SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferranate 300 mg Tablets
Ferrous Gluconate 300 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sugar-coated tablet contains ferrous gluconate dihydrate BP 300.00 mg

equivalent to 34.8 mg elemental Iron.

Excipient with known effect : Also contains sucrose and E 122

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sugar-coated Tablet

Red sugar-coated tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ferrous Gluconate 300 mg 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

Posology:

Children (ages 6 to 12 years)

Prophylactic: 1-2 tablets daily

Therapeutic: 3 tablets daily in divided doses

Ferrous Gluconate 300 mg Tablets are best taken about 1 hour before meals.

Method of administration: 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 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.

This product also contains azorubine carmoisine (E 122). This 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 hour 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, entacepone and co-careldopa.

Carbidopa: Iron compounds impair the bioavailability of carbidopa.

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 oral 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 (contains 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.

Proton pump inhibitors: Proton pump inhibitors may reduce absorption of oral iron.

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.

In addition iron possibility 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 significant amounts (about 0.5 mg/day)

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Gastro-intestinal disorders have been reported with large doses of Iron including gastro-intestinal discomfort, epigastric pain, anorexia, nausea, diarrhoea, constipation, 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 results in constipation and faecal impaction. Darkening of the stools may occur.

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.

Contact irritation can occur with high doses of Ferrous Gluconate Tablets resulting in erosion or ulceration on the gastro-intestinal mucosa and necrosis, and perforation may occur; stricture formation may subsequently follow particularly if they become lodged in the upper gastrointestinal tract.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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.

Children :

1. Administer an emetic such as Syrup of Ipecac.
2. Emesis should be followed by gastric lavage with desferrioxamine solution (2g/l).This should 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/I) immediate supportive measure 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 80mg/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 (2g/l).Desferrioxamine 5 g in 50-100ml 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/I) 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 50 ml 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 5mg/kg/h by slow I.V. infusion to a maximum 80mg/kg/24 hours. Warning: Hypotension may occur if the infusion rate is too rapid.
5. Less severe poisoning: I.M. desferrioxamine 50mg/kg upto 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 group: Antianemic preparations, ATC code: B03AA03

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 the cytochromes, catalase, peroxidase and the metalloflavoprotein enzymes, including xanthine oxidase and the mitochondrial enzyme alpha-glycerophosphate oxidase.

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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 about1mg 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 an iron deficiency, 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 by small amounts of iron in desquamated skin and 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 females due to menstruation. While this averages about 0.5mg per day, 10% of normal menstruating females lose over 2mg per day.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Trisilicate

Maize Starch

Magnesium Stearate

Bleached Shellac

Sucrose

Talc

Titanium Dioxide

Povidone 25

Azorubicine Carmoisine Aluminium Lake E122

Beeswax

Carnauba Wax

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months: High density polystyrene containers with polythene lids and/or polypropylene containers with polypropylene or polythene lids.

36 months: Child-resistant PVC/Aluminium foil packs.

6.4 Special precautions for storage

Containers: Keep containers well closed. Protect from light. Store below 25°C.

Blisters: Store in the original package. Protect from light. This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container

High density polystyrene containers with polythene lids and/or polypropylene containers with polypropylene or polythene lids: 100 and 500

Child-resistant PVC/Aluminium foil packs: 28 and 30

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
11 Boumpoulinas,
Nicosia 1060,
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0133

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/11/2014

10 DATE OF REVISION OF THE TEXT

20/12/2018