

# 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 325.0mg (elemental iron 105mg)

Ascorbic Acid 500mg (as sodium ascorbate)

Excipients: also contains Dye Red Ponceau 4R Lake (E124)

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Prolonged release tablet.

*Product imported from the UK*

Ovoid, biconvex, red film-coated tablets.

## 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.

Tablets should be swallowed whole.

### 4.3 Contraindications

Use in patients with a known hypersensitivity to any of the active ingredients.

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 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.

Ferrorgrad 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.

#### 4.5 Interaction with other medicinal products and other forms of interaction

The absorption of iron salts is decreased in the presence of antacids. Iron salts diminish the absorption of tetracyclines.

A potential chemical interaction between ferric iron and captopril in the gastrointestinal tract has been reported, which results in a significant increase in the area and curve when captopril is ingested with ferrous sulphate.

#### 4.6 Fertility, pregnancy and lactation

Iron containing products if required, should be used during pregnancy after the first 13 weeks.

#### 4.7 Effects on ability to drive and use machines

None

#### 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. Isolated cases of injury to mouth and pharynx, oesophageal ulcer, haemetemesis and ileus have been reported.

#### 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**

Methylacrylate methylmethacrylate copolymer  
Magnesium stearate  
Povidone  
Macrogol 400  
Macrogol 8000  
Maize starch  
Purified talc  
Ethylcellulose  
Hypromellose  
Titanium Dioxide (E171)  
Dye Red Ponceau 4R Lake (E124)

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf Life**

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

### **6.4 Special precautions for storage**

Do not store above 25°C. Store in the original package in order to protect from moisture.

### **6.5 Nature and contents of container**

Overlabelled cardboard outer containing blister strips. Each blister strip contains 15 tablets.  
Pack size: 30

### **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 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Ltd  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/141/1

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 17th December 2010

**10 DATE OF REVISION OF THE TEXT**