SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferrous Sulfate Tablets 200mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains: ferrous sulfate 200mg equivalent to 65 mg ferrous iron.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Iron-deficiency anaemia

4.2 Posology and method of administration

Adults:
Prophylactic dose - one tablet daily.
Therapeutic dose - one tablet 2-3 times daily.

Elderly:
The usual adult dose can be administered (see section 4.4).

Children 6-12 years:
Treatment:
Children weighing > 22kg – one tablet daily.
Children weighing > 44kg – one tablet twice daily.
Children weighing > 66kg – one tablet three times daily.
A liquid preparation maybe more appropriate for children.

Children under 6 years or weighing less than 22kg:
This medicine is not recommended.

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 any ingredients in the formulation; patients receiving repeated blood transfusions; concomitant parenteral iron; haemochromatosis and other iron overload syndromes.

4.4 Special warnings and precautions for use

Administer with caution in patients with haemolytic anaemia, haemoglobinopathies, iron storage or iron absorption diseases, existing gastrointestinal disease.

The label will state
'Important warning: Contains iron. Keep out of the sight and reach 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.

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 medicinal product.

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

Aspiration of ferrous sulfate tablets can cause necrosis of the bronchial mucosa which may result in coughing, haemoptysis, bronchostenosis and/or pulmonary infection (even if aspiration happened days to months before these symptoms occurred). Elderly patients and patients who have difficulties swallowing should only be treated with iron sulfate tablets after a careful evaluation of the individual patient's risk of aspiration. Alternative formulations should be considered. Patients should seek medical attention in case of suspected aspiration.

Excipients
Ferrous Sulfate tablets contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration with tetracyclines may impair absorption of both agents. The absorption of ciprofloxacin, norfloxacin and ofloxacin and bisphosphonates is reduced by oral iron. Cholestyramine may bind iron to the gastrointestinal tract, thus preventing its absorption. The absorption of iron salts is also decreased in the presence of antacids, preparations containing zinc, calcium, phosphorus, trientine, or when taken with tea, coffee, milk, eggs and whole grains. Iron supplements should not be taken within one hour before or two hours after ingestion of these products. Iron salts may reduce the bioavailability of methyldopa. The absorption of levodopa and penicillamine may be reduced. Absorption of iron salts is enhanced by ascorbic acid and meat.
Dimercaprol: Avoid the concomitant use of iron with dimercaprol.

Thyroid hormones: Oral iron reduces the absorption of levothyroxine (thyroxine) thus should be given at least 2 hours apart.

4.6 Pregnancy and lactation

Ferrous salts are recommended for use in pregnancy and lactation, and no contraindications to such are known.

4.7 Effects on ability to drive and use machines

None known.

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.

Large doses may produce gastro-intestinal irritation, nausea, vomiting, epigastric pain, diarrhoea.

Constipation may be caused by continual administration, particularly in older patients, and may lead to faecal impaction.

Iron supplementation may cause the blackening of stool.

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

Bronchial stenosis (see section 4.4)

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 (www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store).

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:

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.

4.9 Overdose

Acute iron overdosage can be divided into four stages. In the first phase, which occurs up to 6 hours after oral ingestion, gastrointestinal toxicity, notably vomiting and diarrhoea, predominates. Other effects may include cardiovascular disorders such as hypotension and tachycardia, metabolic changes including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma. Patients with only mild to moderate poisoning do not generally pass this first phase. The second phase may occur at 6-24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation. In the third phase gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, hepatic necrosis and jaundice, hypoglycaemia, coagulation disorders, oliguria or renal failure, and pulmonary oedema. The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage. Overdosage of ferrous salts is particularly dangerous to young children. Treatment consists of gastric lavage followed by the introduction of 5g desferrioxamine into the stomach. Serum iron levels should be monitored and in severe cases iv desferrioxamine should be given together with supportive and symptomatic measures as required. Gastric lavage with 5% sodium bicarbonate and saline cathartics (*e.g.* sodium sulfate 30g for adults); milk and eggs with 5g bismuth carbonate every hour as demulcents. Blood or plasma transfusion for shock, oxygen for respiratory embarrassment. Chelating agents (*e.g.* disodium calcium edetate) may be tried (500mg/500ml by continuous iv infusion). Dimercaprol should not be used since it forms a toxic complex with iron. Desferrioxamine is a specific iron chelating agent and severe acute

poisoning in infants should always be treated with desferrioxamine at a dose of 90mg/kg im followed by 15mg/kg per hour iv until the serum iron is within the plasma binding capacity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC CODE: B03A A07

Ferrous sulfate is used in the treatment of iron deficiency anaemias.

Iron preparations have no intrinsic therapeutic activity except as a nutrient source: their use without evidence of iron deficiency, or reasonable expectation of its occurrence, is to be deprecated. Excessive iron is toxic and haemochromatosis can result from chronic injection of iron preparations used as tonics, especially in individuals with undiagnosed blood disorders. Patients with chronic anaemia are particularly at risk from iron storage disease. Recently a severe iron overload myopathy has been described in patients given prophylactic iron indiscriminately while receiving haemodialysis. Genetic factors probably contribute to the risk of an iron storage disease.

It should be clear that although iron deficiency is easily treated, its detection does not constitute a complete diagnosis. Every effort should be made to determine why the patient has a state of negative iron balance. Attention should be given to hidden sources of haemorrhage (which may indicate serious urinary or gastrointestinal conditions) and also the possibility of malabsorption of iron caused by latent disease of the small intestine.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and the jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids and is more readily affected when the iron is in the ferrous state or is part of the haem complex (haem-iron unit). Absorption is also increased in conditions of iron deficiency or in the fasting state but decreased if the body stores are overloaded. Around 5-15% of the iron ingested in food is absorbed. **Following absorption,** the majority of iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin. The remainder is stored within ferritin or haemosiderin or is incorporated into myoglobin with smaller amounts occurring in haem-containing enzymes or in plasma bound to transferrin. Only very small amounts are excreted as the body reabsorbs the iron after the haemoglobin has broken down.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Stearic acid EP
Magnesium Stearate EP
Sodium Lauryl Sulfate EP
Microcrystalline cellulose EP
Croscarmellose Sodium EP

Coating:
Opaglos HSE
Titanium Dioxide EP
Sucrose EP
Calcium carbonate light EP
Acacia SD EP
Purified talc EP
Mastercote White SP0962 (HSE)
Wax Polish (HSE)

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a cool dry place

6.5 Nature and contents of container

Tamper evident containers made of polypropylene or polyethylene, with polyethylene closures.

Pack sizes: 28, 50, 100, 250, 500 and 1,000.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 04416/0216

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 January 1993 / 22 May 2008

10 DATE OF REVISION OF THE TEXT

27/07/2020