Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ferrous Gluconate 300mg Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ferrous Gluconate 300mg.
300mg Ferrous Gluconate contains approximately 35mg of iron.

Each tablet also contains the excipients:

Sucrose 117.56mg
Ponceau 4R Red (E124) 3.63mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet (tablet)
Red, circular, biconvex, sugar coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention and treatment of iron deficiency states.

4.2 Posology and method of administration

Adults:
Prevention of iron defiencey anaemia:- 2 tablets daily before food.
Treatment of iron deficiency anaemia:- 4-6 tablets daily in divided doses before food.

Route of administration
Oral

4.3 Contraindications

Use in patients known to have hypersensitivity to the active ingredient.

4.4 Special warnings and precautions for use

1. The absorption of iron salts is decreased in the presence of antacids.

2. This product should be used with caution in patients with haemochromatosis and haemolytic anaemias.

3. This product should only be used for the treatment of iron deficiency anaemia diagnosed by laboratory testing under the supervision of a medical doctor.

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

5. This medicinal product contains Ponceau 4R Red (E124), which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

The absorption of iron salts is decreased in the presence of antacids.

4.6 Pregnancy and lactation

Iron-containing products, if required, should be used during pregnancy after the first thirteen weeks.

4.7 Effects on ability to drive and use machines

No information submitted.

4.8 Undesirable effects

Because iron salts are astringent gastrointestinal irritation may occur. Nausea 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.

4.9 Overdose

Iron poisoning is commonest in childhood and is usually accidental. The symptoms are nausea, vomiting, abdominal pain, diarrhoea, haematemesis; coma and hepatocellular necrosis occur later. Mortality is reduced with intensive and specific therapy. The effective antidote is desferrioxamine, which chelates iron. The stomach should be emptied at once, preferably by inducing vomiting as this is the quickest. Gastric lavage in hospital should be followed as soon as possible using desferrioxamine mesylate solution 2g in 1 litre of water.

A solution of 10g of desferrioxamine mesylate in 50ml water should be left in the stomach. Absorbed iron can also be chelated by an intramuscular injection of 2g of desferrioxamine mesylate in 10ml of water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron bivalent, oral preparation
ATC code: B03A A

Iron has an important role in the formation of red blood cells and is a vital component of the oxygen-carrying pigment, haemoglobin. It is involved in the formation of myoglobin, a pigment which stores oxygen in muscles for use during exercise. It is also an essential component of several enzymes, and is involved in the uptake of oxygen by the cells and the conversion of blood sugar to energy.

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 the 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, 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 the 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 the female 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

At therapeutic doses, no toxic effects are recognized after oral administration of iron salts to experimental animals. The LD_{50} in mice is reported to be 230-1100 $mg.kg^{-1}$ iron.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
- Sodium Starch Glycollate
- Stearic Acid
- Colloidal Anhydrous Silica
- Purified Water

Sugar Coat
- Opaseal*
  (*Contains Polyvinylacetate phthalate)
- Stearic Acid
- Opaglos 6000P*
  (*Contains Yellow Carnauba Wax)
- White Beeswax
- Shellac
- Talc
- Calcium Carbonate
- Acacia
- Titanium Dioxide (E171)
- Sucrose
- Ponceau Red 4R (E124)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed in order to protect from moisture.
Store in the original container in order to protect from light.

6.5 Nature and contents of container

PP tablet containers with LDPE caps and silica gel desiccant.

Pack sizes: 50, 100, 250, 500 and 1000 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Limited,
Waterford Road,
Clonmel,
Co. Tipperary.

8 MARKETING AUTHORISATION NUMBER

PA 0126/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 May 1988

Date of last renewal: 11 May 2008

10 DATE OF REVISION OF THE TEXT

October 2008