# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Ferrous Gluconate Tablets 300 mg.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 300 mg Ferrous Gluconate.

Excipients with known effect: each tablet contains 2.659mg Sucrose, 0.346mg Carmoisine Dioxide Lake, 1.22mg Ponceau 4R and 0.028mg of Sunset Yellow FCF Aluminium Lake.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Red, sugar coated, deep convex tablets.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Ferrous Gluconate 300mg Tablets are indicated for the prevention and treatment of iron deficiency states.

### 4.2 Posology and method of administration

Posology

Adults and the elderly:

Prophylactic: 2 tablets daily

Therapeutic: 4-6 tablets daily in divided doses

*Paediatric population:*

Children (aged 6-12 years):

Prophylactic: 1 or 2 tablets daily
Therapeutic: 3 tablets daily in divided doses.

The above doses are best taken about 1 hour before meals.

Method of administration:

The route of administration for Ferrous Gluconate 300mg tablets is oral.

## 4.3 Contraindications

Hypersensitivity to the active ingredient ferrous gluconate or to any of the excipients listed in section 6.1.

Iron preparations are contra-indicated in patients with haemochromatosis, iron storage or absorption diseases such as and haemosiderosis or haemoglobinuria.

Iron is contraindicated in patients receiving repeated blood transfusions, or in patients receiving parenteral iron therapy or to patients with anaemias not produced by iron deficiency (some conditions, such as thalassemia may cause excess storage of iron).

Alcoholism and hepatitis.

Iron preparations are contraindicated in active peptic ulcer, regional enteritis and ulcerative colitis.

Ferrous Gluconate Tablets should not be used in patients with anaemia not produced by iron deficiency unless iron deficiency is also present.

## 4.4 Special warnings and precautions for use

Large doses may have irritant/corrosive effect on gastro-intestinal mucosa which can lead to necrosis and perforation.

Ferrous Gluconate should be used with caution in patients with haemolytic anaemia. Caution is required in the elderly, who may be at increased risk of serious adverse reactions.

Before starting treatment it is important to exclude any underlying causes of anaemia, e.g. gastric erosions or colonic carcinoma.

Care should be exercised in patients with iron-absorption diseases. Patients post gastrectomy have poor absorption of iron. Caution is advised when

prescribing iron preparations to individuals with history of peptic ulcer, and inflammatory bowel disease, including regional enteritis and ulcerative colitis and care should be exercised in patients with intestinal strictures and diverticulae.

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 deficiency produces microcytic blood film.

Dental caries is a definite risk following long term treatment with this product.

Patients suffering from iron overload are particularly susceptible to infection. Treatment of iron overload should be with caution.

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

Hypersensitivity reactions

Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction, see section 4.8).

These tablets contain sugar and should be administered with care to patients with diabetes.

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This product contains E124, E122 & E110 which may cause allergic reactions.

*The label will state:* 'Important warning: Contains iron. Keep out of the sight and reach 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 and possibly other heavy metals are chelated with concurrent oral administration of acetohydroxamic acid resulting in reduced intestinal absorption of both drugs.

Antacids and mineral supplements: Concurrent administration of antacids may reduce absorption of iron. Compounds containing calcium, magnesium, bicarbonates, carbonates, oxalates or phosphates may impair the absorption of iron because of the formation of less soluble or insoluble complexes and should be administered at least 2 hours apart.

Penicillamine: Iron reduces the absorption of penicillamine, and may decrease the effect of penicillamine. Also the absorption of iron is impaired by

penicillamine. A period of 2 hours should elapse between administration of penicillamine and iron.

Antibacterials: Absorption of both iron and antibiotic may be reduced if Ferrous Gluconate is given with tetracycline antibiotics. Administration of iron preparations and tetracyclines should be separated by 2 to 3 hours. Iron compounds impair the bioavailability of fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin). Administration should be separated by at least 2 hours. , Oral chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis. Neomycin may alter the absorption of iron.

Vitamin E: Concurrent use of Vitamin E may impair the hematologic response in patients with iron deficiency anaemia. Large doses of iron may increase daily requirements of Vitamin E.

Bisphosphonates: The absorption of bisphosphonates is reduced when taken concurrently with iron preparations. Administration should be separated by at least 2 hours.

Dopaminergics: Oral iron preparations may reduce the absorption of dopaminergics such as levodopa, entacapone and co-careldopa.

Methyldopa: Administration of oral iron may reduce the hypotensive effect of methyldopa

Mycophenolate mofetil: Iron reduces absorption of mycophenolate mofetil

Zinc and Aluminium: Iron salts may reduce the absorption of aluminium and zinc salts and absorption of both iron and zinc are reduced if taken concomitantly.

Cholestyramine: Absorption of iron is impaired by cholestyramine.

Trientine: Absorption of oral iron preparations is reduced by trientine. Administration should be separated by at least 2 hours.

Food products: Absorption of iron is impaired by tea (contains tannic acid), eggs, milk and milk products and whole grain breads and cereals (contain phytic acid). Coffee may be a factor in reducing iron bioavailability.

Thyroid hormone: Iron reduces the absorption of thyroxine and so should be taken at least 2 hours apart.

Dimercaprol: Avoid concomitant administration of oral iron with dimercaprol or use of dimercaprol for treatment of iron poisoning due to the formation of toxic compounds.
Proton pump inhibitors may reduce absorption of oral iron.

Carbidopa: Iron compounds impair the bioavailability of carbidopa.
In addition iron possibly reduces the absorption of eltrombopag (a period of 4 hours should elapse between administration of eltrombopag and iron) and nalidixic acid.

## 4.6 Fertility, pregnancy and lactation

Use of any drug during the first trimester of pregnancy should be avoided if possible. Thus administration of iron during the first trimester requires definite evidence of iron deficiency. There is no evidence of any harmful effects due to normal doses of Ferrous gluconate in pregnant women and nursing mothers, but as with all drugs care should be exercised in administering this preparation during pregnancy and lactation. Prophylaxis of iron deficiency during the remainder of pregnancy is justified. Iron is excreted in breast milk but not in clinically significant amounts (about 0.5 mg /day).

## 4.7 Effects on ability to drive and use machines

None reported.

## 4.8 Undesirable effects

Large doses of iron may cause gastro-intestinal discomfort, anorexia, diarrhoea, nausea, heatburn and vomiting. These side effects have been reported to occur in up to 20% or more of patients treated and are related to the amount of elemental iron taken rather than the type of preparation. Continued administration of ferrous gluconate may result in constipation and faecal impaction. Darkening of stools may occur. Higher doses of ferrous gluconate may have irritant and corrosive effects on the gastro-intestinal mucosa and necrosis and perforation may occur; stricture formation may subsequently follow.

Symptoms which may not appear for several hours, include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory failure may follow if diarrhoea and haemorrhage are severe.

Rarely allergic reactions may occur.

Cardiac disorders

Frequency ‘Not known’: Kounis syndrome

**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

Large amounts of Ferrous gluconate are toxic, but in adults rarely prove fatal. In children between 1 and 2 years of age as little as 1 to 2 g of iron can cause death.

*Symptoms*

Iron poisoning is commonest in childhood and is usually accidental.

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 abdominal pain, haematemesis, rectal bleeding, cardiovascular disorders, such as hypotension, tachycardia and circulatory collapse, 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.

*Management*

Local guidelines should be used or the National Poisons Information Centre should be contacted about individual patient management.
The following steps are recommended to minimise or prevent further absorption of the medication.

*Paediatric population:*

1. Administer an emetic such as Syrup of Ipecac.
2. Emesis should be followed by gastric lavage with desferrioxamine solution (2 g/l).
   This should then be followed by the instillation of desferrioxamine 5 g in 50 – 100 ml water, to be retained in the stomach. Inducing diarrhoea in

children may be dangerous and should not be undertaken in young children. Keep the patients 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 90 μmol/l) immediate supportive measures plus I.V. infusion of desferrioxamine should be instituted. Desferrioxamine 15 mg/kg body weight should be administered every hour by slow I.V. infusion to a maximum 80 mg/kg/24 hours. Warning: Hypotension may occur if the infusion rate is too rapid.
4. Less severe poisoning I.M. desferrioxamine 1 g, 4 – 6 hourly is recommended.
5. Serum iron levels should be monitored throughout.

*Adults:*

1. Administer an emetic.
2. In less severe cases gastric lavage may be employed to remove unabsorbed iron from the stomach if the patient presents within one hour of ingestion. The serum-iron concentration should be measured as an emergency. This should be undertaken using a desferrioxamine solution (2 g/l). Desferrioxamine 5 g in 50 – 100 ml water should be introduced to the stomach following gastric emptying. Keep the patient 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 include small bowel emptying.
4. Severe Poisoning: In the presence of shock and/or coma with high serum Iron levels (140μmol/l) immediate supportive measures plus I.V. infusion of desferrioxamine should be instituted without waiting for the results of the serum iron measurement. Desferrioxamine is a specific iron chelating agent which may be administered by intravenous injection. The dose should be adjusted according to the severity of the poisoning. A solution of 10g of desferrioxamine mesylate in 50ml water should be left in the stomach. Absorbed iron can be chelated by an intramuscular injection of 2g of desferrioxamine mesylate in 10ml of water. The recommended dose of desferrioxamine is 5 mg/kg/h by slow I.V. infusion to a maximum 80 mg/kg/24 hours. Warning: Hypotension may occur if the infusion rate is too rapid.
5. Less severe poisoning: I.M. desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given.
6. Serum levels should be monitored throughout.

Dimercaprol should not be used in the treatment of iron poisoning.

## 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: Antianemic preparations, iron preparations
ATC code: B03A A03

Iron is an essential constituent of the body, being necessary for haemoglobin formation and for the oxidative processes of living tissues. More than 80% of the iron present in the body is involved in the support of red blood cell production. Iron is also an essential component of myoglobin, hema enzymes such as cytochromes, catalase, peroxidase, and the metalloflavoprotein enzymes, including xanthine oxidase and the mitochondrial enzyme alpha glycerophosphate oxidase.

## 5.2 Pharmacokinetic properties

Absorption of iron mainly takes place in the duodenum and proximal jejunum. Absorption being aided by the acid secretion of the stomach and being more readily effected when the iron is in the Ferrous state. The absorption of iron varies, in non-iron deficient individuals it is 3-10%, the amount being approximately proportional to the degree of deficiency.

The absorption is more efficient when iron is ingested in its ferrous rather than ferric form on an empty stomach. When administered with food, the amount of iron absorbed may be reduced by 1/2-1/3 as when taken on an empty stomach. It is highly bound to plasma proteins.

There is no existence of physiological system of excretion of iron; however small amounts are lost daily in the shedding of skin, hair and nails, and in faeces, perspiration, breast milk (0.5-1.0 mg/day), menstrual blood and urine. Average daily loss of iron for healthy adult males and postmenopausal females is 1mg/day; in premenopausal females it is 1.5mg/day.

Absorption is increased in the presence of ascorbic acid or succinic acid. Some dietary products such as eggs, which have a high iron content also contain phosphates and phytates which inhibit absorption by the formation of unabsorbable complexes. Absorption is also decreased by antacids, tetracyclines and tea.

## 5.3 Preclinical safety data

Not available

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Colloidal anhydrous silica
Alginic acid
Magnesium stearate
Maize starch
Purified water

*Tablet coating materials:*
Purified talc
Syrup
*Coating varnish comprising of:*
Shellac
IMS
Standard coating cream comprising of
Sucrose
Heavy kaolin
Purified talc
Titanium dioxide (E171)
*Opalux Red AS-F-2864 comprising of:*
Sucrose
Ponceau 4R aluminium lake (E124)
Carmoisine dioxide lake (E122)
Titanium dioxide (E171)
Povidone
Sunset yellow FCF aluminium lake (E110)
Sodium benzoate (E211)

Purified water

*Polish ingredients:*

Carnauba Wax

Beeswax

## 6.2 Incompatibilities

None

## 6.3 Shelf life

Opaque plastic containers: 36 months, as packaged for sale

Blister packs: 36 months, as packaged for sale

## 6.4 Special precautions for storage

Opaque plastic containers: Store in container provided. Do not store above 25°C.
Keep out of the reach and sight of children.

Blisters: Do not store above 25°C. Store in the original package. Keep the blister in the outer carton.
Keep out of the reach and sight of children.

### 6.5 Nature and contents of container

1) Opaque plastic containers composed of either high density polypropylene or high density polyethylene with a tamper evident or child resistant tamper evident closure composed of high density polyethylene in pack sizes of 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1,000 tablets.

2) Aluminium/PVC/paper blister packs (child resistant) in pack sizes of 28 tablets.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

No special instructions for use/handling.

## 7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Key House, Sarum Hill,
Basingstoke,
RG21 8SR
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0073

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th April 1989/18th October 2004

## 10 DATE OF REVISION OF THE TEXT

30/04/2024