NALIS® FERROUS SULPHATE 200 mg TABLETS

SUBMITTED BY

NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE DRUG PRODUCT

Name of product: NALIS® FERROUS SULPHATE 200 mg TABLETS (Equivalent to 65 mg of elemental iron)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Red-coloured, circular, flat and coated tablets.

Each tablet contains:

Ferrous Sulphate 200 mg

Excipients……..**q.s**

Excipients with known effect
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nalis® Ferrous Sulphate 200 mg tablet is indicated in iron deficiency anaemia due to malabsorption of iron from the diet and parasitic infestation. It is indicated in the prophylaxis of iron deficiency anaemia in pregnancy, breast-feeding, and menstruation and after child birth. It could also be used after excessive loss of blood due to accident or post-operation.

4.2 Posology and method of administration

Posology

Adult and children over 12 years: iron deficiency anaemia: one tablet, 3 times daily,

Prophylaxis: one tablet, once 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 Contradindications

Nalis® Ferrous Sulphate 200 mg Tablets should not be administered to patients with haemolytic anaemia, peptic ulcer enteritis or ulcerative colitis and hypersensitivity to iron salts.

4.4 Special warnings and precautions for use

Some post-gastrectomy patients show poor absorption of iron.
Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer, and inflammatory bowel disease, including regional enteritis and ulcerative colitis. Care should be taken in patients with intestinal strictures or diverticulae. Duration of treatment should generally not exceed 3 months after correction of anaemia.
Dental caries is a definite risk following long-term treatment with this product.
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 suffering from iron overload are particularly susceptible to infection. Treatment of iron overload should be with caution.
Co-existing deficiency of vitamin B12 or folic acid should be ruled out since combined deficiency produces microcytic blood film.
Aspiration of iron 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.
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.

4.5 Interaction with other drug products and other forms of interaction

Antibacterials: Iron and tetracyclines reduce the absorption of each other when administered concomitantly. Administration of iron preparations and tetracyclines should be separated by 2 to 3 hours.
Iron may reduce the absorption of quinolones. Administration of iron preparations and quinolones should be separated by at least 2 hours.
The absorption of ciprofloxacin, levofloxacin, norfloxacin and ofloxacin may be reduced by oral iron.
Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.
Antacids and mineral supplements: Compounds containing calcium, magnesium (including antacids and mineral supplements), bicarbonates, carbonates, oxalates or phosphates may impair the absorption of iron. Administration of iron preparations with such compounds should be separated by at least 2 hours.
Bisphosphonates: The absorption of bisphosphonates is reduced when taken concurrently with iron preparations. Administration should be separated by at least 2 hours.
Colestyramine: Absorption of iron is impaired by colestyramine.
Dimercaprol: Concomitant administration of oral iron preparations and dimercaprol should be avoided.
Dopaminergics: Oral iron preparations may reduce the absorption of dopaminergics such as co-careldopa, entacapone and levodopa.
Food Products: Absorption of iron is impaired by tea, eggs or milk.
Methyldopa: Oral iron preparations may antagonise the antihypertensive effect of methyldopa.
Mycophenolate mofetil: Oral iron preparations significantly reduce the absorption of mycophenolate mofetil.
Penicillamine: Oral iron preparations can reduce the absorption of penicillamine. Also the absorption of iron is impaired by penicillamine.
Thyroid hormone: Ferrous sulphate reduces the absorption of levothyroxine and so should be taken at least 2 hours apart.
Trientine: the absorption of oral iron preparations is reduced by trientine. Administration should be separated by at least 2 hours.
Zinc: Iron preparations and zinc preparations can reduce the absorption of each other.

4.6 Fertility, pregnancy and lactation

Pregnancy
Use of any drug during the first trimester of pregnancy should be avoided if possible. Thus administration of iron during the first trimester however requires evidence of iron deficiency. Prophylaxis of iron deficiency during the remainder of pregnancy is justified.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Immune system disorders:
Allergic reactions have been reported
Gastro-intestinal disorders : abdominal pain, nausea and vomiting (these are usually dose related), constipation, diarrhoea and dark stools.
Contact irritation can occur with ferrous sulphate tablets resulting in erosion or ulceration, particularly if they become lodged in the upper gastrointestinal tract.
Gastro-intestinal, including discomfort and anorexia.

Post-marketing: The following ADR has been reported during post-marketing surveillance. The frequency of this reaction is considered not known (cannot be estimated from the available data).
Gastro-intestinal 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, of bronchial necrosis or bronchial stenosis (see section 4.4), 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 to the regulatory bodies such as NAFDAC.

4.9 Overdose

Symptoms:
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.

Management:
Treatment consists of gastric lavage followed by the introduction of 5 g desferrioxamine into the stomach. Serum iron levels should be monitored and in severe cases i.v. 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 30 g for adults); milk and eggs with 5 g 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 (500 mg/500 ml 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 90 mg/kg im followed by 15 mg/kg per hour i.v. until the serum iron is within the plasma binding capacity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ferrous sulfate contains iron.
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.

5.2 Pharmacokinetic 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 the through mucosal cell directly into the blood stream where it is immediately attached to the transferrin.

5.3 Preclinical safety data

Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch B.P

Calcium Carbonate B.P

Microcrystalline Cellulose B.P

Povidone B.P

Magnesium Stearate B.P

Talc Powder B.P

Sodium Starch Glycollate B.P

Sodium Methyl Paraben B.P

Sodium Propyl Paraben B.P

Acacia Gum B.P

Gelatin B.P

Ponceau 4R B.P

Tween 80 B.P

6.2 Incompatibilities

Refer to section 4.5

6.3 Shelf life

Two years

6.4 Special precautions for storage

Keep container tightly closed, do not store above 25 °C.

6.5 Nature and contents of container

1,000 tablets packed in cellophane nylon and then packed in airtight, white, plastic jars containing leaflet and silica gel dessicant. 48 of such jars are finally packed into corrugated shippers.

6.6 Special precautions for disposal of used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

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9. NAFDAC REGISTRATION NUMBER(S):

A11-100456