SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferrous Gluconate 300 mg Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active ingredient:	mg/tablet
Ferrous gluconate	300.0

For excipients please see section 6.1

3 PHARMACEUTICAL FORM

Coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The tablets are for oral administration in the prevention and treatment of iron deficiency anaemia.

4.2 Posology and method of administration

Adults:

Prevention: Two tablets daily

Treatment: Four to six tablets daily in divided doses

Children 6-12 years:

Prevention and treatment: One to three tablets daily in divided doses.

Ferrous gluconate 300 mg coated tablets are best taken about one hour before meals.

4.3 Contraindications

Hypersensitivity to iron preparations or to any of the excipients.

Iron preparations are contraindicated in patients with haemochromatosis, haemosiderosis or haemoglobinuria.

Iron salts should not be given to patients receiving repeated blood transfusions or 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.

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.

Care should be exercised in patients with iron-absorption diseases, existing gastro-intestinal disease, intestinal strictures and diverticulae.

Caution is required in the elderly, who may be at risk of serious adverse reactions.

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

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

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.

Concomitant use of iron and dimercaprol should be avoided (formation of toxic compounds).

Concurrent use with iron, of antacids containing calcium salts, carbonates or magnesium trisilicate, and other medications containing bicarbonates, carbonates, oxalates or phosphates will decrease iron absorption because of the formation of less soluble or insoluble complexes; iron supplements should not be used within 1 hour before or 2 hours after ingestion of any of these preparations.

The absorption of iron is also slowed down by the concurrent intake of coffee, eggs, milk and milk products, tea (contains tannic acid) and whole grain breads and cereals (contain phytic acid).

The absorption of iron is also reduced by the concurrent administration of trientine.

Some inhibition of iron absorption may occur if it is taken with colestyramine.

Concomitant administration of penicillamine with iron medications reduces absorption and may decrease the effect of penicillamine, a period of 2 hours should elapse between administration of penicillamine and iron.

Concurrent use of tetracyclines with iron reduces absorption and resultant therapeutic effects of both medications. If treatment with both drugs is required, the iron salt should be administered 3 hours before or 2 hours after tetracycline.

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.

Iron salts may reduce the absorption of aluminium and zinc salts and the absorption of iron is also reduced with concurrent administration with zinc salts.

Oral iron antagonises the hypotensive effect of methyldopa.

Oral iron reduces the absorption of bisphosphonates (give at least two hours apart), fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin) entacapone, mycophenolate.

Proton pump inhibitors may reduce absorption of oral iron.

Iron also reduces the absorption of levothyroxine, a period of 2 hours should elapse between administration of levothyroxine and iron.

In addition iron possibly reduces the absorption of eltrombopag (a period of 4 hours should elapse between administration of eltrombopag and iron), nalidixic acid, levodopa and carbidopa.

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

Neomycin may alter the absorption of iron.

4.6 Fertility, Pregnancy and lactation

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. Iron is excreted in breast milk but not in 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, heartburn 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.

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.

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:

Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse.

Hyperglycaemia and metabolic acidosis may also occur. If overdosage is suspected treatment should be implemented immediately. In severe cases, after a latent phase hepatocellular necrosis and renal failure may occur.

Treatment:

The following steps are recommended to minimise or prevent further absorption of the medication.

Children:

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. Gastric lavage may be necessary to remove drug already released into the stomach. 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 (140 µmol/l) immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted. 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antianaemic preparations, ATC code: B03AA03.

Iron is an essential component in the physiological formation of haemoglobin, adequate amounts of which are necessary for effective erythropoiesis and the resultant oxygen transport capacity of the blood. A similar function is provided by iron in myoglobin production. It also serves as a co-factor of several essential enzymes.

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 a 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 ½-1/3 as when taken on an empty stomach. It is highly bound to plasma proteins.

There is no existence of a physiological system of excretion of iron; however small amounts are lost daily in the shedding of skin, hair, 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 1 mg/day; in premenopausal females it is 1.5 mg/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 non-absorbable complexes. Absorption is also decreased by antacids, tetracyclines and tea.

5.3 Preclinical safety data

There are no preclinical safety data that could be of relevance to the prescriber, which are not already included in other relevant sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Purified talc, Starch (potato)

Tablet coating:

Sucrose, Purified talc, Maize starch, Shellac, Dispersed red 15011 (which comprises of Carmoisine Lake [E122] and Ponceau 4R Lake [E124]) i.e. colourant, Industrial Methylated Spirit, Titanium dioxide and Opaglos 6000 (which comprises of Carnauba wax, Beeswax and Shellac).

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a dry place below 25ºC.

Store in the original package. Keep out of the sight and reach of children.

6.5 Nature and contents of container

This medicinal product is presented in a child resistant blister pack containing 28 tablets (arranged as two strips of fourteen tablets). The strips have been subjected to – and passed – child and adult resistance testing (based on placebos) in accordance with the latest standard: BS EN 14375:2003, being the standard for non-reclosable packaging.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Medipoint UK Ltd
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Morden
Surrey
SM4 5PE
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 57630/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/09/2005

10 DATE OF REVISION OF THE TEXT

27/04/2023