SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferrous Sulphate 200 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg dried ferrous sulphate. For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet
White, sugar coated tablets, marked “APS” on one side and “200/1702” on the reverse or “APS” and “1702” on one side, plain on reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ferrous sulphate tablets are indicated for the treatment and prophylaxis of uncomplicated iron deficiency anaemia.

4.2 Posology and method of administration

Posology:

Each 200 mg ferrous sulphate tablet is equivalent to 65 mg of ferrous iron.

Adults:

Treatment: 400 - 600 mg (two or three tablets) daily in divided doses. In patients with chronic renal failure a higher dose may be necessary.

Prophylaxis: 200 – 400 mg (one or two tablets) daily.

Children: 6 - 12 years of age.

Treatment: 200 mg (one tablet) twice daily.

Prophylaxis: 200 mg (one tablet) daily.

The Elderly:

The usual adult dose, but it should be used with caution where constipation, faecal impaction and colonic perforation are complications of treatment.

During Pregnancy:

Recommended only for use during the second trimester onwards.

Treatment and prophylaxis: 200 - 400 mg (one to two tablets) daily.

Method of administration:
For oral administration.
The tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water. Tablets should be taken before meals or during meals, depending on gastrointestinal tolerance.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
Ferrous sulphate is contra-indicated in patients with haemolytic anaemias, haemosiderosis, haemochromatosis and in patients receiving repeated blood transfusions.

Ferrous sulphate is also contra-indicated in regional enteritis, ulcerative colitis and active peptic ulcer.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase- isomaltase insufficiency should not take this medicine

4.4 Special warnings and precautions for use

Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

Patients post-gastrectomy have poor absorption of iron.

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

Care is advised in patients with intestinal strictures and diverticula.

Duration of treatment should generally not exceed 3 months after correction of anaemia.

Co-existing deficiency of vitamin B_{12} or folic acid should be ruled out since combined deficiencies produce microcytic blood film.

Iron deficiency in a male patient warrants careful investigation to determine its cause which then forms the basis of primary treatment.

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 products and other forms of interaction

Iron and tetracyclines interfere with absorption of each other.

Absorption of iron is impaired by penicillamine, antacids, neomycin, cholestyramine, tea, eggs or milk.

Absorption of ciprofloxacin, levofloxacin, norfloxacin and ofloxacin is reduced by oral iron.

Oral iron can reduce the absorption of bisphosphonates.

Absorption of entacapone and levodopa may be reduced by oral iron.

Concomitant administration of zinc and oral iron can reduce the levels of both drugs.

The hypotensive effect of methyldopa may be reduced by oral iron.

The absorption of oral iron can be reduced with concomitant administration of trientine.

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

Concurrent administration of iron salts and allopurinol is not recommended as allopurinol may possibly interfere with the hepatic mobilisation of iron.

Iron retards the absorption of fluoride by forming complexes of low solubility in the gastrointestinal tract.

The effects of penicillamine may be reduced by iron.

4.6. Pregnancy and lactation

Administration of drugs during the first trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained and should not be administered unless clearly indicated. For the remainder of the pregnancy, iron therapy may be indicated but only on advice of a physician.

4.7. Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

List of adverse reactions

The frequencies of adverse events are ranked according to the following: very common (≥1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data)

The following side effects have been observed associated with ferrous sulphate therapy:

Post-marketing: The following ADRs have been reported during post-marketing surveillance. The frequency of these reactions is considered not known (cannot be estimated from the available data).

Gastrointestinal disorders:

Anorexia, nausea, vomiting, gastrointestinal discomfort, constipation, diarrhoea, dark stools and allergic reactions. These side effects may be minimised by taking the tablets after food.

Not Known: mouth ulceration*

* in the context of incorrect administration, when the tablets are chewed, sucked or kept in mouth. Elderly patients and patients with deglutition disorders may also be at risk of oesophageal lesions or of bronchial necrosis, in case of false route.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75 mg/Kg of elemental iron is considered extremely dangerous in young children.

Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse.
Hyperglycaemia and metabolic acidosis may also occur. However, if overdosage is suspected, treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24 to 48 hours, manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, diffuse vascular congestion, coagulopathy and/or convulsions. In many cases full recovery may be complicated by long term effects such as hepatic necrosis, toxic encephalitis, CNS damage and pyloric stenosis.

The following steps are recommended to minimise or prevent further absorption of the medication:
Children

An emetic such as syrup of Ipecac should be administered. Emesis should be followed by gastric lavage with desferrioxamine solution (2 g/l). This should then be followed by the installation of desferrioxamine 5 g in 50-100 ml of water, to be retained in the stomach. Inducing diarrhoea in children may be dangerous and should not be undertaken in young children. The patient should be watched very closely to detect possible aspiration of vomitus, maintain suction apparatus and standby emergency oxygen in case of need.

In more severe cases i.e. in the presence of shock and/or coma with high serum iron levels (serum iron > 90 μMol/l) immediate supportive measures plus intravenous infusion of desferrioxamine should be instituted. Desferrioxamine 15 mg/Kg bodyweight should be administered every hour by slow intravenous infusion to a maximum of 80 mg/Kg in 24 hours.

Warning: Hypotension may occur if the infusion rate is too rapid.
In less severe cases the administration of intramuscular desferrioxamine 1 g every four to six hours is recommended.

Serum iron levels should be monitored throughout.

Adults
An emetic should be administered and gastric lavage may be necessary to remove drug already released into the stomach, this should be done by using a desferrioxamine solution (2 g/l).

Following gastric emptying, desferrioxamine 5 g in 50-100 ml water should be introduced into the stomach. The patient should be watched very closely to detect possible aspiration of vomitus, maintain suction apparatus and standby emergency oxygen in case of need. A drink of mannitol or sorbitol should be given to induce small bowel emptying.

In more severe cases i.e. in the presence of shock and/or coma with high serum iron levels (serum iron > 142 μMol/l) immediate supportive measures plus intravenous infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/Kg per hour by slow intravenous infusion to a maximum 80 mg/Kg in 24 hours.

Warning: Hypotension may occur if the infusion rate is too rapid.
In less severe cases intramuscular desferrioxamine 50 mg/Kg up to a maximum dose of 4 g should be given.

Serum iron levels should be monitored throughout.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC Code: BO3A A07 Iron bivalent, oral preparations.

Iron from ferrous sulphate is absorbed in the small intestine by an active process. In the intestinal cell it is combined with apoferritin to form ferritin which is a storage compound. Aggregated ferritin may be referred to as haemosiderin and constitutes about 1/3 of normal iron stores.

In the plasma, iron is carried in the ferric form and is bound to a specific protein, transferrin. About 80% of the iron in plasma is delivered to the erythroid marrow to form haemoglobin in the developing erythrocytes.

Iron is a haematinic essential for satisfactory erythropoiesis during haemoglobin synthesis.

5.2. Pharmacokinetic properties

Ferrous sulphate is incompletely and irregularly absorbed from the gastrointestinal tract. Absorption of iron is a complicated process. Iron is absorbed throughout the gastrointestinal tract but it is greater in the duodenum and proximal jejunum.

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.

Very little iron is lost from the body. In normal man about 1 mg per day is lost. Two thirds of this is excreted from the gastrointestinal tract as extravasated red cells, iron in bile and iron in exfoliated mucosal cells. The rest is accounted for by small amounts in urine and in desquamated cells. In the female additional losses occur due to menstruation and the average extra loss is about 0.5 mg but may be as much as 2 mg per day. There is also a greater requirement for iron during pregnancy. Transfer of iron across the placenta is an active process. Excess iron ingested is stored as ferritin and haemosiderin.

5.3. Preclinical safety data

Preclinical information has not been included because the safety profile of ferrous sulphate has been established after many years of clinical use. Please refer to section 4.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Tablets contain:
Microcrystalline Cellulose (E460)
Starch
Stearic Acid
Povidone (E1201)
Talc (E553b)

Tablet coating:
Sucrose
Talc (E553b)
Titanium Dioxide (E171)
Gelatin
Opaglos

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Keep tightly closed. Store in a dry place below 25°C.

6.5. Nature and contents of container

Amber glass bottles or, HDPE or polypropylene containers with caps or child resistant closures in packs of 50, 100 or 1000 tablets.

Not all pack sizes may be marketed.

6.6. Instruction for use/handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited
Eastbourne
BN22 9AG
England

Trading address:
Leeds LS27 0JG
England

8. MARKETING AUTHORISATION NUMBER

PL 00289/0264

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/10/2004

10 DATE OF REVISION OF THE TEXT

08/02/2017