

## **PRODUCT SUMMARY**

### **1. NAME OF THE MEDICINAL PRODUCT**

Ferrous Sulphate Tablets BP 200mg.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains 200mg of Dried Ferrous Sulphate BP.

### **3. PHARMACEUTICAL FORM**

White sugar-coated tablets.

### **4. CLINICAL PARTICULARS**

#### **4.1. Therapeutic indications**

For the treatment and prophylaxis of 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. **Contra-Indications**

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 B<sub>12</sub> 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. Care is also needed in patients with intestinal stricture and diverticulae.

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 sucrase-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. Interactions with other Medicinal 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. Therefore, oral iron preparations should not be taken within one hour before or two hours after ingestion of such items.

The absorption of ferrous sulphate is reduced by magnesium trisilicate, calcium salts, trientine, tetracyclines 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

### **5.1 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**

Iron is primarily absorbed from the duodenum, this is an active process regulated by levels of serum iron in the blood. In the plasma iron is transported in combination with B globulin transferrin, a loose combination allowing easy release to any tissue in the body.

Approximately 5 - 10% of dietary iron is absorbed during prophylaxis and 10 - 30% in iron deficient subjects. Ferrous iron is easily absorbed compared to ferric iron. Transfer of iron across the placenta is an active process. Excess iron ingested is stored as ferritin and haemosiderin.

The main excretory pathway is by way of the epithelial cells sloughed from the skin and gastrointestinal tract. The unneeded iron is carried out as ferritin. Other excretory pathways are hair, urine, faeces, sweat and bile.

### **5.3. Pre-clinical safety data**

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Dextrose Monohydrate	B.P.
Lactose	B.P.
Maize Starch	B.P.
Glycerol	B.P.
Povidone	B.P.
Industrial Methylated Spirits	HSE
Calcium Carbonate	B.P.
Magnesium Stearate	B.P.
Shellac	B.P.C.
Castor Oil No. 1	B.P.
Talc	B.P.
Titanium Dioxide	B.P. (E171)
Sucrose	B.P.
Mineral Water Sugar	B.P.
Purified Water	B.P.
Methylhydroxybenzoate	B.P.
Propylhydroxybenzoate	B.P.
Acacia	B.P.
Polyethylene Glycol 6000	B.P.

## **6.2. Incompatibilities**

None known.

## **6.3. Shelf life**

3 years (36 months).

## **6.4. Special precautions for storage**

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

## **6.5. Nature and content of container**

Polypropylene securitainers with tamper evident polypropylene caps.  
Pack sizes; 50, 100, 1000's.

## **6.6. Instructions for use, handling and disposal**

Keep out of reach of children.

**ADMINISTRATIVE DATA**

**7.     MARKETING AUTHORISATION HOLDER**

Goldshield Pharmaceuticals Ltd  
NLA Tower  
12-16 Addiscombe Road  
Croydon  
CR0 0XT  
United Kingdom.

**8.     MARKETING AUTHORISATION NUMBER(S)**

PL: 12762/0111.

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

25<sup>th</sup> July 2001.

**10    DATE OF REVISION OF THE TEXT**

20/12/2010