# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Galfer 140 mg/5ml Oral Suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

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

Excipient(s) with known effect

Dose per 5 ml contains:
Methyl parahydroxybenzoate 4.69 mg
Ethyl parahydroxybenzoate 0.94 mg
Propyl parahydroxybenzoate 0.63 mg
Maltitol liquid 5 g
Benzyl alcohol 0.65 micrograms
Ethanol 0.117 micrograms
Sodium benzoate 2.6 micrograms
Lactose 0.023 mg

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral suspension (oral liquid)

This medicine is a brown liquid suspension with a chocolate/mint odour.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

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

### 4.2 Posology and method of administration

Posology

a) Prevention of iron deficiency:
**Adults, the elderly and children over 12 years:**
Two 5 ml spoonfuls (10 ml) 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 15 mg Iron per day. Dosage of Galfer Oral Suspension to be determined by the physician.

**b) Treatment of iron deficiency:**

**Adults, the elderly and children over 12 years:**
Two 5 ml spoonfuls (10 ml) 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 Oral Suspension 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 Oral Suspension 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.

Method of administration
For oral administration.

**4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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**

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.

Contains iron. Keep out of the sight and reach of children as overdose may be fatal.

This product should only be used for the treatment of iron deficiency anaemia diagnosed by laboratory testing under the supervision of a medical doctor.

Excipient warnings
This medicine contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

This medicine contains 10 g liquid maltitol in each 10 ml dose. Patients with rare hereditary problems of fructose intolerance should not take this medicine. This medicine may have a mild laxative effect. Calorific value 2.3 kcal/g.

This medicine contains 5.2 micrograms sodium benzoate per 10 ml dose, which may increase neonatal jaundice, which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue.

This medicine contains 1.3 micrograms benzyl alcohol per 10 ml dose. Benzyl alcohol may cause allergic reactions. Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates ("gasping syndrome"). The minimum amount of benzyl alcohol at which toxicity may occur is not known. Caution should be exercised when used for more than a week in young children (less than 3 years old), due to increased risk of accumulation of benzyl alcohol in this age group. High volumes should be used with caution and only if necessary, especially in subjects who are pregnant or breastfeeding, or subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

This medicine contains 0.234 micrograms of alcohol (ethanol) in each 10 ml. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free'.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**4.5 Interaction with other medicinal products and other forms of interactions**

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 Oral Suspensionhas no influence on the ability to drive and use machines.

**4.8 Undesirable effects**

Side effects including nausea, diarrhoea, vomiting, blackening of the stools and constipation occur rarely.

**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 the national reporting system:
HPRA Pharmacovigilance
Website: www.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.

The stomach should be emptied at once by induction of vomiting and gastric lavage. Desferrioxamine mesilate (5 to 10 g in 50 to 100 ml 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.

## 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
Citric acid monohydrate (E330)
Aluminium magnesium silicate
Chocolate flavour (17.42.5444) (containing propylene glycol (E1520), benzyl alcohol (E1519), ethanol, sodium benzoate (E211), milk (lactose))
Peppermint flavour (17.40.1951) (containing propylene glycol (E1520), benzyl alcohol (E1519))
Liquid maltitol
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years.
Use within 28 days of first opening

### 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**

Clonmel Healthcare Ltd
Waterford Road
Clonmel, Co. Tipperary
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA0126/314/002

**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**

June 2021