

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferrous Sulphate 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ferrous sulphate BP 200 MG.

3 PHARMACEUTICAL FORM

Tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Iron-deficiency anaemia.

4.2. Posology and Method of Administration

Adults

Iron deficiency anaemia- 1 tablet two to three times a day; prophylaxis- 1 tablet once or twice a day.

Children and adolescents: (6-18 years)

Treatment:

Children weighing over 22kg: one tablet a day.

Children weighing over 44kg: one tablet twice a day.

Children weighing over 66kg: one tablet three times a day.

Prophylaxis:

One tablet daily

Children under 6 years or weighing less than 22kg: Not recommended.

Method of Administration:

Oral

4.3 Contraindications

Do not use in patients hypersensitive to any of the ingredients in the formulation.

Must not be used in anaemias other than those due to iron deficiency.

Iron preparations are contra-indicated:

- in patients with haemochromatosis, paroxysmal nocturnal haemoglobinuria and haemosiderosis
- in patients receiving repeated blood transfusions.
- when used concomitantly with parental iron therapy.
- in patients with active peptic ulcer, regional enteritis and ulcerative colitis.

4.4 Special warnings and precautions for use

Before starting treatment, it is important to exclude any underlying cause of the anaemia (e.g. gastric erosion, colonic carcinoma).

Co-existing deficiency of vitamin B₁₂ or folic acid should be ruled out since combined deficiencies produce microcytic blood film

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

Oral iron, particularly modified-release preparations may exacerbate diarrhoea in patients with inflammatory bowel disease.

As with all iron preparations, ferrous sulphate should be used with care in patients with known or suspected gastrointestinal strictures or intestinal diverticular disease.

Patients with post-gastrectomy have a poor absorption of iron.

Caution is advised when prescribing iron preparations to individuals with a history of peptic ulcer.

Patients with rare hereditary problems of galactose intolerance or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Aspiration of iron tablets induces inflammatory lesions at the site of iron deposit and may cause bronchial stenosis.

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 inhibits the absorption of tetracyclines from the gastrointestinal tract and tetracycline inhibits the absorption of iron. If both drugs must be given, tetracyclines should be taken three hours after or two hours before oral iron supplements.

Iron reduces the absorption of penicillamine, bisphosphonates, ciprofloxacin, entacapone, levodopa, levofloxacin, levothyroxine (thyroxine) (give at least 2 hours apart), moxifloxacin, mycophenolate, norfloxacin, ofloxacin, zinc.

Concurrent administration of oral iron preparations with tea, coffee, eggs, food or medications containing bicarbonates, carbonate, oxalates or phosphates, milk or milk products, whole grain breads and cereals and dietary fibre, may decrease iron absorption.

The absorption of ferrous sulphate is reduced by magnesium trisilicate, calcium salts, trientine and cholestyramine.

Chloramphenicol delays plasma clearance of iron and incorporation of iron into red blood cells by interfering with erythropoiesis.

Avoid concomitant use of iron with dimercaprol.

Ferrous sulphate also reduces the hypotensive effect of methyldopa.

Absorption of iron salts is enhanced by ascorbic acid and meat.

4.6 Pregnancy and Lactation

Pregnancy

Ferrous sulphate tablets can be used during pregnancy if clinically indicated.

Lactation

No adverse effects of ferrous sulphate have been shown in breastfed infants of treated mothers. Ferrous sulphate tablets can be used during breast-feeding if clinically indicated.

4.7 Effects on ability to drive and use machines

None stated.

4.8. Undesirable effects

Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side-effects.

Hypersensitivity reactions have been reported. These range from rashes, sometimes severe, to anaphylaxis.

- Gastro-intestinal irritation and darkening of stools can occur with iron salts. Nausea and epigastric pain are dose-related but the relationship between dose and altered bowel habit (constipation or diarrhoea) is less clear.
- Iron preparations taken orally can be constipating, particularly in older patients and occasionally lead to faecal impaction.
- If side-effects occur, the dose may be reduced; alternatively, another iron salt may be used but an improvement in tolerance may simply be a result of a lower content of elemental iron.

4.9 Overdose

Symptoms:

Ingestion of 20 mg/kg elemental iron is potentially toxic and 200-250 mg/kg is potentially fatal. No single method of assessment is entirely satisfactory - clinical features as well as laboratory analysis must be taken into account. The serum iron taken at about 4 hours after ingestion is the best laboratory measure of severity.

Serum Iron	Severity
< 3 mg/L (55 micromol/L)	Mild toxicity
3-5 mg/L (55-90 micromol/L)	Moderate toxicity
> 5 mg/L (90 micromol/L)	Severe toxicity

Early signs and symptoms include nausea, vomiting, abdominal pain and diarrhoea. The vomit and stools may be grey or black. In mild cases early features improve but in more serious cases there may be evidence of hypoperfusion (cool peripheries and hypotension), metabolic acidosis and systemic toxicity. In serious cases there can be recurrence of vomiting and gastrointestinal bleeding, 12 hours after ingestion. Shock can result from hypovolaemia or direct cardiotoxicity.

Evidence of hepatocellular necrosis appears at this stage with jaundice, bleeding, hypoglycaemia, encephalopathy and positive anion gap metabolic acidosis. Poor tissue perfusion may lead to renal failure. Rarely, gastric scarring causing stricture or pyloric stenosis (alone or in combination) may lead to partial or complete bowel obstruction 2-5 weeks after ingestion.

Management:

Supportive and symptomatic measures include ensuring a clear airway, monitor cardiac rhythm, BP and urine output, establishing IV access and administering sufficient fluids to ensure adequate hydration. Consider whole bowel irrigation. If metabolic acidosis persists despite correction of hypoxia and adequate fluid resuscitation, an initial dose of 50 mmol sodium bicarbonate may be given and repeated as necessary, for adults guided by arterial blood gas monitoring (aim for a pH of 7.4). Consider the use of desferrioxamine, if /the patient is symptomatic (other than nausea), serum iron concentration is between 3-5 mg/L (55-90 micromol/L) and still rising. Haemodialysis does not remove iron effectively but should be considered on a supportive basis for acute renal failure as this will facilitate removal of the iron-desferrioxamine complex

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Iron is absorbed mainly in the small intestine, but can be absorbed along the entire length of the alimentary canal. It is absorbed most easily in the ferrous state, passing into and through the mucosal cell directly into the blood stream where it is immediately attached to transferrin.

5.2 Pharmacokinetic properties

Most of the iron in the body is present as haemoglobin. The remainder is present in the storage forms ferritin or haemosiderin, in the reticuloendothelial system or as myoglobin with smaller amounts occurring in haem-containing enzymes or in plasma bound to transferrin.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

• Core ingredients-

Light kaolin,

Glucose monohydrate,

Maize Starch,

Povidone K29/32,

Stearic acid,

Magnesium stearate,

Sodium lauryl sulphate.

• Coating material-

Titanium dioxide E171,

Sucrose,

Glucose syrup,

Spray-dried acacia,

Calcium carbonate,

Purified talc,

Colloidal silicone dioxide

and Bees wax.

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a cool dry place protected from light, below 25°C.

6.5 Nature and contents of container

Polypropylene securitainer with a low density polyethylene cap containing 50, 100, 500, or 1000 tablets.

Blister pack Aluminium/PVC/PVdC in 28 tablets per pack.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Forley Generics Ltd

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CR0 0XT

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 16201/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 July 1999

10 DATE OF REVISION OF THE TEXT

20/12/2010