SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ferrous Gluconate Tablets BP 300mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 300mg of the active substance ferrous gluconate

Excipient(s) with known effect

Sucrose
Certolake ponceau 4R

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet

Red, circular, biconvex sugar-coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ferrous gluconate tablets 300mg are indicated for the prevention and treatment of iron deficiency states.

4.2 Posology and method of administration

Posology

Adults, the elderly and children over 12 years

Prophylactic:	2 tablets daily
Therapeutic:	4-6 tablets daily in divided doses

Children (6-12 years)

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

Ferrous Gluconate is not recommended in children under 6 years.

Ferrous gluconate tablets are best taken about 1 hour before meals.

Method of administration

The route of administration for ferrous gluconate tablets is oral.

4.3 Contraindications

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

Patients with haemochromatosis, anaemias not produced by iron deficiency unless iron deficiency is also present, iron storage or absorption diseases such as haemosiderosis or haemoglobinopathies, patients with inflammatory bowel disease, intestinal strictures and diverticulae, active peptic ulcer and patients receiving repeated blood transfusions.

Should not be administered concomitantly with parenteral iron.

4.4 Special warnings and precautions for use

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.

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. 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 B_{12} 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.

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.

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

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 and should be administered at least 2 hours apart.

Penicillamine: Iron reduces the absorption of penicillamine. Also the absorption of iron is impaired by penicillamine.

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.

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: 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, eggs or milk. 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.

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.

Prophylaxis of iron deficiency during the remainder of pregnancy is justified.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Gastro-intestinal disorders have been reported including gastro-intestinal discomfort, epigastric pain, anorexia, nausea, vomiting, constipation, and diarrhoea. Darkening of the stools may occur.

Rarely allergic reactions may occur.

Contact irritation can occur with ferrous gluconate tablets resulting in erosion or ulceration, particularly if they become lodged in the upper gastrointestinal tract.

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

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 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.

Management
Local guidelines should be used or the National Poisons Information Centre should be contacted about individual patient management.

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. In severe toxicity desferrioxamine should be given by continuous intravenous infusion without waiting for the results of the serum iron measurement. Desferrioxamine is a specific iron chelating agent which may be administered by intravenous injection using desferrioxamine mesylate solution 2g in 1 litre of water. 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. Dimercaprol should not be used in the treatment of iron poisoning.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron bivalent, oral 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, haem enzymes such as cytochromes, catalase, peroxidase, and the metalloflavoprotein enzymes, including xanthine oxidase and the mitochondrial enzyme alpha glycerophosphate oxidase.

5.2 Pharmacokinetic properties

After acidification and partial digestion of food in the stomach, its content of iron is presented to the intestinal mucosa as either inorganic or heme iron. These fractions are taken up by the absorptive cells of the duodenum and upper small intestine and the iron is either transported directly into the plasma or is stored as mucosal ferritin. Normal absorption is about 1mg per day in the adult male and about 1.4mg per day in the adult female. Increased uptake and delivery of iron into the circulation occurs when there is iron deficiency, and when iron stores are depleted or when erythropoiesis is increased. Only 10% of total iron is lost per year from normal men and that accounts for 1mg per day. Two thirds of this iron is excreted from the gastrointestinal tract as extravasated red cells, iron in bile and iron in exfoliated mucosal cells. The other third is accounted for in the urine. Physiological losses of iron in the male vary over a relatively narrow range decreasing to about 0.5mg in the iron deficient individual and increasing to as much as 1.5mg or possibly 2mg per day when excessive iron is consumed. Additional losses of iron occur in the female due to menstruation while this averages about 0.5mg per day, 10% of normal menstruating females loose over 2mg per day.

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium starch glycollate
Stearic acid
Colloidal silicon dioxide
Sucrose
Opaseal
Talc
Calcium carbonate
Acacia
Titanium dioxide
Certolake ponceau 4R
Opaglos 6000P

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

Do not use after the ‘Use Before’ date given on the pack

6.4 Special precautions for storage

Store below 25°C in a dry place

6.5 Nature and contents of container

Polypropylene tubes with low-density polyethylene caps.

Pack sizes of 28, 250, 500, 1000, 5000 tablets.

Blister packs with white PVC contained in cardboard cartons.

Pack sizes of 28 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special instructions

7. MARKETING AUTHORISATION HOLDER

Strides Pharma UK Ltd
Unit 4 Metro Centre
Tolpits Lane
Watford
Hertfordshire
WD18 9SS
Trading as: Co-pharma

8. MARKETING AUTHORISATION NUMBER(S)

PL 13606/0038

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7 January 1998 / 4 April 2003

10. DATE OF REVISION OF THE TEXT

19/02/2018