

FOLIC ACID MYLAN

Folic Acid Tablet 5 mg



What is in this leaflet

Please read this leaflet carefully before you start taking FOLIC ACID MYLAN.

This leaflet answers some common questions about FOLIC ACID MYLAN

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FOLIC ACID MYLAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What FOLIC ACID MYLAN is used for

FOLIC ACID MYLAN is used to treat:

- 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
- 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.

FOLIC ACID MYLAN contains the active ingredient *folic acid*. It belongs to the Vitamin B group of medicines.

It works by helping in the pathways in the body which synthesis or convert amino acids. It is involved in the maturing of all rapidly growing tissues particularly those in bone marrow and the stomach and intestines.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available with a doctor's prescription or from a pharmacy.

This medicine is not expected to affect your ability to drive a car or operate machinery.

There is not enough information to recommend the use of this medicine for children under the age of 12 months.

Before you take FOLIC ACID MYLAN

When you must not take it

Do not take FOLIC ACID MYLAN if you have an allergy to:

- any medicine containing *folic acid*
- any of the ingredients listed at the end of this leaflet.
- Megaloblastic anaemia caused by Vitamin B12

deficiency (cyanocobalamin)

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

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 12 months. Safety and effectiveness in children younger than 12 months have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- megaloblastic anaemia which has not excluded vitamin B12 deficiency as the cause
- You are also taking diphenylhydantoin a medicine used to control seizures

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Folic acid will not correct folate deficiency due to dihydrofolate reductase inhibitors such as methotrexate. Folinic acid should be used in these cases.

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

If you have not told your doctor about any of the above, tell them before you start taking FOLIC ACID MYLAN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking FOLIC ACID MYLAN.

Some medicines may interfere with FOLIC ACID MYLAN. These include:

- medicines used to treat epilepsy, such as anti convulsant drugs.
- multivitamin preparations which contain aluminium, magnesium, zinc, antibiotics or sulphonamides
- large amounts of alcohol
- medicines used to treat cancer, such as 5-fluorouracil or methotrexate
- medicines used to treat infections, such as trimethoprim
- medicines used to prevent malaria, such as pyrimethamine
- medicines used to treat bowel disease, such as sulfasalazine.
- Medicines used to treat chronic diarrhoea, such as cholestyramine
- medicines used to treat high blood pressure.
- The requirement for folic acid maybe increased in

patients using analgesics, oestrogens or oral contraceptives

These medicines may be affected by FOLIC ACID MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take FOLIC ACID MYLAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

- **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 Over the age of 12 months: 5 to 15mg daily according to the severity of the deficiency.
- **Prevention 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.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

FOLIC ACID MYLAN should not be added to multivitamin preparations as it may lower the concentration of vitamin B12 in the blood.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking FOLIC ACID MYLAN

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FOLIC ACID MYLAN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while being given this medicine, tell your doctor immediately

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take FOLIC ACID MYLAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how FOLIC ACID MYLAN affects you.

Be careful when drinking alcohol while you are taking this medicine.

This medicine may not work as well if you drink alcohol.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FOLIC ACID MYLAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include are the same as the side effects but may be more severe. The symptoms of a side effect are listed under Side effects below.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FOLIC ACID MYLAN.

This medicine helps most people with megaloblastic anaemia caused by folic acid deficiency and folate deficiencies, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- diarrhoea or wind
- rash
- irritability
- sleep disturbances

The above list includes the more common side effects of your medicine.

They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- difficulty breathing, wheezing, or coughing
- change in heart rate or chest pain
- fits or seizures
- allergic reaction.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking FOLIC ACID MYLAN

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store FOLIC ACID MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop [using/taking] this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

NEW ZEALAND

Telephone: 0800 168 169

Date of Preparation

15 June 2021.
(Based on datasheet dated 15 June 2021).

Product description

What it looks like

FOLIC ACID MYLAN, 5 mg, tablet is a 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.

Ingredients

Active ingredient(s):

FOLIC ACID MYLAN contains 5 mg of (*folic acid*) as the active ingredient.

Inactive ingredient(s):

FOLIC ACID MYLAN tablet also contains:

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

Sulfites may be present in this product in trace amounts.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

FOLIC ACID MYLAN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland