

## Package leaflet: Information for the user

### Folic Acid 400 microgram Tablets

#### Folic acid

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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. You must talk to a doctor if you do not feel better or if you feel worse.

#### **What is in this leaflet**

1. What Folic Acid 400 microgram Tablets are and what they are used for
2. What you need to know before you take Folic Acid 400 microgram Tablets
3. How to take Folic Acid 400 microgram Tablets
4. Possible side effects
5. How to store Folic Acid 400 microgram Tablets
6. Contents of the pack and other information

#### **1. What Folic Acid 400 microgram Tablets are and what they are used for**

Folic Acid is a member of the vitamin B group. It is essential for good health. Folic acid is required for the manufacture of nucleic acids (such as DNA), the genetic material of cells. It is vital for the development and proper function of the central nervous system.

Folic acid 400 microgram tablets are indicated for the prevention of first time neural tube defects in the foetus. The neural tube is part of the nervous system and is located within the spine. Neural tube defects cause stillbirth, neonatal death and severe disabilities such as Spina Bifida. It is for use by women who are planning a pregnancy.

Studies have shown that over 70% of first time neural tube defects such as Spina Bifida can be prevented by taking folic acid (0.4mg) daily.

#### **2. What you need to know before you take Folic Acid 400 microgram Tablets**

##### **Do not take Folic Acid 400 microgram Tablets**

- If you are allergic to folic acid or any of the other ingredients of this medicine (listed in section 6).
- If you have a deficiency of vitamin B<sub>12</sub>, possibly caused by pernicious anaemia or a vegetarian diet.

#### **Warning and precautions**

##### **Talk to your doctor or pharmacist before taking Folic Acid 400 microgram Tablets**

- If you are under therapy for a folate-dependent tumour.
- If you have a family history of neural tube defects (NTDs), as you may need a higher dose of folic acid than this product provides.
- If you suffer from diabetes, as you may need a higher dose of folic acid than this product provides.

- If you are obese, as you may need a higher dose of folic acid than this product provides.

### **Other medicines and Folic Acid 400 microgram Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following:

- Anti-epileptics (medicines used to treat epilepsy and fits) such as phenytoin, phenobarbital or primidone. Your doctor may need to change the amount of ant-epileptic medicine you are taking, because folic acid tablets may reduce the effect of these medicines.
- Antibacterials (used to treat infections) e.g. chloramphenicol and co-trimoxazole.
- Sulfasalazine, an anti-inflammatory drug used for the treatment of arthritis or inflammatory bowel disease, including ulcerative colitis or Crohn's disease.
- Methotrexate, a disease modifying anti-rheumatic drug used to treat severe active rheumatoid arthritis, severe psoriasis and certain types of cancer.

### **Folic Acid 400 microgram Tablets with food or drink**

The tablets should be swallowed with water.

### **Pregnancy and breast-feeding**

Folic acid is indicated for use during pregnancy and lactation.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

There is no information on the effects of Folic Acid 400 microgram Tablets on the ability to drive or use machines. However, no negative effect is anticipated.

### **Folic Acid 400 microgram Tablets contain 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 Folic Acid 400 microgram Tablets**

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

The recommended dose is

#### **Adult females**

Women planning a pregnancy should take one tablet (0.4 mg) daily. You should begin taking this product at least **14 weeks** before you become pregnant and continue taking it for at least the first **12 weeks** of pregnancy.

The tablets should be swallowed with water.

#### **If you take more Folic Acid 400 microgram Tablets than you should**

If you take too many tablets you should contact your doctor. However, large doses of folic acid are unlikely to cause harm.

#### **If you forget to take Folic Acid 400 microgram Tablets**

If you forget to take your dose of Folic Acid 400 microgram Tablets take it as soon as you remember. Do not take a 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.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **If you have an allergic reaction to Folic Acid 400 microgram Tablets see a doctor straight away**

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Sudden wheezing, fluttering or tightness of the chest or collapse.

#### **Tell your doctor if you get any of these side effects:**

- Feeling sick (nausea)
- Being sick (vomiting)
- Upset stomach

Severe allergic reaction (anaphylactic reaction): frequency not known.

#### **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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Folic Acid 400 microgram Tablets**

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

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

Do not store above 25°C.

Store in the original package.

Keep the blister in the outer carton.

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 Folic Acid 400 microgram Tablets contain**

The active substance is Folic Acid.

The other ingredients are lactose monohydrate, maize starch, pregelatinised maize starch (Starch 1500) and magnesium stearate.

##### **What Folic Acid 400 microgram Tablets look like and contents of pack**

Folic Acid 400 microgram Tablets are pale yellow circular tablets.

Folic Acid 400 microgram Tablets are available in packs of 28 and 98 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary, Ireland

**This leaflet was last revised in January 2019.**