Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Galfer FA 305 mg / 0.35 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	Per Capsule
Ferrous Fumarate (Equivalent to 100mg elemental iron)	305.0 mg
Folic Acid	350 micrograms

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule
Scarlet/yellow hard gelatin capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention and treatment of iron deficiency anaemia in pregnancy and for the prevention of megaloblastic anaemia of pregnancy, after the first 13 weeks.

4.2 Posology and method of administration

For oral administration.

Adults only: One capsule daily after the first 13 weeks of pregnancy and the first month post partum.

4.3 Contraindications

1. Use in non-pregnant patients.

2. Use in children.

3. The diagnosis of pernicious anaemia should be excluded before use of this preparation.

4. Use in patients with megaloblastic anaemia due to vitamin B_{12} deficiency.

5. Use in patients with anaemias other than those due to iron deficiency.

6. Hypersensitivity to any of the ingredients.

7. Use in patients with haemosiderosis, haemochromatosis and haemoglobinopathies.

8. Use in patients with inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal strictures and diverticulae.

9. Concomitant use with parenteral iron.

10. Use in patients with active peptic ulcer.

11. Use in patients who require repeated blood transfusion.

4.4 Special warnings and precautions for use

1. Iron preparations colour the faeces black, which may interfere with tests used for detection of occult blood in the stools.
2. Iron preparations should be used with caution in patients with erythropoietic protoporphyria.

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, proton pump inhibitors which reduce stomach acid, calcium, magnesium and other mineral supplements, zinc and trientine. If treatment with both iron and trientine is necessary a suitable interval is advised. Iron also chelates with acetohydroxamic acid reducing the absorption of both.

2. Iron and tetracyclines interfere with the absorption of each other; allow an interval of 2 – 3 hours if treatment with both drugs is necessary.

3. The hypotensive effect of methyldopa is reduced by iron.

4. Iron reduces the absorption of fluoroquinolones, levodopa, carbidopa, entacapone, biphosphonates, penicillamine, thyroid hormones such as levothyroxine (give at least 2 hours apart), mycophenolate, cefdinir and zinc. Iron possibly reduces the absorption of eltrombopag (give at least 4 hours apart).

5. Absorption of iron is impaired by neomycin, cholestyramine, food (e.g. tea, coffee, wholegrain cereals, eggs and milk), but may be increased by ascorbic or citric acid. Bicarbonates, carbonates, oxalates, or phosphates, may impair the absorption of iron by the formation of insoluble complexes.

6. Concomitant use of iron and dimercaprol should be avoided.

7. The response to iron may be delayed in patients receiving systemic chloramphenicol. Chloramphenicol delays plasma clearance of iron and incorporation of iron into red blood cells by interfering with erythropoiesis.

8. Serum levels of anticonvulsant drugs may be reduced by the co-administration of folate e.g. folic acid possibly reduces the plasma concentration of phenobarbital, phenytoin and primidone.

9. Absorption of folic acid is possibly reduced by sulfasalazine.

10. Concomitant use of folic acid with raltitrexed should be avoided.

4.6 Fertility, pregnancy and lactation

Galfer FA is indicated for the prevention and treatment of iron deficiency anaemia in pregnancy and for the prevention of megaloblastic anaemia of pregnancy, after the first 13 weeks. It should only be taken during the first 13 weeks of pregnancy in consultation with a doctor. However, administration of drugs during the first trimester of pregnancy requires careful assessment of the potential risks versus benefits to be gained. Galfer FA may be used during breastfeeding.

4.7 Effects on ability to drive and use machines
None stated.

4.8 Undesirable effects
Side effects may be minimised by taking the product with or after food or by starting with a small dose and increasing gradually.

The incidences of undesirable effects are tabulated below. They are listed by system organ class and frequency defined as follows:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Gastrointestinal Disorders	*Rare:* Gastro-intestinal disturbances (e.g. nausea, vomiting, constipation, diarrhoea)
Immune System Disorders	*Rare:* Allergic reactions *Not known:* Anaphylactic reaction
Metabolism and Nutrition Disorders	*Not known:* Haemosiderosis may occur as a result of excessive or mistaken therapy.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continue 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

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.

Treatment of iron overdose in pregnancy should be as for the non-pregnant patient and if clinically indicated, treatment with desferrioxamine should not be withheld.
The stomach should be emptied at once by induction of vomiting and gastric lavage. Desferrioxamine mesilate (5 to10g 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 the severity of the poisoning and serum iron levels should be monitored throughout.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B03A D02 – Iron in combination with folic acid.

A daily dose of 100mg of iron and 200-500 micrograms of folic acid is recommended for the prevention of iron and folic acid deficiencies during pregnancy. Galfer FA contains 305 mg ferrous fumarate, equivalent to 100 mg of elemental iron, and 350 micrograms of folic acid, and thus one capsule daily provides a suitable prophylactic dose.

5.2 Pharmacokinetic properties

Folic acid is rapidly absorbed, mainly from the proximal part of the small intestine. Iron is irregularly and incompletely absorbed from the gastro-intestinal tract, the main site of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids, and is more readily effected when the iron is in the ferrous state. Absorption is also increased in conditions of iron deficiency or in the fasting state, but is decreased if body stores are overloaded.

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

5 years for capsules stored in polypropylene/polyethylene containers.

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

6.4 Special precautions for storage

Do not store above 25°C.
Polypropylene container: Keep container tightly closed.
Foil blister: Store in the original package.

6.5 Nature and contents of container
Cylindrical polypropylene containers with polyethylene snap-close caps containing 100, 250 or 500 capsules.

PVdC/Aluminium foil blisters containing 28 capsules.

Not all pack sizes may be marketed.

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
Waterford Road

Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER
PA0126/317/001

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

July 2019