

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fersamal tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 210mg ferrous fumarate BP

3 PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prophylaxis and treatment of iron deficiency states.

For prophylaxis during pregnancy, a combination of iron and folic acid is usually recommended.

4.2 Posology and method of administration

Adults and the elderly: 1 tablet three times a day.
Dose may be increased to 2 tablets three times a day, if required.

Children: Not recommended, suggest use of Fersamal syrup.

Method of administration: Oral

The tablets are easy to swallow but may also be crushed or chewed being almost tasteless.

4.3 Contraindications

Known hypersensitivity to any of the ingredients of the product. Paroxysmal nocturnal haemoglobinuria. Haemosiderosis, haemochromatosis. Active peptic ulcer. Repeated blood transfusions. Regional enteritis and ulcerative colitis. Must not be used in 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 required when treating patients with iron deficiency anaemia who have treated or controlled peptic ulceration.

Duration of treatment of uncomplicated iron deficiency anaemia should not usually exceed 6 months (3 months after reversal of the anaemia has been achieved).

Because anaemia due to combined iron and Vitamin B₁₂ or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to treatment with iron alone should be screened for Vitamin B₁₂ or folate deficiency.

Fersamal should be kept out of the reach of children.

The label will state: Important Warning:

Contains Iron.

Keep out of the reach and sight 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 reduces the absorption of penicillamine. Absorption of both iron and antibiotics may be reduced if Fersamal is given with a tetracycline.

Concurrent administration of antacids may reduce the absorption of iron.

Chloramphenicol delays plasma iron clearance, incorporation of it 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 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, including discomfort, anorexia, nausea, vomiting, constipation, diarrhoea, and darkening of stools.

4.9 Overdose

Acute overdosage of oral iron requires emergency treatment. In young children, 200 to 250mg/kg ferrous fumarate is considered to be extremely dangerous.

Symptoms and signs of abdominal pain, vomiting and diarrhoea occur within 60 minutes of ingestion of an overdose.

Cardiovascular collapse and coma may follow. Some spontaneous improvement may occur after this, and in some patients there is recovery. In other patients, after about 16 hours, deterioration may occur with diffuse vascular congestion, pulmonary oedema, convulsions, anuria, hypothermia, severe shock metabolic acidosis, coagulation abnormalities, or hypoglycaemia.

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

Desferrioxamine mesylate is given intramuscularly - dissolve 2 gm desferrioxamine mesylate in 2 or 3 ml of water for injection.

A solution of 5 gm desferrioxamine mesylate in 50 to 100 ml 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 cause CNS damage.

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Iron is an essential constituent of the body, and is necessary for haemoglobin formation and for the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anaemias. Preparations of iron are administered by mouth, by intramuscular or intravenous injection.

Soluble ferrous salts are most effective by mouth. Ferrous fumarate is an easily absorbed source of iron for replacement therapy. It is a salt of ferrous iron with an organic acid and is less irritant to the gastro-intestinal tract than salts with inorganic acids.

5.2 Pharmacokinetic properties

In the acid conditions of the gastric contents, ferrous fumarate is dissociated and ferrous ions are liberated. These irons are absorbed in the proximal portion of the duodenum.

The ferrous iron absorbed by the mucosal cells of the duodenum is oxidised to the ferric form, and this is bound to a protein to form ferritin.

Ferritin in the mucosal cells releases iron into the blood, where it is bound to transferrin and passed into the iron stores - liver, spleen, and bone marrow.

These stores are a reserve of iron for synthesis of haemoglobin, myoglobin, and iron containing enzymes.

Iron is lost from the body through loss of cells in urine, faeces, hair, skin, sputum, nails, and mucosal cells, and through blood loss.

Ferrous fumarate has the same pattern of absorption and excretion as dietary iron.

5.3 Preclinical safety data

No further data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch BP
Sodium lauryl sulphate BP
Gelatin BP
Liquid paraffin BP
Purified water BP

6.2 Incompatibilities

None.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

No special precautions.

6.5 Nature and contents of container

Polypropylene containers with tamper evident, high density polyethylene child resistant closure containing 100 or 1000 tablets.

PVC/PVDC blisters with aluminium foil backing material containing 28, 56 and 112 tablets

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

GOLDSHIELD PHARMACEUTICALS LIMITED
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2 November 1993

10 DATE OF REVISION OF THE TEXT

01 February 2010