

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Galfer 140 mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Each 5ml contains 140mg Ferrous Fumarate equivalent to 45 mg elemental iron.

Excipients: each 5ml contains 6.250mg Nipasept sodium (containing sodium methyl parahydroxybenzoate (E219), sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) and 5.0g of Liquid Maltitol E965)).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension (oral liquid)

A brown liquid suspension with a chocolate/mint odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This product is indicated for the prevention and treatment of iron deficiency states.

4.2 Posology and method of administration

For oral administration.

a) Prevention of iron deficiency:

Adults, the elderly and children over 12 years:

Two 5ml spoonfuls (10ml) taken once daily.

Infants and young children (under 12 years):

1-2 mg elemental Iron per Kg body weight per day. Maximum dose not to exceed 15mg Iron per day. Dosage of Galfer Syrup to be determined by the physician.

b) Treatment of iron deficiency:

Adults, the elderly and children over 12 years:

Two 5ml spoonfuls (10ml) taken twice daily.

Infants less than one month old:

2-4 mg elemental iron per Kg body weight per day. To be taken in divided doses. Maximum dose not to exceed 15 mg Iron per day. Dosage of Galfer Syrup to be determined by the physician.

Infants over one month old and children under 12 years:

3-6 mg elemental Iron per Kg body weight per day. To be taken in divided doses. Dosage of Galfer Syrup to be determined by the physician.

Administration to infants and children should take place under medical supervision.

Medical advice should be sought if symptoms do not improve after four weeks of use of this product as these symptoms may reflect an underlying disease process.

4.3 Contraindications

Use in patients with a known hypersensitivity to the active ingredient.

Patients with Haemosiderosis, haemochromatosis, haemoglobinopathies, inflammatory bowel disease, intestinal strictures and diverticulae, active peptic ulcer, repeated blood transfusions, regional enteritis, ulcerative colitis and anaemias not produced by iron deficiency unless iron deficiency is also present.

Concomitant use with parenteral iron.

Concomitant use with dimercaprol

4.4 Special warnings and precautions for use

Post-gastrectomy patients have poor absorption of iron.

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

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

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

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

Prolonged or excessive use in children without medical supervision may lead to toxic accumulation.

Caution is advised in individuals with a family history of haemochromatosis or an iron overload syndrome. It should be noted that these conditions may be under diagnosed. Overdose may be fatal.

Keep out of the sight and reach of children.

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 interaction

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

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

Iron reduces the absorption of zinc and absorption of oral iron is reduced by zinc.

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

The absorption of iron is reduced with calcium, magnesium and other mineral supplements, bicarbonates, carbonates, zinc and trientine and impaired by antacids, colestyramine, tea, eggs or milk and may be increased by ascorbic or citric acid.

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

Reduced hypotensive effect of methyldopa.

4.6 Fertility, pregnancy and lactation

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

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 Syrup does not affect the ability to drive or operate machinery.

4.8 Undesirable effects

Oral liquid preparations containing iron salts may blacken the teeth. To prevent this, the mouth may be rinsed with water after use to minimise exposure.

Side effects including anorexia, nausea, diarrhoea, vomiting, gastrointestinal discomfort, blackening of the stools, constipation and allergic reactions occur rarely.

These side effects may be minimised by taking the suspension 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.

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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +3531 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:

The stomach should be emptied at once by induction of vomiting and gastric lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B03A A02 Iron bivalent, oral preparations.

Elemental iron in the ferrous form is effective as a prophylaxis against iron deficiency, and as a replacement therapy in mild to moderate iron deficiency anaemia. Good serum rise and haemoglobin response are obtained. Gastro-intestinal disturbance is low as ferrous fumarate has low irritant characteristics.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastro-intestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretions of the stomach or 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

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate (E219)
Sodium ethyl parahydroxybenzoate (E215)
Sodium propyl parahydroxybenzoate (E217)
Citric acid monohydrate (E330)
Aluminium magnesium silicate
Chocolate flavour (17.42.5444)
Peppermint flavour (17.40.1951)
Liquid Maltitol (E965)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type III amber glass bottles with tamper evident child resistant caps with polycone liner as closures (high density polyethylene outer surface/polypropylene inner surface).
Pack sizes: 100 ml and 300 ml.

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

Thornton & Ross Limited
Linthwaite
Huddersfield HD7 5QH
England

8 MARKETING AUTHORISATION NUMBER

PA0610/012/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th July 1988

Date of last renewal: 25th July 2008

10 DATE OF REVISION OF THE TEXT

July 2015