SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Galfer FA Capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients:	**Per Capsule**
Ferrous Fumarate BP (Equivalent to 100mg elemental iron)	305.0mg
Folic Acid BP	350 micrograms

Excipient(s) with known effect
Not applicable

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The prophylaxis of iron and folic acid deficiencies during pregnancy

4.2 Posology and method of administration

Posology

Adults: One capsule daily throughout pregnancy or as directed by a physician.

Paediatric population: Not applicable.

Elderly: Not applicable.

Method of administration

For oral administration.

4.3 Contraindications

Contra-indicated in patients with megaloblastic anaemia due to vitamin B_{12} deficiency and in patients with a known hypersensitivity to the product or its ingredients. Not intended for the prevention or treatment of anaemia in men, non-pregnant women or children.

Use in patients with haemosiderosis, haemochromatosis and haemoglobinopathies.

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

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

Concomitant use with parenteral iron.

Use in patients with active peptic ulcer.

Use in patients who require repeated blood transfusion.

4.4. Special warnings and precautions for use

Galfer FA is intended only for the prevention of iron and folic acid deficiencies in pregnancy; the dose of folic acid provided is inadequate for the treatment of megaloblastic anaemias. The development of anaemia despite prophylaxis with Galfer FA requires further investigation and appropriate therapy.

Iron preparations should be used with caution in patients with erythropoietic protoporphyria.

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

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.

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

Iron chelates with concomitantly administered tetracyclines, and absorption of both agents may be impaired, allow an interval of 2-3 hours if treatment with both drugs is necessary. Iron also chelates with acetohydroxamic acid reducing the absorption of both.

Absorption of iron may be reduced in the presence of antacids and proton pump inhibitors which reduce stomach acid. Iron absorption may also be reduced in the presence of food (e.g. tea, coffee, wholegrain cereals, eggs and milk), neomycin and cholestyramine. Bicarbonates, carbonates, oxalates, or phosphates, may impair the absorption of iron by the formation of insoluble complexes. Iron absorption may be increased by ascorbic or citric acid.

Iron absorption may be reduced with calcium, oral magnesium salts and other mineral supplements, zinc and trientine. If treatment with both iron and trientine is necessary a suitable interval is advised.

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.

The hypotensive effect of methyldopa is reduced by iron.

Concomitant use of iron and dimercaprol should be avoided as toxic complexes may form.

Iron reduces the absorption of fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, 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).

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.

Concomitant use of folic acid with raltitrexed should be avoided.

Absorption of folic acid is possibly reduced by sulfasalazine.

4.6. Fertility, pregnancy and lactation

Galfer FA is suitable for use during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

Galfer FA has no influence on the ability to drive and use machines.

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 continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9. Overdose

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

Symptoms:
Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycemia and metabolic acidosis may occur. However, if overdosage is suspected, treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24-48 hours manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, diffuse vascular congestion, coagulopathy and/or convulsions. In many cases, full recovery may be complicated by long-term effects such as hepatic necrosis, toxic encephalitis, CNS damage and pyloric stenosis.

Treatment:
The following steps are recommended to minimise or prevent further absorption of the medication.

Children:

1. Administer an emetic such as syrup of ipecac.

2. Emesis should be followed by gastric lavage with desferrioxamine solution (2g/l). This should then be followed by the installation of desferroxamine 5g in 50 – 100ml water, to be retained in the stomach. Inducing diarrhoea in children may be dangerous and should not be undertaken in young children. Keep the patient under constant surveillance to detect possible aspiration of vomitus – maintain suction apparatus and standby emergency oxygen in case of need.

3. Severe poisoning:
In the presence of shock and/or coma with high serum iron levels (serum iron >90umol/l) immediate supportive measure plus IV infusion of desferrioxamine should be instituted. Desferrioxamine 1 5mg/kg body weight should be administered every hour by slow IV infusion to a maximum 80mg/kg/24 hours.

Warning:
Hypotension may occur if the infusion rate is too rapid.

4. Less severe poisoning: i.m desferroxamine 1g 4-6-hourly is recommended.

5. Serum iron levels should be monitored throughout.

Adults:
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.

1. Administer an emetic.

2. Gastric lavage may be necessary to remove drug already released into the stomach.
This should be undertaken using a desferrioxamine solution (2g/l). Desferrioxamine 5g in 50-100ml water should be introduced into the stomach following gastric emptying. Keep the patients under constant surveillance to detect possible aspiration of vomitus; maintain suction apparatus and standby emergency oxygen in case of need.

3. A drink of mannitol or sorbitol should be given to induce small bowel emptying.

4. In the presence of shock and/or coma with high serum iron levels (>142umol/l) immediate supportive measures plus IV infusion of desferrioxamine should be instituted.
The recommended dose of desferrioxamine is 5mg/kg/h by a slow IV infusion up to a maximum of 80mg/kg/24 hours.

Warning:
Hypotension may occur if the infusion rate is too rapid.

5. Less severe poisoning:
i.m. deferrioxamine 50mg/kg up to a maximum dose of 4g should be given.

6. Serum iron levels should be monitored throughout.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clinical efficacy and safety
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 305mg ferrous fumarate, equivalent to 100mg of elemental iron, and 350 micrograms of folic acid, and thus one capsule daily provides a suitable prophylactic dose.

5.2 Pharmacokinetic properties

Absorption
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 affected 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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose BP

Capsule Shell Constituents:

Quinoline Yellow (E104)
Erythrosine (E127) Pharm Fr
Indigotine (E132) Pharm Fr
Titanium Dioxide (E171) Pharm Fr
Gelatin Ph Eur

6.2 Incompatibilities

None stated.

6.3 Shelf life

Containers: 5 years (60M).
Blisters: 3 years (36M).

6.4 Special precautions for storage

Store in a cool place.
Keep container tightly closed.
Keep out of reach of children.

6.5 Nature and contents of container

Cylindrical polypropylene containers with polyethylene snap-close caps.
Pack sizes: 100 and 250 capsules.

Child resistant vial complying with British Standard (BSI 5321).
Pack size: 30 capsules.

PVdC/Aluminium foil blisters.
Pack size: 28 capsules.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0105

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 May 2003

10 DATE OF REVISION OF THE TEXT

10/05/2018