and other forms of interaction - Iron salts diminish the absorption of tetracyclines. Tetracycline antibiotics should be taken at least 2 hours before or 3 hours after taking Ferrograd. Concurrent administration of oral iron preparations may interfere with the oral absorption of some quinolone anti-infective agents (e.g. ciprofloxacin, norfloxacin, ofloxacin), resulting in decreased serum and urine concentrations of the quinolones. Therefore, oral iron preparations should not be ingested within one hour before or within four hours of a dose of an oral quinolone.

Thyroid hormones: Oral iron reduces the absorption of levothyroxine (thyroxine) thus should be given at least 2 hours apart.

Iron salts may reduce the bioavailability of metyldopa, the absorption of levodopa and penicillamine may also be reduced. The absorption of iron salts is decreased in the presence of antacids and preparations containing zinc, calcium, phosphorus or when taken with tea, coffee, milk, eggs, wholegrain cereals and dietary fibre. Therefore, oral iron preparations should not be taken within one hour before or two hours after ingestion of these products. Iron absorption may be increased by ascorbic or citric acid.

4.6 Fertility, pregnancy and lactation - Iron containing products if required, should be used during pregnancy after the first 13 weeks. Iron is excreted in breast milk so consult your doctor if you intend breast feeding.

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

4.8 Undesirable effects - Those associated with conventional oral iron preparations, i.e. nausea, vomiting, abdominal pain or discomfort, diarrhoea and/or constipation, are less likely to occur because of the sustained release nature of the formulation. Isolated cases of injury to mouth and pharynx, oesophageal ulcer, haematemesis and ileus have been reported.