

PART II

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Fersaday Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 322 mg Ferrous Fumerate BP equivalent to 100 mg of Ferrous Iron.

3. PHARMACEUTICAL FORM

Film coated tablet.

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 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 ulceration, 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 Special Precautions for Use

Precautions:

Some post-gastrectomy patients show poor absorption of iron.

Care is needed when treating 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 microcytic anaemia resistant to therapy with iron alone should be screened for vitamin B12 or folate deficiency.

4.5 Interactions

Iron reduces the absorption of penicillamine.

Absorption of both iron and antibiotic may be reduced if Fersaday is given with a 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 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 to 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 which in some patients is followed by recovery. In others, 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 mesylate and then gastric lavage. In the meantime it is helpful to give milk and/or 5% sodium bicarbonate by mouth.

Dissolve 2 grams of desferrioxamine mesylate in 2 or 3 ml of water for injections and give intramuscularly. A solution of 5 grams desferrioxamine 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 solution 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 for 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 BP, Hydroxypropylmethylcellulose, gelatin BP, Opaspray Tan K-1-3618, Acetylated monoglyceride, Sodium lauryl sulphate BP and liquid paraffin Ph. Eur.

**6.2 Incompatibilities**

None known.

**6.3 Shelf Life**

2 years.

**6.4 Special Precautions for Storage**

Store below 25°C. Protect from light.

**6.5 Nature and Contents of Containers**

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

**6.6 Instructions for Use/Handling**

None.

**7. NAME AND ADDRESS OF MARKETING AUTHORISATION HOLDER**

Goldshield Group Plc.,  
NLA Tower, Croydon,  
Surrey, CR0 0XT,  
United Kingdom.

trading as:

Goldshield Pharmaceuticals.

**8. MARKETING AUTHORISATION NUMBER**

PA 701/4/1

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

**10. DATE OF (PARTIAL) REVISION OF THE TEXT**

March 1996