SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Galfer Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ferrous Fumarate BP 305.0mg
(equivalent to 100mg elemental iron).

3. PHARMACEUTICAL FORM

Capsule.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the treatment and prophylaxis of uncomplicated iron deficiency anaemia.

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 the second trimester onwards: The adult dose is appropriate.

4.3 Contraindications

(i) Hypersensitivity to the product or ingredients.

(ii) Haemosiderosis and haemochromatosis.

(iii) Active peptic ulcer.

(iv) Repeated blood transfusion.

(v) Inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal strictures and diverticulae

(vi) Anaemias other than those due to iron deficiency.

(vii) Haemoglobinopathies

(viii) Concomitant use with parenteral iron

(ix) Concomitant use with dimercaprol

4.4 Special warnings and precautions for use

(i) Patients post-gastrectomy have poor absorption of iron.

(ii) Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer.

(iii) Duration of treatment should generally not exceed 3 months after correction of anaemia.

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

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

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

(vii) Prolonged or excessive use in children without medical supervision may lead to toxic accumulation

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

(i) Iron and tetracyclines reduce the absorption of each other. Iron reduces absorption of zinc, and absorption of oral iron is reduced by zinc.

(ii) Iron reduces the absorption of penicillamine, fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, and levothyroxine.

(iii) Absorption of iron is reduced with calcium, magnesium and other mineral supplements, bicarbonates, carbonates, zinc and trientine and impaired by antacids, cholestyramine, tea, eggs or milk, but may be increased by ascorbic or citric acid.

(iv) Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.

(v) Reduced hypotensive effect of methyldopa.

4.6 Fertility, pregnancy and lactation

Pregnant women also need to take folic acid.

Administration of drugs during the first trimester of pregnancy requires careful assessment of the potential risks versus the 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.

No adverse effects of ferrous fumarate have been shown in breastfed infants of treated mothers. Ferrous fumarate can be used during breast-feeding if clinically indicated.

4.7 Effects on ability to drive and use machines

Galfer Capsules do not affect the ability to drive or operate machinery.

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. Iron preparations can be particularly constipating in older patients and occasionally lead to faecal impaction. Iron preparations can also exacerbate diarrhoea in patients with inflammatory bowel disease; care should be taken with patients who have intestinal strictures or diverticular disease.

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.

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.

Symptom:

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/1). This should then be followed by the installation of desferrioxamine 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/1) 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 desferrioxamine 1g 4-6-hourly is recommended.

5. Serum iron levels should be monitored throughout.

Adults:

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/1).

   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. Severe poisoning.

   In the presence of shock and/or coma with high serum iron levels (>142umol/1) 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

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 GI 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. Pre-clinical Safety Data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Microcrystalline Cellulose

Capsule shell ingredients:

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

6.2. Incompatibilities

None stated.

6.3 Shelf life

Containers: 3 years (36M)
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

None stated.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 00240/0104

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

31 May 2003

10 DATE OF REVISION OF THE TEXT

29/01/2019