Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fersaday 100 mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 322mg Ferrous Fumarate equivalent to 100mg Ferrous Iron.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film coated tablet.
Brown biconvex, film-coated tablets engraved 'Fersaday' around the periphary on one face and plain on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fersaday Tablets are indicated for the Prophylaxis and treatment of iron deficiency states.

4.2 Posology and method of administration

For oral administration only.

Adults:
The usual adult dose is one tablet daily. In severe or refractory iron deficiency, one Fersaday Tablet may be given twice a daily. The foil enclosing the tablets is printed with the days of the week in sequence.

Children:
This presentation of ferrous fumarate is not intended for the treatment of children.

4.3 Contraindications

Hypersensitivity to any constituent of the product.
Use in patients with paroxysmal nocturnal haemoglobinuria, haemosiderosis, haemochromatosis, active peptic ulcer, repeated blood transfusions, regional enteritis, and ulcerative colitis.

Use in the treatment of anaemias other than those due to iron deficiency.

4.4 Special warnings and precautions for use

Some post gastrectomy patients show poor absorption of iron.

Care is needed when treating patients with iron deficiency anaemia in patients with treated or controlled peptic ulceration.

Fersaday Tablets should be kept out of reach of children.
Duration of treatment of uncomplicated iron deficiency anaemia should not usually exceed 6 months (or 3 months after reversal of the anaemia has been achieved).

The product should be used with caution in patients with haemolytic anaemia.

Since anaemia due to combined iron and vitamin B12 or folate deficiencies may be microcytic in type, patients with microytic anaemia resistant to therapy with iron alone should be screened for vitamin B12 or folate deficiency.

4.5 Interaction with other medicinal products and other forms of interaction

Iron reduces the absorption of penicillamine.

Absorption of both iron and antibiotic may be reduced if Fersaday is given with tetracycline.

Concurrent administration of antacids may reduce absorption of iron.

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

Some inhibition of iron absorption may occur if it is taken with cholestyramine, tea, eggs or milk.

4.6 Pregnancy and lactation

Administration of Fersaday tablets during the first trimester of pregnancy may be undesirable.

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, anorexia, nausea, vomiting, constipation and diarrhoea. Darkening of the stools may occur.

4.9 Overdose

Ingestion of an overdose of iron orally requires emergency treatment as follows :

In young children 200-250mg/kg ferrous fumarate is considered to be extremely dangerous.

Symptoms and signs of abdominal pain, vomiting and diarrhoea appear within 60 minutes. Cardiovascular collapse with coma may follow. Some improvement may occur after this phase in some patients, and may be followed by recovery. In other patients, after about 16 hours, deterioration may occur involving diffuse vascular congestion, pulmonary oedema, convulsions, anuria, hypothermia, severe shock, metabolic acidosis, coagulation abnormalities or hypoglycaemia.

Vomiting should be induced immediately, followed as soon as possible by parenteral injection of desferrioxamine and then gastric lavage. In the meantime it is useful to give milk and/or 5% sodium bicarbonate by mouth.

Dissolve 2 grams of desferrioxamine mesylate in 2 or 3ml of water for injections and give intramuscularly. A solution of 5 grams desferrioxamine mesylate in 50 to 100ml of fluid may be left in the stomach. If desferrioxamine is not available, leave 300ml of 1% to 5% sodium bicarbonate in the stomach. Fluid replacement is essential.

Recovery may be complicated by long term sequelae, such as hepatic necrosis, pyloric stenosis, or acute toxic encephalitis which may lead to CNS damage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ferrous Fumarate is an iron salt.

Iron is an essential constituent of the body, being necessary for haemoglobin formation and the oxidative processes of living tissues.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastro-intestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is usually increased in conditions of iron deficiency or when given in the fasting state. Absorption of iron may be reduced in certain disease states.

5.3 Preclinical safety data

Ferrous Fumarate is a long-established product the pre-clinical properties of which are well established.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Sodium laurilsulfate
Gelatin
Liquid paraffin
Acetylated monoglyceride
Hypromellose

Opaspray Tan K-1-3618:
Hydroxypropylcellulose
Titanium dioxide (E171)
Talc
Iron oxide yellow (E172)
Iron oxide red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Aluminium foil blister strips containing 14 tablets presented in a cardboard carton. Each carton contains 2 calendar pack blister strips.

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.

7 MARKETING AUTHORISATION HOLDER

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Trading as:
Goldshield Pharmaceuticals.

8 MARKETING AUTHORISATION NUMBER

PA0701/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 January 1987

Date of last renewal: 16 October 2003

10 DATE OF REVISION OF THE TEXT

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