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

For excipients, see 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

The route of administration for ferrous gluconate tablets is oral

Adults and the elderly

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 tablets are best taken about 1 hour before meals

4.3 Contraindications

Use in patients with known hypersensitivity to the active ingredient or any of the excipients.

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

The label will state:
"Important warning: Contains iron. Keep out of the 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).

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

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

- 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.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of other medicines on ferrous gluconate

Dimercaprol should not be used for the treatment of iron poisoning or in patients taking iron supplements due to the formation of toxic complexes.

The absorption of iron from the gut may be reduced by concomitant administration of the following medications:

- Antacids
- Magnesium trisilicate
- Tetracycline antibiotics
- Trientine
- Zinc salts
- Colestyramine
- Calcium supplements or calcium containing products
- Tea, coffee

Effect of ferrous gluconate on other medications
Administration of oral iron may reduce the hypotensive effect of methyldopa

Absorption of the following medications are reduced in the presence of ferrous gluconate:

- Fluoroquinolone antibiotics
- Tetracycline antibiotics
- Levodopa, carbidopa, entacapone
- Biphosphonates
- Penicillamine
- Levothyroxine
- Zinc salts

- Oral chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.
- Neomycin may alter the absorption of iron.
- Entacapone and proton pump inhibitors may reduce absorption of oral iron.
- Iron reduces absorption of mycophenolate.

4.6 Pregnancy and lactation

Ferrous gluconate may be safely taken by pregnant and nursing mothers

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Because iron salts are astringent gastrointestinal irritation may occur. Nausea, vomiting, blackening of the stools and epigastric pain may occur and are dose related but the relationship between dose and altered bowel habit, giving rise to constipation or diarrhoea is less clear.

- Anorexia.
- Rarely allergic reactions may occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine

4.9 Overdose

Symptoms
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 or intramuscular injection. The dose and route of parenteral administration should be adjusted according to the severity of the poisoning. Dimercaprol should not be used in the treatment of iron poisoning.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B03A A03, Iron bivalent, oral preparations

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

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 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

Co-pharma Ltd
Unit 4 Metro Centre
Tolpits Lane
Watford
Hertfordshire
WD18 9SS

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

19.06.2015