

PACKAGE LEAFLET: INFORMATION FOR THE USER

Folic Acid 2.5mg/5ml Oral Solution

Folic Acid 2.5mg/5ml

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 Oral Solution is and what it is used for
2. What you need to know before you take Folic Acid Oral Solution
3. How to take Folic Acid Oral Solution
4. Possible side effects
5. How to store Folic Acid Oral Solution
6. Contents of the pack and other information

1. What Folic Acid Oral Solution is and what it is used for

The name of your medicine is Folic Acid Oral Solution, which contains folic acid, a vitamin essential in the production and maintenance of new cells.

Folic Acid Oral Solution is used in the treatment of:

- anaemia due to a lack of folic acid in adults and children
- anaemia in pregnancy
- anaemia associated with alcoholism
- anaemia, as a side effect from medicines used to control fitting
- anaemia due to damaged red blood cells e.g. Sickle Cell anaemia
- sprue (tropical and non-tropical) – a disorder where essential nutrients are not absorbed from the diet.
- coeliac disease, a disorder caused by gluten in the diet

2. What you need to know before you take Folic Acid Oral Solution

Do not take Folic Acid Oral Solution:

- if you are allergic to folic acid, hydroxybenzoate esters or to any of the other ingredients of this medicine (listed in section 6).
- if you have cancer (unless you have anaemia due to a deficiency of folic acid)

Warnings and precautions

Talk to your doctor before taking Folic Acid Oral Solution:

- if you are receiving a coronary stent (a tube that is inserted in the artery that leads to the heart, in order to stop blockages)
- if you have a tumour
- if you suffer from pernicious anaemia (a disorder preventing the absorption of vitamin B12) or could be suffering from a lack of vitamin B12
- if you are under going haemodialysis due to kidney failure

Other medicines and Folic Acid Oral Solution

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

The following medicines can affect or be affected by treatment with Folic Acid Oral Solution:

- phenytoin, phenobarbital and primadone (used to control epileptic fits)
- fluorouracil, a drug used to treat certain tumours
- antibiotics. Some antibiotics (trimethoprim and sulphonamides, sometimes combined as co-trimoxazole) reduce the effect of folic acid. All antibiotics can interfere with folic acid blood test results. Chloramphenicol may interfere with folate metabolism
- some indigestion remedies (edible clay and antacids containing aluminium or magnesium). Allow at least a two hour gap between taking Folic Acid Oral Solution and indigestion remedies
- preparations containing zinc such as vitamins or food supplements (this may be important in pregnancy)
- sulfasalazine, used to treat the inflammatory bowel conditions ulcerative colitis and Crohn's disease
- cholestyramine, used to reduce cholesterol levels in the blood
- methotrexate, used to treat Crohn's disease, rheumatoid arthritis or cancer.

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.

This medicine can be taken in pregnancy to treat anaemia.

If you are breast-feeding please speak with your doctor before taking this medicine.

Driving and using machinery

This medicine does not affect your ability to drive a car or operate machinery.

Folic Acid Oral Solution contains hydroxybenzoates and phenylalanine

This medicine contains hydroxybenzoates which are used as preservatives. These ingredients may cause allergic reactions, which may happen some time after you start taking this medicine.

This medicine contains phenylalanine. May be harmful for people with phenylketonuria.

3. How to take Folic Acid Oral Solution

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

Your doctor will decide the right dose for you; this will be on the pharmacist's label. Check this carefully, it will tell you how much of this medicine to take and how often to take it. This medicine should be swallowed.

The recommended doses are as follows:

Adults and the elderly

- 10 to 20ml, twice a day, for up to 14 days or until an appropriate blood response is achieved.
- this may be reduced to 2.5 to 10ml, twice a day, for ongoing treatment.

Pregnant women

- 1ml per day.

Children (persons aged 12 years and younger)

- 5 to 15ml, twice a day.

If you take more Folic Acid Oral Solution than you should

If you take (or anybody else, including a child), takes more Folic Acid Oral Solution than you should, it is unlikely that this medicine will cause any harm. If you are at all concerned contact your doctor. Always take the bottle and leaflet with you.

If you forget to take Folic Acid Oral Solution

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. 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.

Stop taking Folic Acid Oral Solution and see a doctor or go to a hospital straight away if you have:

itchy/red skin, rash, swelling of the face, lips, tongue or throat or itching, difficulty breathing or swallowing, shock (cold sweaty skin; weak pulse; rapid, shallow breathing; dry mouth; dilated pupils; dizziness; weakness and/or fainting).

This may mean you are having an allergic reaction (hypersensitivity) or a severe allergic reaction (anaphylactic reaction).

Other side effects that some patients have had with Folic Acid Oral Solution include:

- loss of appetite (anorexia)
- feeling sick
- bloating of the stomach

- flatulence (wind)
- worsening of the symptoms of vitamin B12 deficiency. Folic acid should never be used to treat anaemia without a full investigation of the cause.

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 national reporting systems listed below.

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta

ADR Reporting
www.medicinesauthority.gov.mt/adrportal

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

5. How to store Folic Acid Oral Solution

Keep out the sight and reach of children.

- Folic Acid Oral Solution should be stored in a refrigerator (2°C - 8°C). Store in the original container to protect from light; do not transfer to another container.
- Folic Acid Oral Solution should not be taken after the expiry date on the bottle label and carton; the expiry date refers to the last day of the month.
- Throw away any unused Folic Acid Oral Solution three months after opening the bottle.

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 Oral Solution contains

The active substance is: folic acid (2.5mg per 5ml of Folic Acid Oral Solution). The other ingredients are: mannitol (E421), glycerol (E422), methyl hydroxybenzoate (E218), ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), disodium hydrogen phosphate dodecahydrate, dihydrogen phosphate sodium dehydrate disodium edetate, strawberry flavour (contains phenylalanine, cherry juice concentrate and maltol) and purified water.

What Folic Acid Oral Solution looks like and contents of the pack

Folic Acid Oral Solution is a clear yellow solution, which tastes and smells of strawberry. The medicine is supplied in a 150ml amber glass bottle, with a child restraint screw cap, in a cardboard outer container.

Marketing Authorisation Holder:

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This medicinal product is authorised in the following Member States in the EEA, under the following names:

Cyprus – Folic Acid Wockhardt 2.5mg/5ml Oral Solution

Malta – Folic Acid 2.5mg/5ml Oral Solution

Poland – Wockhardt Folic Acid 2.5mg/5ml Oral Solution

Republic of Ireland – Folic Acid 2.5mg/5ml Oral Solution

This leaflet was last revised in 12/2020