

PACKAGE LEAFLET: INFORMATION FOR THE USER

Folsyra Evolan 5 mg tablets folic acid

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have 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. See section 4.

What is in this leaflet?

1. What <Invented name> is and what is it used for
2. What you need to know before you use <Invented name>
3. How to use <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what is it used for

<Invented name> contains folic acid, a type of vitamin B required for normal blood formation. Normally, sufficient folic acid is acquired through dietary intake, but in certain conditions additional folic acid may be required. Long-term folic acid deficiency may take the form of a particular type of anaemia. <Invented name> is administered to cure or prevent folic acid deficiency.

2. What you need to know before you use <Invented name>

Do not take <Invented name>

- If you are allergic to folic acid, or any of the other ingredients of <Invented name> (listed in section 6).

Warnings and precautions

<Invented name> must only be used if prescribed by a doctor, since folic acid may mask vitamin B₁₂ deficiency.

Other medicines and <Invented name>

The efficacy of the treatment may be affected if the medicine is used concurrently with other medicines. This primarily concerns certain antiepileptics, antidepressants and anti-diabetic medication, and cholestyramine (for high blood lipids), contraceptive pills and certain antibiotics. You must inform your doctor if you are taking any of these medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

No negative effects on foetuses have been demonstrated.

<Invented name> passes over into breast milk, but is not likely to have an effect on breast-fed children.

Driving and using machines

<Invented name> does not affect the ability to drive or use machines.

<Invented name> contains lactose monohydrate

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

3. How to use <Invented name>

Always use <Invented name> exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The normal daily dose for adults with anaemia due to folic acid deficiency is 1 tablet of 5 mg a day for two weeks, and thereafter the dose is normally reduced to 1 tablet of 1 mg a day, though a higher dose may be required if the folic acid deficiency persists. Since <Invented name> tablets are not available in doses of 1 mg, another product should be used for this dosage.

The normal dose for children is: For children of age 10–18 years with folic acid deficiency, the use is 1 tablet of 1 mg a day. Since <Invented name> tablets are not available in the strength of 1 mg, another product should be used.

For prophylactic treatment before and during pregnancy, <Invented name> must be used as instructed by your doctor.

If you use more <Invented name> than you should

If you take too many tablets, or if a child has accidentally taken the medicine contact your doctor or hospital for risk assessment and advice.

4. Possible side effects

Like all medicines, <Invented name> can cause side effects, although not everybody gets them.

When using <Invented name>, some patients may experience adverse events (side effects).

Very common (may affect more than 1 in 10 people)

Common (may affect up to 1 in 10 people)

Uncommon (may affect up to 1 in 100 people)

Rare (may affect up to 1 in 1000 people)

Very rare (may affect up to 1 in 10 000 people)

Not known (frequency cannot be estimated from the available data)

Rare: Itching, skin rashes, hives.

Not known: severe allergic reaction (anaphylactic reaction)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C.

Do not use this medicine after the expiry date which is stated on the carton package and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

- The active substance is 5 mg of folic acid per tablet.
- The other ingredients are lactose monohydrate, powdered cellulose, talc, colloidal anhydrous silica, magnesium stearate.

What <Invented name> looks like and contents of the pack

<Invented name> consists of yellow to yellow-orange, dotted, round, planoconvex tablets with a score line on one side, diameter 7 mm.

The tablet can be divided into two equal halves.

Pack size is 100 and 105 tablets (blister) and 1000 tablets (plastic bottle).

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder
<To be completed nationally>

Manufacturer

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