

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

1. What Folic Acid Tablets are and what they are used for

Folic acid is a member of the Vitamin B group it is the active ingredient of Folic Acid Tablets. It is essential for good health and is present in fresh and processed foods.

You should use this medicines if you are trying to become pregnant or think you are pregnant and also for the first three months of your pregnancy.

Folic Acid is necessary for the development and growth of healthy cells and tissues. It is vital for the development and proper function of the central nervous system.

Folic acid is used to help prevent babies being born with neural tube defects such as Spina Bifida. The neural tube is part of the nervous system and is located in the spine. The baby's neural tube develops during the early stages of pregnancy and it is at this particular critical stage that neural tube defects such as Spina Bifida can occur.

2. What you need to know before you take Folic Acid Tablets

Do not take Folic Acid Tablets:

- if you are allergic to folic acid or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from untreated 'pernicious anaemia' or Vitamin B12 (cobalamin) deficiency
- if you have a folate dependant tumour (cancer affected by folic acid intake)
- if you have cancer or a tumour (unless you have anaemia due to a deficiency of folic acid).

Warnings and precautions

Talk to your doctor or pharmacist before taking Folic Acid Tablets:

- if you suffer from Vitamin B12 deficiency and have not been seen by your doctor, as your doctor will need to examine you and may wish to give you another medicine to take together with Folic Acid Tablets in order to treat this condition.

- if you have pre-existing diabetes, are obese, have a family history of neural tube defects or have had a previous neural tube defect during pregnancy as your doctor may wish to prescribe a higher dose of folic acid for you.

Other medicines and Folic Acid 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:

- Antiepileptics (medicines used to treat epilepsy and fits) such as phenytoin, phenobarbital or primidone. Your doctor may need to change the amount of antiepileptic medicine you are taking because folic acid may reduce the effect these medicines.
- Antibacterial (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.

Pregnancy and breast-feeding

Pregnancy

Folic Acid Tablets are intended for use before you become pregnant and during the first 12 weeks of pregnancy. If you think you are pregnant you should start taking Folic Acid Tablets. Folic acid is needed for the development of your baby's spine and brain in the early weeks of pregnancy.

Breast-feeding

Folic Acid Tablets can be taken whilst 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 any medicine.

Driving and using machines

Folic Acid Tablets are not likely to affect your ability to drive or use machines.

Folic Acid Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Folic Acid 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.

Women planning a pregnancy or who are in the first three months of pregnancy:

The recommended dose is one tablet (400 micrograms) daily. The tablet should be swallowed with water.

You should begin taking this medicine before you become pregnant or if you think you are pregnant and continue taking it for at least the first 12 weeks of pregnancy.

If you take more Folic Acid 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 Tablets

If you forget to take a dose, take it as soon as you remember. If it is nearly time for your next dose, skip the missed dose. 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 experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department:

- severe allergic reaction (anaphylactic reaction); signs of which may include itchy/red skin, rash, sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse.

The frequency of such reactions is not known (frequency cannot be estimated from the available data).

Other possible side effects include

Rare (may affect up to 1 in 1,000 people):

- loss of appetite
- feeling and/or being sick
- bloating of the stomach
- flatulence (wind).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Folic Acid 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 label and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Tablets contains

- The active substance is folic acid. Each tablet contains 400 micrograms (0.4 mg) of folic acid (as folic acid hydrate).
- The other ingredients are Hydroxypropylcellulose, Croscarmellose sodium, Cellulose, microcrystalline, Silica, colloidal anhydrous and Stearic acid.

What Folic Acid Tablets looks like and contents of the pack

Folic Acid Tablets are off-white to yellowish, round, bevelled-edged, convex tablets, 7 mm in diameter.

They are available in blister packs containing 30, 60 and 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Generic Pharma International (GPI) Limited,
1 Stephenstown Industrial Park,
Balbriggan, Co Dublin,
K32 VP92, Ireland

Manufacturers

SANTA SA
Str. Panselelor nr. 25, nr. 27, nr. 29
Brasov, jud. Brasov, cod 500419
Romania

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland – Folic Acid 400 microgram Tablets

United Kingdom (Northern Ireland) – Folic Acid 400 microgram Tablets

This leaflet was last revised in 07/2022