

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 more 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.

FOLIK 5mg

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1. What FOLIK is and what it is used for

Each tablet contains 5mg of the active ingredient, FOLIK. FOLIK is a member of the vitamin B complex that is needed for healthy red blood cells. The tablets are used to treat certain types of anaemia caused by faulty development of red blood cells such as after stomach surgery or during pregnancy. They can also be used to prevent the long term breakdown of red blood cells (in certain conditions) or in kidney dialysis.

2. Before you take FOLIK

You must not take **FOLIK** and should talk to your doctor immediately:

If you have been told you suffer from Vitamin B12 deficiency including pernicious anaemia, or any other blood disorder.

If you are sensitive/allergic to **FOLIK** or any other ingredients in these tablets.

If you are suffering from cancer.

If you have Addison's disease and low vitamin B12 levels in your body.

Pregnancy and breast-feeding:

If you are pregnant, planning to become pregnant or are breast feeding ask your doctor or pharmacist for advice before taking any medicine. **FOLIK** can be used during pregnancy.

Ask your doctor or pharmacist for advice if you are not sure.

Important information about some of the ingredients of **FOLIK**:

FOLIK contain lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines:

Tell your doctor if:

you are taking phenytoin or other drugs for epilepsy such as sodium valproate, carbamazepine or a barbiturate.

you are taking lithium for mental health problems. you are taking aspirin for pain relief or to thin your blood.

you are taking the antibiotic trimethoprim, chloramphenicol or co-trimoxazole.

you are taking methotrexate (for rheumatoid arthritis or cancer).

you are taking sulphasalazine (for bowel problems or rheumatoid arthritis).

you are taking triamterene, a diuretic (or 'water tablet'). you drink alcohol.

you need to breathe a gas and air mixture to put you to sleep for an operation or to relieve pain while you are awake.

You should talk to your doctor if you are taking any of the above medicines. Please note that these

statements may also apply to products used some time ago or at some time in the future. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine – even those not prescribed.

3. How to take FOLIK

Your doctor will have decided the right dose of **FOLIK** for you so follow his or her instructions.

The tablets should be swallowed with a glass of water. The usual dose for adults and children over 1 year of age is one tablet daily. This dose is usually continued for up to four months.

FOLIK will have been especially prescribed by your doctor and the dose will be dependent on the condition being treated and may vary.

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take two doses at the same time. If you or someone else accidentally takes too many tablets, tell your doctor at once. If you cannot do this, go to the nearest hospital casualty department. Take with you the container or carton and any tablets that are left so that the hospital can easily tell what medicine has been taken.

REMEMBER – your medicine has been prescribed for you. Do not give this medicine to anyone else even if they have the same symptoms.

4. Possible side effects

Like all medicines, **FOLIK** can cause side effects, although not everybody gets them. Tell your doctor if you notice any of the following side effects, they get worse or you notice any not listed:

Rare

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

Severe allergic reaction (anaphylactic reaction) (affecting more than 1 in 10,000 but less than 1 in 1,000 patients) Allergic reaction (hypersensitivity) e.g. itchy/ red skin, rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils). Stomach and intestines: loss of appetite, feeling sick, a bloated feeling, wind.

If you have side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FOLIK

Do not store above 25°C. Store in the original package. Keep out of the reach and sight of children.

Use by date: Do not use **FOLIK** after the expiry date on the pack.

If you have any medicine left over at the end of your

treatment, please return this to your pharmacy who will dispose of it safely.

6. Further Information

This leaflet does not include all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. Ingredients

Each tablet contains 5mg of the active ingredient, folic acid.

The tablets also contain:

microcrystalline cellulose croscarmellose sodium colloidal silicon dioxide sodium lauryl sulfate Mg stearate.

What the medicine looks like

Box of 20 (2x10) tablets (round, yellow) of 5 mg folic acid in blister pack..

Manufacturer and Marketing Authorisation Holder:

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75 300 Lukavac
Bosnia and Herzegovina

Date and number of marketing authorization:

FOLIK, tablet 20x 5 mg:

Number: 04-07.3-2-5150/15 Date: 20.11.2015.

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