Summary of Product Characteristics

1. Name of the Finished Pharmaceutical Product:

1.1 Product Name : **FEROFLIC CAPSULE** (Capsule of Ferrous Sulphate with Folic Acid)

1.2 Strength: 150 mg & 500 mcg

1.3 Pharmaceutical Form : Hard gelatin capsule

2. Qualitative and Quantitative Composition:

Each capsule contains:

Dried Ferrous Sulphate	BP	150 mg (In Sustained Release form)
Folic Acid	BP	500 mcg

(Appropriate Overages of vitamins added to compensate loss during storage) Full list of Excipients given in section 6.1

3. Pharmaceutical Form

"Hard gelatin capsule

Pink transparent /clear transparent, size "2", hard gelatin capsules filled with dark brown, yellow and white pellets

4. Clinical Particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults only: One capsule a day during pregnancy. Some pregnant patients may need a higher dose of iron because of dietary or other factors.

Children and elderly: Not recommended.

Method of Administration:

Oral Administration

The capsules should not be sucked, chewed or kept in the mouth, but swallowed whole with water. Capsules should be taken before meals or during meals, depending on gastrointestinal tolerance.

4.3 Contraindication

This product is contraindicated in the following situations:

- Hypersensitivity to the active substance or any of the other ingredients in this formulation
- Patients receiving repeated blood transfusions; concomitant parenteral iron; haemochromatosis and other iron overload syndromes.

4.4 Special warnings and special precautions for use

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

This product contains sucrose. 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.

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

Failure to respond to treatment may indicate other causes of anaemia and should be further investigated.

The folic acid content is unlikely to mask pernicious anaemia should this condition be present; pregnancy during pernicious anaemia is very rare.

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

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.

Breast-feeding: 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.

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

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.

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 characterized 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.

This 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 Pharmacodynamics properties

Pharmacotherapeutic group : Iron in combination with folic acid

ATC code : B03AD03

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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

N.P. Seeds
Povidone
Sucrose
Purified Talc
Methacrylic Acid
Copolymer Cetyl Alcohol
Diethyl Phthalate
Colour Ponceau 4R
Titanium Dioxide
Ponceau 4R Lake
Isopropyl Alcohol
Purified Water
Empty Hard Gelatin Capsule

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Protect from light and moisture. Keep out of the reach of children.

6.5 Nature and contents of container

10 x 10 Capsules in Normal Blister Pack

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. Marketing Authorization Holder

ZIM Laboratories Limited B-21/22,
MIDC Area, Kalmeshwar,
Nagpur 441 501,
Maharashtra State,
India

8. MARKETING AUTHORISATION NUMBERS

05673/07695/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/02/2021

10. DATE OF REVISION OF THE TEXT

17/07/2023