SUMMARY PRODUCT CHARACTERISTIC (SPC)

FOLIC ACID

5 mg tablets

1. Name of the medicinal product - FOLIC ACID

2. Qualitative and quantitative composition

Each tablet of *FOLIC ACID, 5 mg* contains:
active ingredient*:* folic acid – 5 mg;
For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablets.
Yellow scored on one side and beveled on both sides cylindrical tablets with a few small darker spots, the end surface of which are flat.

4. Clinical particulars

4.1. Therapeutic indications

FOLIC ACID is indicated for the treatment of megaloblastic anaemia due to folic acid deficiency. It is also used for prophylaxis in chronic haemolytic states, in renal dialysis, and in drug induced folate deficiency.
FOLIC ACID is used for the prevention of recurrence of neural tube defects.

4.2. Posology and method of administration

Adults
In folate deficient megaloblastic anaemia:
5 mg daily for 4 months
Up to 15 mg daily may be necessary for malabsorption states
For prophylaxis in chronic haemolytic states or in renal dialysis:
5 mg every 1-7 days depending on diet and underlying disease.
In drug induced folate deficiency:
5 mg daily

Prevention of recurrence of neural tube defects
5 mg daily starting before conception and continuing throughout the first trimester of pregnancy is recommended.
Children
Over 1 year: As adult dose
Up to 1 year: 500 µg/kg daily
For dosage and administration of children with various weights it should use FOLIC ACID 1 mg tablets too.

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 folic acid deficiency.

Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before longterm folate therapy. Folate given to such patients for 3 month or longer has precipitated cobalamin neuropathy. No harm result from short courses of folate

Folic acid should never be given alone in the treatment of Addisonian pernicious anaemia and other vitamin B12 deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord.

4.4. Special warnings and precautions for use

FOLIC ACID should not be administered for treatment of pernicious anaemia or undiagnosed megaloblastic anaemia without sufficient amounts of cyanocobalamin (vitamin B_{12}) as folic acid alone 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 folic acid to patients who may have folate dependent tumours.

FOLIC ACID is 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 folic acid may be reduced by sulfasalazine.

Concurrent administration with cholestyramine may interfere with folic acid absorption. Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine.

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

Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and 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 folic acid and this combination should be avoided.

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

Folic acid may reduce intestinal absorption of zinc (of particular importance in pregnancy).

4.6. Fertility, pregnancy and lactation

Pregnancy

FOLIC ACID deficiency 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 folic acid have 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

Folic acid is 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

FOLIC ACID is generally well tolerated although the following side effects have been reported:

Blood and lymphatic system disorders:

FOLIC ACID may 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 online to the ″Center of Drug and Medical Technologies Expertise″ SNPO of MoH of RA via www.pharm.am or call the hotline numbers: (+374 10) 20 05 05 and (+374 96) 22 05 05.

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

Pharmacotherapeutic group: Folic acid and derivatives, Folic acid

ATC code: B03BB01

The mucosa of the duodenum and upper part of the jejunum are rich in dihydrofolate reductase, where folates and folic acid are absorbed. Once absorbed, folic acid is rapidly reduced and then methylated to form tetrahydrofolic acid derivatives which are rapidly transported to the tissues.

5.2. Pharmacokinetic properties

FOLIC ACID is 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 (100 mg/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

microcrystalline cellulose
lactose monohydrate
povidone
sodium starch glycolate
magnesium stearate.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.
Do not use this medicine after the expiry date.

6.4. Special precautions for storage

Store at a temperature not exceeding 25°C.

6.5. Nature and contents of container

2 blisters (1 blister packet with 24 tablets) (48 tablets) with leaflet in the cardboard box.
5 blisters (1 blister packet with 10 tablets) (50 tablets) with leaflet in the cardboard box.

6.6. Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

"ARPIMED" LLC
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8. Date of first authorisation/renewal of the authorisation

23.11.2010 (date of first authorisation)

9. Date of revision of the text