Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Iron Folate (Ferrous Sulfate 200 mg + Folic Acid 0.4 mg Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Dried Ferrous Sulphate BP 200 mg

eq. to Ferrous Iron 65 mg

Folic Acid BP 0.4 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film Coated Tablets

Red coloured, round, biconvex, film coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of iron-deficiency anaemia. For the treatment of folate deficient megaloblastic anaemia due to malnutrition, malabsorption syndromes and increased utilisation as in pregnancy. For the prophylaxis of drug induced folate deficiency e.g. caused by administration of phenytoin, phenobarbital and primidone. For the prophylaxis against folate deficiency in chronic haemolytic states or in renal dialysis. For the prevention of neural tube defects for women planning a pregnancy and known to be at risk

4.2 Posology and Method of administration

Route of administration: Oral

The usual recommended dose for non-pregnant and pregnant is one tablet once a day. It has to be taken on an empty stomach, at least 1 hour before or 2 hours after a meal.

4.3 Contraindications

- Ferrous Sulphate and Folic Acid are contraindicated in patients with a hypersensitivity to any of the ingredients in the formulation.
- Iron preparations are contraindicated in patients with haemochromatosis and haemosiderosis. Iron is contraindicated in patients receiving repeated blood transfusions.

- Oral iron preparations are contraindicated when used concomitantly with parental iron therapy.
- Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency.
- Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.

4.4 Special warnings and precautions for use

- Ferrous Sulphate tablets should be kept out of children reach. Acute iron poisoning occur rarely in adults; however it could happen if children swallow this medication.
- 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.
- Before starting treatment, it is important to exclude any underlying cause of the anaemia (e.g. gastric erosion, colonic carcinoma).
- Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose – galactose mal absorption should not take this medicine
- Caution should be exercised when administering Folic Acid to patients who may have folate dependent tumours.

4.5 Interaction with other medicinal products and other forms of interact.

- Ferrous Sulphate reduces absorption of tetracyclines, ciprofloxacin, levofloxacin, norfloxacin, ofloxacin, bisphosphates, zinc salts and penicillamine. It may also reduce the absorption of entacapone and levodopa.
- The absorbtion of ferrous sulphate is reduced by magnesium trisilicate, trientine, zinc and tetracyclines.
- Ferrous Sulphate also reduces the hypotensive effect of methyldopa.
- If folic acid supplements are given to treat folate deficiency, which can be caused by the use of antiepileptics (phenytoin, phenobarbital and primidone), the serum antiepileptic levels may fall, leading to decreased seizure control in some patients.
- Chloramphenicol and co-trimoxazole may interfere with folate metabolism.
- Sulfasalazine can reduce the absorption of folic acid.
- Folic acid may interfere with the toxic and therapeutic effects of methotrexate.

4.6 Fertility, Pregnancy and Lactation

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

There are no known hazards to the use of folic acid in pregnancy; supplements of folic acid are often beneficial. No adverse effects have been observed in breast fed infants whose mothers were receiving folic acid.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

- Large doses may produce gastro-intestinal irritation, nausea, vomiting, epigastric pain, diarrhoea abdominal distension and flatulence and anorexia

- Constipation may be caused by continual administration; iron supplementation may cause the blackening of stool.
- Hypersensitivity reactions have been reported. These ranges from rashes, sometimes severe, to anaphylaxis, erythema, pruritus, urticaria and dyspnoea.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Overdose symptoms may include nausea, severe stomach pain, bloody diarrhoea, coughing up blood or vomit that looks like coffee grounds, shallow breathing, weak and rapid pulse, pale skin, blue lips, and seizure (convulsions). Seek emergency medical attention if overdosage of this medicine occurs, or if anyone has accidentally swallowed it. An overdose of iron can be fatal, especially in a young child.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Mechanism of action

Ferrous Sulphate:

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

Folic Acid:

Folic acid is a member of the vitamin B group. It is used in the treatment and prevention of folate deficiency states.

5.2 Pharmacokinetic properties

Ferrous Sulphate:

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.

Folic Acid:

Absorption: Folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestine to form 5-methyltetrahydrofolate (5MTHF). Folic acid given therapeutically

enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases.

Distribution: Via portal circulation. 5MTHF from naturally occurring folate is extensively plasma bound. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. Folate is distributed into breast milk.

Metabolism: Therapeutically given folic acid is converted into the metabolically active form 5MTHF in the plasma and liver. There is an enterohepatic circulation for folate.

Elimination: Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine. Folic acid is removed by haemodialysis.

5.3 Preclinical safety data

Not Applicable

6.0 Pharmaceutical particulars

6.1 List of excipients

Maize Starch, Sodium Lauryl Sulpahte, Liquid Glucose, Lactose, Povidone K-30, Ethylcellulose, Purified Talc, Magnesium Stearate, Guar, Sodium lauryl Sulfate, Sodium Starch Glycolate (Type A), Croscarmellose Sodium, Colloidal Anhydrous Silica, Isopropyl Alcohol, Purified Water, Sheffcoat PVA (red)5Y00044/Instacoat-EHP (Red) A10D00001.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C in a dry place. Protect from light.

6.5 Nature and contents of container

10 Tablets packed in Blister Aluminium foil with Amber PVdC film and such 10 blisters packed in a unit carton along with package insert.

6.6 Special precautions for disposal and other handling

None reported

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 04628/5455/REN/2017

9. Date of first authorisation/renewal of the authorisation

Sep 16, 2019

10. Date of revision of the text

August 2023