National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Alben Ferrous Sulphate + Folic Acid Capsule 200mg/1mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsules contains:

Ferrous Sulphate……..200mg

Folic Acid……..……1mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Hard gelatin capsule.
- Dark red capsule.

4. Clinical Particulars

4.1 Therapeutic indications

- It is a haematinic preparation for prophylaxis and treatment of iron and folic acid deficiency during pregnancy.

4.2 Posology and method of administration

- **Posology**

  - Adults only: One capsule a day.

    Some pregnant patients may need a higher dose of iron because of dietary or other factors.

  - Children and elderly: Not recommended.

- **Method of administration**

  Capsule for oral administration.

  It is recommended that the capsules be taken with fluid, preferably with or after food.

4.3 Contraindications

Alben Ferrous sulphate + folic acid capsules are contraindicated in patients with pernicious anaemia and in those who have a history of hypersensitivity to folic acid or any other component of the preparation.

4.4 Special warnings and precaution for use

In patients who have anaemia, the cause and the nature of the anaemia must be established before using the preparation. Alben Ferrous sulphate + folic acid capsule may occasionally cause gastro-intestinal irritation and abdominal pain with nausea and vomiting.

4.5 Interactions 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

Pregnancy

There are no known hazards to the use of folic acid in pregnancy, supplements of folic acid are often beneficial. Non-drug - induced folic acid deficiency, or abnormal folate metabolism, is related to the occurrence of birth defects and some neural tube defects. Interference with folic acid metabolism or folate deficiency induced by drugs such as anticonvulsants and some antineoplastics early in pregnancy results in congenital anomalies. Lack of the vitamin or its metabolites may also be responsible for some cases of spontaneous abortion and intrauterine growth retardation.

Lactation

Folic acid is actively excreted in human breast milk. Accumulation of folate in milk takes precedence over maternal folate needs. Levels of folic acid are relatively low in colostrum but as lactation proceeds, concentrations of the vitamin rise. No adverse effects have been observed in breast fed infants whose mothers were receiving folic acid.

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 gastrointestinal 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.

Alben Ferrous sulphate + folic acid capsules are designed to reduce the possibility of gastrointestinal irritation.
Hypersensitivity reactions have been reported. These range from rashes, sometimes severe, to anaphylaxis.

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 capsules 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

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 characterized by gastrointestinal obstruction and possibly late hepatic damage.
The sustained- release 'spansule' capsule presentation of ferrous sulfate may delay excessive absorption of iron and allow more time for initiation of appropriate countermeasures.
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 B03AD03 (Iron in combination with folic acid)

The product is an oral iron and folic acid preparation for the prophylaxis and treatment of iron deficiency and prophylaxis of folic acid deficiency during pregnancy.

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

The product is formulated to avoid iron release in the stomach where gastric irritation may be caused.
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.
The folic acid is available immediately.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

- Lactose
- Aerosil
- Magnesium Stearate

6.2 Incompatibilities

- Not Applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

- Store in a cool dry place below 30°C protected from light and out of reach of children.
- Store in the original package.

6.5 Nature and contents of container<and special equipment for use, administration or implantation>

- Blister strips: Aluminium foils/PVC contained in cardboard cartons.
- PVC Aluminium foils

➢ **Pack sizes:**

- 10 capsule blisters and 3 such blister in a monocarton.

6.6 Special precautions for disposal<and other handling>

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Applicant/Manufacturer

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