

Package leaflet: Information for the user

Folic Acid 5mg 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 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. See section 4.

What is in this leaflet

1. What Folic Acid 5 mg Tablets are and what they are used for
2. What you need to know before you take Folic Acid 5 mg Tablets
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1. WHAT FOLIC ACID 5 mg TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Folic Acid 5 mg Tablets. It contains folic acid which belongs to a group of vitamins called 'B vitamins'.

Folic acid 5 mg Tablets are used to treat the following:

- Anaemia which can be caused by:
 - a lack of vitamins
 - pregnancy
 - gastrectomy (a portion or all of your stomach has been surgically removed).
- An illness called 'Sprue'. In this illness parts of your food cannot be absorbed by the gut.
- Pellagra (a vitamin deficiency) - the symptoms include dermatitis, inflammation of the tongue, diarrhoea, disorientation, depression and confusion.
- As an adjunct (i.e., taken in combination with other medicines) in the management of pernicious anaemia (your body is unable to absorb vitamin B₁₂ properly from your food).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FOLIC ACID 5 mg TABLETS

Do not take Folic Acid 5 mg Tablets

- if you are allergic (hypersensitive) to folic acid or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include a rash, itching or shortness of breath.
- if you have pernicious anaemia. Folic acid 5 mg Tablets **should not be used as the only treatment** of pernicious anaemia, since it will not prevent degeneration of the spinal cord (sub-acute combined degeneration of the spinal cord).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Folic Acid 5 mg Tablets

- if you are having treatment for pernicious anaemia (the production of red blood cells is affected) caused by vitamin B₁₂ deficiency. You will need to take other medicines in combination with Folic Acid 5 mg Tablets to treat this condition.
- if you are under therapy for a folate-dependent tumour (an abnormal growth).

Children and adolescents

There are no special warnings for children and adolescents over and above those already stated.

Other medicines and Folic Acid 5 mg Tablets

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

- Medicines used to treat epilepsy and fits (e.g. phenytoin and primidone)
- Trimethoprim (antibacterial and antimalarial drug)
- Proguanil and pyrimethamine (antimalarial drug)
- Methotrexate and fluorouracil (anticancer drug)
- Chloramphenicol (antibiotic)

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, this medicine is unlikely to cause any harm to you or your unborn child.

Driving and using machines

Folic Acid 5 mg Tablets are not likely to affect you being able to drive or use any tools or machines.

Folic Acid 5 mg 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 5 mg TABLETS

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

Adults

The recommended dose for adults is:

- 10mg (2 tablets) to 20mg (4 tablets) each day
- If you are on long term treatment your doctor may prescribe a reduced dose of 2.5 mg to 10 mg each day.

Use in children and adolescents

The recommended dose for children is:

- 5 mg (1 tablet) to 15 mg (3 tablets) each day
- The doctor may reduce this dose after symptoms have subsided.

The tablets should be swallowed with water.

If you take more Folic Acid 5 mg Tablets than you should

Contact your doctor or pharmacist or telephone your nearest casualty department immediately. Remember to take the pack and any remaining tablets with you.

The symptoms of overdose may include bitter taste, loss of appetite, nausea, flatulence, nightmares, agitation, depression. The frequency and intensity of epileptic attacks may increase in patients receiving antiepileptic medicine (especially phenobarbital, phenytoin or primidone).

If you forget to take Folic Acid 5 mg Tablets

Take one as soon as you remember and continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Folic Acid 5 mg Tablets

Do not stop taking your tablets without consulting with your doctor first.

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 5 mg Tablets see a doctor immediately.

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- In rare cases, severe allergic reaction (anaphylactic shock) may occur which may include sudden itching of the skin, wheezing, fluttering or tightness of the chest, or collapse.

Tell your doctor as soon as possible if you get any of these side effects

- Feeling sick (nausea)
- Being sick (vomiting)
- Upset stomach
- Sleep disturbances
- Agitation
- Depression

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 HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: 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 5 mg 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 blister after 'EXP'. The expiry refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Keep blister in the outer carton in order to protect from light.

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 5 mg Tablets contain

- The active substance is folic acid 5 mg.
- The other ingredients are lactose monohydrate, cellulose powdered (E460), talc (E553b), colloidal anhydrous silica (E551) and magnesium stearate (E470b).

What Folic Acid 5 mg Tablets look like and contents of the pack

Folic Acid 5 mg Tablets are yellow to orange-yellow, speckled, round, biplane tablets.

Pack sizes: 14, 28, 56, 84 and 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketingauthorisationholder

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

Manufacturer

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

And

STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

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