

PACKAGE LEAFLET: Information for the patient

ACID FOLIK

Tablets – 5 mg

(Folic acid)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Acid folik is and what it is used for
2. Before you take Acid folik
3. How to take Acid folik
4. Possible side effects
5. How to store Acid folik
6. Other information

1. WHAT ACID FOLIK IS AND WHAT IT IS USED FOR

Folic acid is found in foods (such as liver, dried beans, peas, lentils, oranges, asparagus, beet, spinach, etc.), mainly as reduced folate polyglutamate. Synthetic folic acid taken orally is a monoglutamate and is absorbed completely after use, even in presence of malabsorption syndrome. Normal serum levels of the general folic acid range from 5 to 15 ng/mL. In general, serum levels < 5 ng/mL indicate deficiency of folic acid, while levels < 2 ng/mL usually lead to megaloblastic anemia.

Folic acid is used in the treatment of megaloblastic anemia due to insufficient folic acid (which can be displayed from malnutrition, pregnancy, antiepileptic drugs etc.)

Folic acid is used for the prevention of folate deficiency state.

Your doctor may have given folic acid for another purpose. Ask your doctor if you want to know why you were given Acid folik.

2. BEFORE YOU TAKE ACID FOLIK

Do not take Acid folik if:

- you are allergic to folic acid;
- you are allergic to any of the inactive excipients mentioned at the end of this leaflet;
- you have undiagnosed megaloblastic anemia or megaloblastic anemia due to vitamin B₁₂ deficiency;
- you have a malignant disease.

If you think you have any of the above-mentioned conditions, do not take the tablets, talk initially to your doctor and follow the given advices.

Take special care with Acid folik

Folic acid should never be used alone for the treatment of pernicious anemia and other pathologies that derive from vitamin B₁₂ deficiency, because it can cause the manifestation of subacute and combined bone marrow degeneration.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, even those without a prescription. Tell your doctor if you are taking any of the following:

- aminosalicic acid;
- acetylsalicic acid (aspirin);
- contraceptives that are taken by mouth;
- methotrexate, trimethoprim (inhibitors of dihydrofolate reductase) or other folic acid antagonists;
- sulfasalazine, used as an anti-inflammatory agent in bowel diseases and rheumatoid arthritis;
- hydantoin, antiepileptic;
- antituberculars;
- alcohol;

- fluorouracil.

These medicines may be affected by Acid folik, or may affect the way it acts. You may need to use different amounts of this drug or take other medicines. Your doctor or pharmacist will advise you.

Pregnancy

If you are pregnant or you are planning a pregnancy, ask your doctor before using it.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding your baby. Although it is excreted with breast milk, the concomitant administration of folic acid during breastfeeding is acceptable.

Driving and using machines

Be careful while driving or using machinery until you see how Acid folik affects you.

Important information about some of the excipients of Acid folik

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ACID FOLIK

Always take Acid folik tablets exactly as your doctor has advised you.

If you feel that the effects of folic acid are too strong or too weak, talk to your doctor or pharmacist.

It is recommended to take the tablets in the same hour every day.

Folic acid tablets should be swallowed whole with a glass of water.

For the treatment of megaloblastic anemia:

In adults, it is used with a dose of 5 mg / day (maximum 15 mg / day) for 4 months. Treatment then is continued with 5 mg / day every 1 - 7 days (approximately 1 mg / day depending on the causal disease).

In children up to 1 year old, it is used 0.5 mg / kg / day, while children over 1 year old receive the adult dose.

Prophylaxis in patients with chronic hemolysis or with dialysis: it is used 5 mg / day.

Prophylaxis in pregnant women and breast - feeding mothers: it is used 0.2 - 0.5 mg / day.

However, your doctor may advise you to take another dose depending on your condition and response to the drug.

Your doctor may ask you to take Acid folik for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Acid folik

If you take more Acid folik than it should be taken, or if the children have taken by mistake this drug, please contact your doctor, the hospital, or call the emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Acid folik

If you forget a dose, take the following dose when it is time to take it usually.

Do not take a double dose to supplement the forgotten dose.

If you have any further question on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All drugs may cause side effects. Sometimes they are serious, most of times not. Do not be alarmed by this list of possible side effects. There may not appear none of them.

Tell your doctor if any of the following side effects disturbs you:

- allergic reactions – rash, erythema;
- nausea, abdominal distension;
- central nervous system effects, sleep disorders, irritability, nervous depression, confusion and impaired judgement (including chest pain and arrhythmias).

Side effects with unknown frequency have also been reported:

- severe allergic reaction (anaphylactic reaction).

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ACID FOLIK

Keep this medicine out of the sight and reach of children.

Do not use Acid folik after the expiry date which is stated on the package.

Do not store above 25 °C! Store in the original package!

6. OTHER INFORMATION

What Acid folik 5 mg tablets contain

The active substance is folic acid.

One tablet contains 5 mg folic acid.

The excipients are: starch, lactose, microcrystalline cellulose, povidone, talc, sodium starch glycolate.

Content of the pack:

Box with 60 tablets.

Marketing Authorisation Holder and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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