Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Galfer 305 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	Per Capsule
Ferrous Fumarate	305.0 mg
(Equivalent to 100 mg elemental iron)	

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule

Scarlet/green hard gelatin capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention and treatment of iron deficiency states.

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years:

Prophylaxis: One capsule daily.

Treatment: One capsule twice daily.

Children under 12 years: Not recommended.

Elderly patients: The adult dose is appropriate.

Pregnant women during second trimester onwards:

The adult dose is appropriate.

4.3 Contraindications

1. Hypersensitivity to the product or ingredients.

2. Haemosiderosis and haemochromatosis.

3. Active peptic ulcer.

4. Repeated blood transfusion.

5. Inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal strictures and diverticulae.

6. Anaemias other than those due to iron deficiency.

7. Haemoglobinopathies.

8. Concomitant use with parenteral iron.

4.4 Special warnings and precautions for use

1. Patients post-gastrectomy have poor absorption of iron.

2. Caution is advised when prescribing iron preparations to individuals with history of a peptic ulcer.

3. Duration of treatment should generally not exceed 3 months after correction of the anaemia.

4. Co-existing deficiency of vitamin B12 or folic acid should be ruled out since combined deficiencies produce microcytic blood film.

5. Iron deficiency in a male patient warrants careful investigation to determine its cause which forms the basis of primary treatment.

6. Iron preparations colour the faeces black, which may interfere with tests used for detection of occult blood in the stools.

This product should only be used for the 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 interactions

1. The absorption of iron salts is decreased in the presence of antacids, calcium supplements, zinc and trientine.

2. The presence of iron may impair absorption of concomitantly administered tetracyclines.

3. The hypotensive effect of methyldopa is reduced.

4. Iron reduces the absorption of fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, penicillamine and zinc.

4.6 Fertility, pregnancy and lactation

“Administration of drugs during the first trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained and should not be administered unless clearly indicated. For the remainder of the pregnancy, iron therapy may be indicated but only on the advice of a physician.”

Pregnant women also need to take folic acid.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Anorexia, nausea, vomiting, gastro-intestinal discomfort, constipation, diarrhoea, dark stools and allergic reactions. These side-effects may be minimised by taking the capsules after food.

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 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

"Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75mg/kg of elemental iron is considered dangerous in young children."

In the first phase of acute iron overdosage, which occurs up to 6 hours after oral ingestion, gastrointestinal toxicity, notably vomiting and diarrhoea, predominates. Other effects may include cardiovascular disorders, such as hypotension and tachycardia, metabolic changes, including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma.

Patients with only mild to moderate poisoning do not generally progress past this phase.

The second phase may occur at 6 to 24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation. In the third phase, gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, hepatic necrosis and jaundice, hypoglycaemia, coagulation disorders, oliguria or renal failure, and pulmonary oedema. The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage.

The stomach should be emptied at once by induction of vomiting and gastric lavage. Desferrioxamine mesilate (5 to 10g in 50 to 100ml of water) may be given by mouth, or by stomach tube, to chelate any iron left in the stomach and prevent further absorption following gastric lavage. To eliminate iron already absorbed, desferrioxamine mesilate should be given intramuscularly, or if the patient is hypotensive or in shock, intravenously by slow infusion. The dose and route of parenteral administration should be adjusted according to severity of the poisoning.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B03A A02 – Iron Bivalent, oral preparations.

Iron is a haematinic essential for satisfactory erythropoiesis during haemoglobin synthesis.

5.2 Pharmacokinetic properties

Absorption of iron is a complicated process. Iron is absorbed throughout the gastro-intestinal tract but it is greatest in the duodenum and proximal jejunum.

Approximately 5-10% of dietary iron is absorbed during prophylaxis and 10-30% in iron deficient subjects. Ferrous ion is easily absorbed compared to ferric ion. Transfer of iron across the placenta is an active process. Excess iron ingested is stored as ferritin and haemosiderin.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose

Capsule Shell Constituents

Quinoline Yellow (E104)
Erythrosine (E127)
Indigotine (E132)
Titanium Dioxide (E171)
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years for capsules stored in PVdC / aluminium blister packs.

6.4 Special precautions for storage

Do not store above 25°C.

Foil blister: Store in the original package.

6.5 Nature and contents of container

PVdC-Aluminium foil blisters containing 28 capsules.

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

Clonmel Healthcare Ltd
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/314/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 June 1976

Date of last renewal: 04 June 2006

10 DATE OF REVISION OF THE TEXT

June 2019