NEW ZEALAND DATA SHEET

FOLIC ACID MYLAN

1. Product Name

FOLIC ACID MYLAN, 5 mg, tablet.

2. Qualitative and Quantitative Composition

Each tablet contains 5 mg of folic acid.

Excipient(s) with known effect

Lactose

Sulfites may be present in this product in trace amounts.

If you have been told by your doctor that you have an intolerance to some sugars and sulfites, contact your doctor before taking this medicinal product.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

7 mm, flat bevelled edged, yellow tablet with score line on one side and blank on the other.

The score line is not intended for breaking the tablet.

4. Clinical Particulars

4.1 Therapeutic indications

FOLIC ACID MYLAN 5 mg tablets are indicated for the treatment of megaloblastic anaemia when folate deficiency is identified as the exclusive cause. Folate deficiency is a consequence of inadequate dietary intake, malabsorption, or increased utilisation in conditions such as pregnancy, lactation, haemolytic anaemia, hyperthyroidism, exfoliative dermatitis, and chronic infection.

FOLIC ACID MYLAN 5 mg tablets are also indicated for prophylaxis of folate deficiency resulting from renal dialysis, pregnancy and lactation when the mother is malnourished, and chronic haemolytic states such as thalassaemia major or sickle-cell anaemia.

4.2 Dose and method of administration

Dose

Approximately 400 micrograms/day of folic acid is considered a suitable average intake. Body stores of folate in healthy people have been reported between 5 to10 mg but could be much higher.

Folate is present, mostly combined with several L(+)-glutamic acid moieties, in many foods, but in particular, liver, kidney, yeast, nuts and leafy green vegetables. Folic acid is readily oxidised to unavailable forms and is easily destroyed during cooking.

Special populations

Paediatric

FOLIC ACID MYLAN 5 mg tablets are not suitable for administration to infants aged under 12 months.

Method of administration

Folic acid should not be added to multivitamin preparations as it may lower concentration of vitamin B_{12} in the blood.

FOLIC ACID MYLAN 5 mg tablets

- **Folate-deficient megaloblastic anaemia:**

  Adults: An initial dosage of 10-20mg folic acid daily for 14 days is recommended or until a haematopoietic response has been obtained. The daily maintenance dose is 2.5 to 10mg.
  FOLIC ACID MYLAN cannot meet all dosing regimens.

  Children: 5 to 15mg daily according to the severity of the deficiency.

- **Prophylaxis of folate deficiency:**
  1 tablet (5 mg) taken daily or weekly may be necessary in chronic haemolytic cases such as thalassaemia major or sickle-cell anaemia, depending on the diet and rate of haemolysis.

- **Expected pregnancy:**
  5 mg taken daily for 4 weeks before conception and during the first trimester of pregnancy for women who are at risk of having a pregnancy affected by neural tube defects.

4.3 Contraindications

Hypersensitivity to folic acid or to any of the excipients listed in section 6.1.

Megaloblastic anaemia resulting from cyanocobalamin (Vitamin B12) deficiency should not be treated with folic acid as the neurological defects of vitamin B12 deficiency will not be alleviated and may become irreversible.

Caution is advised in patients who may have folate-dependant tumours.

4.4 Special warnings and precautions for use

Folic acid should never be administered for the treatment of undiagnosed megaloblastic anaemia without first excluding vitamin B12 deficiency as the cause. The haematopoietic response to folic acid therapy may be misinterpreted as an improvement in the condition of vitamin B12 deficient patients, but irreversible neurological lesions may develop as a consequence of masking the true deficiency state.

Patients receiving concurrent administration of diphenylhydantoin and folic acid should be monitored for possible loss of seizure control.

Folic acid does not correct folate deficiency due to dihydrofolate reductase inhibitors, such as methotrexate. Folinic acid should be used for this purpose.

Folic acid should not be added to multivitamin preparations as it may lower the concentration of vitamin B12 in the blood.

4.5 Interaction with other medicines and other forms of interaction

Folic acid may interact with antacids which contain aluminium or magnesium, antibiotics and cholestyramine, sulphonamides including sulphasalazine and zinc supplements.

Folate depletion is a side effect of folate antagonists such as 5-fluorouracil, methotrexate, trimethoprim, pyrimethamine and sulphonamides. Potentially severe deficiencies may be treated with calcium folinate therapy.

The requirements for folic acid may be increased in patients receiving analgesics, anticonvulsant particularly hydantoin and carbamazepine, oestrogens and oral contraceptives.

Chronic alcoholism decreases the absorption of folic acid. Abstinence from alcohol will partially reverse this effect.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category A.

Folic acid crosses the placenta, however adequate and well controlled studies in humans have shown that therapeutically acceptable doses of folic acid may be safely administered to pregnant women.

Breast-feeding

Folic acid is excreted in breast milk, but problems in humans have not been documented with intake of normal daily requirements.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

FOLIC ACID MYLAN has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Folic acid is generally well tolerated.

Although uncommon, nausea diarrhoea, flatulence and gastro-intestinal disturbances have been associated with folic acid therapy.

Hypersensitivity reactions such as bronchospasm, erythema, fever rash or itching have been reported rarely.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

No reports of over dosage have been reported.

Folic acid has a low acute and chronic toxicity profile. Adults receiving a daily dose of 400 mg for 5 months followed by a daily dose of 10 mg for 5 years did not present any adverse side effects.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antianemic preparations

ATC code: B03BB

Mechanism of action

Folic acid is a member of the vitamin B group and is the substrate for the production of tetrahydrofolate by enzymatic reduction in vivo. Tetrahydrofolate is a coenzyme for various metabolic pathways including purine and pyrimidine nucleotide synthesis, and ultimately DNA synthesis. It is also involved in some amino acid conversions, and in the formation and utilisation of formate. It is involved in the maturation of all rapidly proliferating tissues particularly those of bone marrow and gastrointestinal tract. Folic acid deficiency develops from inadequate dietary intake through malnutrition or malabsorption or may result from increased utilisation in pregnancy or conditions such as haemolytic anaemia. Folate deficiency is also an adverse side effect of chemotherapeutic agents that function as folate antagonists by interfering with folate metabolism.

Conclusive evidence that folic acid therapy when taken as a supplement by women during the periconceptional period significantly reduces the incidence of foetal neural tube defects was established by a multinational, multicentre, controlled clinical study organised by the Medical Research Council in the United Kingdom. In the final report of this study published in 1991, investigators concluded that a daily supplement of folic acid would be beneficial to all women planning a pregnancy. A later randomised controlled clinical study conducted in Hungary established that a daily dose of 0.8 mg folic acid was effective for reducing the incidence of neural tube defects.

5.2 Pharmacokinetic properties

Absorption

Orally administered folic acid is rapidly absorbed mainly from the wall of the proximal small intestine as the 5-methyltetrahydrofolate metabolite. This metabolite is extensively bound to plasma proteins in the portal circulation.

Distribution

Folic acid is rapidly absorbed from normal diets and is widely distributed in body tissues with the liver as the principal storage site. Folate is also distributed in breast milk.

Biotransformation

No data available.

Elimination

There is an enterohepatic circulation for folate; approximately 4 to 5 micrograms is excreted in the urine daily. Urinary levels of excreted folate are a function of dose.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical Particulars

6.1 List of excipients

FOLIC ACID MYLAN tablet also contains

- *Maize starch*
- *Lactose*
- *Crospovidone*
- *Povidone*
- *Magnesium stearate*

Sulfites may be present in this product in trace amounts.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 30°C.

Protect from light.

6.5 Nature and contents of container

White HDPE bottle and a green polypropylene wadded screw cap. Pack-sizes of 100 tablets.

Blue HDPE bottle and a blue polypropylene induction seal screw cap. Pack-sizes of 100 tablets.

Not all pack types may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. Medicines Schedule

Pharmacy Only Medicine

8. Sponsor Details

Mylan New Zealand Ltd
PO Box 11183
Ellerslie
AUCKLAND
Customer Services Freephone: 0800 579 811

Freephone: 0800 168 169

9. Date of First Approval

15 June 2021

10. Date of Revision of the Text

15 June 2021

Summary table of changes

Section	Summary of new information
All	New data sheet