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## FOLIC ACID TABLETS 5mg\_POM

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### PACKAGE LEAFLET: INFORMATION FOR THE USER

## FOLIC ACID TABLETS 5mg

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 any further questions, ask your doctor or pharmacist or nurse.
- 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 Folic Acid tablet is and what it is used for
2. What you need to know before you take Folic Acid tablet
3. How to take Folic Acid tablet
4. Possible side effects
5. How to store Folic Acid tablet
6. Contents of the pack and other information

#### 1. What Folic Acid tablet is and what it is used for

Each tablet contains 5mg of the active ingredient, folic acid. Folic acid is a member of the vitamin B complex that is needed for healthy red blood cells. The tablets are used to treat:

- folate deficiency anaemia caused by poor diet, poor absorption of food (such as in coeliac disease or a digestive disorder called sprue) or increased use of folate in the body (as in pregnancy).

to prevent:

- folate deficiency caused by some medicines (e.g. those used to treat epilepsy such as phenytoin, phenobarbital and primidone).
- folate deficiency caused by long-term red blood cell damage or kidney dialysis.
- neural tube defects in babies (e.g. spina bifida), where women are at risk of having an affected child.

#### 2. What you need to know before you take Folic Acid tablet

**Do not take Folic Acid tablets and tell your doctor if you have:**

- an allergy (hypersensitivity) to folic acid or any of the other ingredients of this medicine (listed in section 6)
- an untreated vitamin B<sub>12</sub> deficiency such as in certain anaemias and lifelong vegetarians
- pernicious anaemia (a form of anaemia caused by lack of vitamin B<sub>12</sub>) or another condition caused by vitamin B<sub>12</sub> deficiency
- a malignant (cancerous) disease.

#### Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Folic Acid tablets if you:

- have a folate dependent tumour
- are pregnant
- have any disease that reduces the amount of vitamin B<sub>12</sub> in the body.

#### Other medicines and Folic Acid tablets:

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- antiepileptics (to treat epilepsy) such as phenytoin, phenobarbital, primidone, sodium valproate and carbamazepine.
- lithium for mental health problems.
- aspirin for pain relief or to thin your blood.
- antibacterials (to treat infections) such as trimethoprim, chloramphenicol or co-trimoxazole.
- methotrexate (to treat Crohn's disease, psoriasis or rheumatoid arthritis).
- sulphasalazine (to treat ulcerative colitis, Crohn's disease or rheumatoid arthritis).
- triamterene, a diuretic (or 'water tablet').
- alcohol.
- a gas and air mixture to put you to sleep for an operation or to relieve pain while you are awake.

#### 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 taking this medicine.

#### Important information about some of the ingredients of Folic Acid tablet:

Folic Acid Tablets 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.

#### 3. How to take Folic Acid tablet

Always take Folic Acid tablets exactly described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The tablets should be swallowed with a glass of water.

#### Doses:

##### Adults (including the elderly):

- To treat folate deficiency anaemia: 5mg a day for 4 months, which may be increased up to a maximum of 15mg a day.
- To prevent folate deficiency caused by some medicines: 5mg a day for 4 months, which may be increased up to a maximum of 15mg a day.
- To prevent folate deficiency caused by long-term red blood cell damage or kidney dialysis:

5mg every 1-7 days.

- To prevent neural tube defects in babies, where women are at risk of having an affected child: 5mg a day started before conception and continued throughout the first three months.
- To treat folate deficiency during pregnancy: 5mg a day continued to birth.

#### Use in children and adolescents:

For young children a more suitable form of the medicine should be used.

- To treat folate deficiency anaemia: Children 1-18 years old: 5mg a day for 4 months. The maintenance dose is 5mg every 1-7 days.
- To treat haemolytic anaemia and metabolic disorders: Children 1-12 years old: 2.5mg-5mg once a day. Children 12-18 years old: 5-10mg once a day.
- To prevent folate deficiency in kidney dialysis: Children 1-12 years old: 250micrograms per kg of body weight (up to a maximum of 10mg) once a day. Children 12-18 years old: 5-10mg once a day.

#### If you take more Folic acid tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

#### If you forget to take the Folic acid tablets

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

Do not take double dose to make up for a forgotten dose.

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

#### 4. Possible side effects

Like all medicines, Folic Acid tablets 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** (may affect up to 1 in 1,000 people)

- **Allergic reaction (hypersensitivity)** e.g. itchy/ red skin, rash.
- **Severe allergic reaction (anaphylactic reaction)** - 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Folic Acid tablet

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

Do not use Folic Acid after the expiry date on the pack. 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 to protect the environment.

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. Contents of the pack and other information

##### What Folic acid tablet contains

Each tablet contains 5mg of the active ingredient, folic acid. The other excipients are lactose, pregelatinised starch, sucrose and stearic acid.

##### What Folic acid tablet looks like and contents of the pack

Plain yellow tablets. Folic Acid Tablets are available in blister packs of 28 tablets.

##### Marketing Authorization Holder

Flamingo Pharma (UK) Ltd., 1<sup>st</sup> Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom.

##### Manufacturer

Flamingo Pharma (UK) Limited  
The Bloc, 38 Springfield Way,  
Anlaby, Hull, HU10 6RJ,  
United Kingdom

##### Product licence number

**PL 43461/0091**

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