1. Name of the medicinal product
Emzor folic acid 5mg Tablets

2. Qualitative and quantitative composition
Emzor folic acid5mg

Excipients with known effect

Lactose

For the full list of excipients see section 6.1.

3. Pharmaceutical form
Tablet

Plain yellow, biconvex tablet with break-line on one face and CP on the reverse.

4. Clinical particulars
4.1 Therapeutic indications
Emzor folic acidis indicated for the treatment of megaloblastic anaemia due to Emzor folic aciddeficiency. It is also used for prophylaxis in chronic haemolytic states, in renal dialysis, and in drug induced folate deficiency.

Emzor folic acidis used for the prevention of recurrence of neural tube defects.

4.2 Posology and method of administration
Posology

Adults

In folate deficient megaloblastic anaemia:

5mg daily for 4 months

Up to 15mg daily may be necessary for malabsorption states

For prophylaxis in chronic haemolytic states or in renal dialysis:

5mg every 1-7 days depending on diet and underlying disease.

In drug induced folate deficiency:

5mg daily

Prevention of recurrence of neural tube defects

5mg daily starting before conception and continuing throughout the first trimester of pregnancy is recommended.

Paediatric population

Over 1 year : As adult dose

Up to 1 year: 500µg/kg daily

Method of administration

The tablets are for oral use.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with malignant disease, unless megaloblastic anaemia due to Emzor folic aciddeficiency.

4.4 Special warnings and precautions for use
Emzor folic acidshould not be administered for treatment of pernicious anaemia or undiagnosed megaloblastic anaemia without sufficient amounts of cyanocobalamin (vitamin B_{12}) as Emzor folic acidalone will not prevent and may precipitate development of subacute combined degeneration of the spinal cord. Therefore a full clinical diagnosis should be made before initiating treatment.

Folate should not be routinely used in patients receiving coronary stents.

Caution should be exercised when administering Emzor folic acidto patients who may have folate dependent tumours.

Emzor folic acidis removed by haemodialysis.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction
Absorption of Emzor folic acidmay be reduced by sulfasalazine.

Concurrent administration with cholestyramine may interfere with Emzor folic acidabsorption. Patients on prolonged cholestyramine therapy should take Emzor folic acid1 hour before or 4 to 6 hours after receiving cholestyramine.

Antibiotics may interfere with the microbiological assay for serum and erythrocyte Emzor folic acidconcentrations and may cause falsely low results.

Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of Emzor folic acidand this may be serious in patients with megaloblastic anaemia.

Serum levels of anticonvulsant drugs (phenytoin, phenobarbital, primidone) may be reduced by administration of folate and therefore patients should be carefully monitored by the physician and the anticonvulsant drug dose adjusted as necessary.

Fluorouracil toxicity may occur in patients taking Emzor folic acidand this combination should be avoided.

Edible clay or antacids containing aluminium or magnesium may reduce Emzor folic acidabsorption. Patients should be advised to take antacids at least two hours after administration of folic acid.

Emzor folic acidmay reduce intestinal absorption of zinc (of particular importance in pregnancy).

4.6 Fertility, pregnancy and lactation
Pregnancy

Emzor folic aciddeficiency during pregnancy may lead to the appearance of foetal malformations. Imbalance in folate requiring trophoblast cells may also lead to detachment of the placenta.

Very high doses of Emzor folic acidhave been shown to cause foetal abnormalities in rats; however, harmful effects in the human foetus, mother or the pregnancy have not been reported following ingestion of folic acid.

Breastfeeding

Emzor folic acidis excreted in breast milk.

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 known

4.8 Undesirable effects
Emzor folic acidis generally well tolerated although the following side effects have been reported:

Blood and lymphatic system disorders:

Emzor folic acidmay worsen the symptoms of co-existing vitamin B_{12} deficiency and should never be used to treat anaemia without a full investigation of the cause.

Immune system disorders:

Rare: Allergic reactions, comprising erythema, rash, pruritus, urticarial, dyspnoea, and anaphylactic reactions (including shock).

Gastrointestinal disorder:

Abdominal distension, flatulence, anorexia and nausea.

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

4.9 Overdose
No cases of acute overdosage appear to have been reported, but even extremely high doses are unlikely to cause harm to patients. No special procedures or antidote are likely to be needed.

5. Pharmacological properties
5.1 Pharmacodynamic properties
The mucosa of the duodenum and upper part of the jejunum are rich in dihydrofolate reductase, where folates and Emzor folic acidare absorbed. Once absorbed, Emzor folic acidis rapidly reduced and then methylated to form tetrahydroEmzor folic acidderivatives which are rapidly transported to the tissues.

5.2 Pharmacokinetic properties
Emzor folic acidis readily absorbed following oral dosage, and is extensively bound to plasma proteins.

5.3 Preclinical safety data
Toxicity studies in animals (rats and rabbits) have shown that massive doses (100mg/kg upwards) produce precipitation of folate crystals in renal tubules, particularly proximal tubules and ascending limb of the loop of Henle. Tubular necrosis is followed by recovery.

6. Pharmaceutical particulars

6.1 List of excipients
Lactose

Maize starch

Acacia spray-dried

Magnesium stearate

Stearic acid

6.2 Incompatibilities
None known

6.3 Shelf life
3 years for tablets in polypropylene or polyethylene containers or glass bottles.

3 years for tablets in strip packs of opaque white or clear PVC film and 20µm aluminium foil.

6.4 Special precautions for storage
Store in the original package in order to protect from light

Do not store above 25°C

6.5 Nature and contents of container
Polypropylene or polyethylene containers or glass bottles in pack sizes of 100, 500 or 1000 tablets.

Strip packs of opaque white or clear PVC film and 20µm aluminium foil. Tablets will be packed in multiple strips of 14 tablets resulting in a pack of 28 tablets.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder
Emzor Pharmaceutical Industries Limited
Flowergate Mixed Development Scheme.Km 1 Sagamu/Benin Expressway Sagamu,Ogun State.