Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ferrograd C 325mg/500mg Prolonged release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Dried Ferrous Sulphate 325.0 mg (elemental iron 105 mg)
Sodium ascorbate 562.4 mg (ascorbic acid/Vitamin C 500 mg)

Excipients with known effect:
Each tablet contains 23.4mg Dye Red Ponceau 4R Lake (E124)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet.
Ovoid, biconvex, two layered, red film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention and treatment of iron deficiency anaemia and for the simultaneous treatment of vitamin C deficiency.

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.

* Medical advice should be sought if symptoms do not improve after four weeks of use of this product at these symptoms may reflect an underlying disease process.

Method of administration:
The tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water. Tablets should be taken before meals or during meals, depending on gastrointestinal tolerance.

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.

• Individuals with haemochromatosis and iron overload syndromes.

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, it is advised that this product should be used with caution in individuals with a

family history of haemochromatosis, or iron overload syndromes. It should be noted that conditions may be underdiagnosed. Overdose may be fatal. 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. The administration of therapeutic doses of sodium ascorbate may interfere with the Clinistix test for glycosuria giving a false negative result.

Ferrograd C contains the colour E124, 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.

Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

Aspiration of iron sulfate tablets can cause necrosis of the bronchial mucosa which may result in coughing, haemoptysis, bronchostenosis and/or pulmonary infection (even if aspiration happened days to months before these symptoms occurred). Elderly patients and patients who have difficulties swallowing should only be treated with iron sulfate tablets after a careful evaluation of the individual patient's risk of aspiration. Alternative formulations should be considered. Patients should seek medical attention in case of suspected aspiration.

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 C.

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 methyldopa, 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 C has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Those associated with conventional oral iron preparations, such as nausea, vomiting, abdominal pain or discomfort, diarrhoea and/or constipation, are less likely to occur, because of the sustained release pattern of the formulation. Haemetemesis and ileus have been reported.

Post marketing: The following ADRs have been reported during post-marketing surveillance. The frequency of these reactions is considered not known (cannot be estimated from the available data).

Respiratory, thoracic and mediastinal disorders:

Bronchial stenosis (see section 4.4)

Gastrointestinal disorders:
mouth ulceration*
*in the context of incorrect administration, when the tablets are chewed, sucked, or kept in mouth. Elderly patients and patients with deglutition disorders may also be at risk of oesophageal lesions or of bronchial necrosis, in case of false route.

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: medsafety@hpra.ie.

4.9 Overdose

Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding. However, following a massive overdosage, these initial symptoms may be absent due to the sustained release formulation. Therefore, if overdosage 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.

Vitamin C overdosage may cause acidosis and haemolytic anaemia in predisposed individuals (glucose-6-phosphate dehydrogenase deficiency). Renal failure may occur in massive vitamin C overdosage.
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

Ferrograd C combines the advantages of ferrous sulphate in the Gradumet matrix with a large dose of vitamin C to further enhance absorption. It is indicated in iron-deficiency anaemia, especially when poor absorption is a problem, and to promote haemopoiesis in patients where an underlying vitamin C deficiency limits optimal haemoglobin formation. In patients whose haemoglobin has returned to normal, Ferrograd C may be of particular value in replenishing the depleted stores of iron.

5.2 Pharmacokinetic properties

The Gradumet device allows controlled release of ferrous sulphate over a number of hours 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

Tablet core

Methylacrylate methylmethacrylate copolymer
Magnesium stearate
Povidone
Macrogol 8000
Maize starch
Purified talc

Film coating

Subcoat:
Povidone
Ethylcellulose
Macrogol 400

Colour coating

Hypromellose
Macrogol 400
Macrogol 8000
Titanium Dioxide (E171)
Dye Red Ponceau 4R Lake (E124)

Glossing

Purified Talc
Macrogol 8000

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Carton containing 30 (2 x 15) 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

PA1235/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

April 2023