

Package leaflet:
Information for the user
Folinic Acid (as Calcium Folate) 15 mg Tablets
calcium folinate

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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Folinic Acid Tablets contain folinic acid as calcium folinate. Folinic acid is one of the B group of vitamins.

Folinic acid is used to reduce the harmful effects of certain types of medicines called folic acid antagonists, e.g. methotrexate. Folinic acid may also be used to treat some types of anaemia (megaloblastic anaemias) when they occur during pregnancy and infancy or they are caused by liver disease, inadequate food intake or poor food absorption.

It may also be used to treat an overdose of folic acid antagonists such as methotrexate.

You must talk to a doctor if you do not feel better or if you feel worse.

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

Do not take Folinic Acid Tablets

- if you are allergic to folinic acid or any of the other ingredients of this medicine (listed in section 6)
- if you have a type of anaemia (pernicious anaemia) caused by too little vitamin B12
- if you have one of the following hereditary sugar intolerances:
 - galactose intolerance
 - Lapp lactase deficiency
 - glucose-galactose malabsorption

Tell your doctor if any of the above applies to you before this medicine is used.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Folinic Acid Tablets.

Take special care with Folinic Acid tablets if:

- your kidneys do not work properly – you may need to take a higher dose or need to take this medicine for longer
- if you have epilepsy

Other medicines and Folinic Acid Tablets

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

Special care is needed if you are taking or using other medicines as some could interact with folinic acid, for example:

- taking the anti-cancer medicines capecitabine, fluorouracil, or medicines of the same family (fluoropyrimidines), and folinic acid together may be linked to seizures (fits) and fainting
- the effectiveness of phenobarbitone, phenytoin and primidone (used to treat epilepsy) may be reduced by folinic acid. Your doctor may check blood levels of these medicines and change your dose to prevent increased seizures (fits)
- the effectiveness of folinic acid can be reduced by chloramphenicol (an antibiotic)

Pregnancy, breast-feeding and fertility

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.

Your doctor will advise you whether you should take this medicine whilst pregnant or breast-feeding.

Driving and using machines

There is no evidence that calcium folinate has any effect on the ability to drive or use machines.

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

Folinic Acid Tablets contain lactose

These 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 medicine.

3. How to use Folinic Acid Tablets

Always take Folinic Acid exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The tablets should be swallowed whole with a drink of water. Your doctor may also ask you to drink more than usual.

Recommended Dose

Reduction of harmful effects of folic acid antagonists

If used to reduce the harmful effects of folic acid antagonist medicines such as methotrexate, treatment with Folinic Acid is usually started 12 to 24 hours after the folic acid antagonist has been given. The dose is usually one 15 mg tablet every 6 hours for 2 to 3 days. You will probably also be asked to take another medicine to make your urine alkaline at the same time as this will also help reduce the toxic effects of the folic acid antagonist.

Where high doses of folic acid antagonists have been used, or where there has been an overdose of such medicines, Folinic Acid treatment is usually given by injection.

Megaloblastic anaemia

In the treatment of megaloblastic anaemia the dose is one 15 mg tablet daily for adults and children over 12 years of age.

Treatment of Overdosage of Folic Acid Antagonists

If an overdosage of a folic acid antagonist happens, you will be given a dose of folinic acid that will either be the same amount as, or a larger amount than the wrong dose of the folic acid antagonist taken. It should be taken as soon as possible after, as it may not work as well after this time.

If you take more Folinic Acid Tablets than you should

Tell your doctor or pharmacist immediately.

If you forget to take Folinic Acid Tablets

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

4. Possible side effects

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

Very rare: may affect up to 1 in 10,000 people

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint. This is a serious side effect. You may need urgent medical attention.

Uncommon: may affect up to 1 in 100 people

- fever

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

- an increase in convulsions (fits) in patients with epilepsy
- depression
- agitation
- problems with the digestive system
- difficulty sleeping (insomnia)

If any of the following happens, tell your doctor as soon as possible:

- fits
- fainting

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 HPRA 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 Folinic Acid TABLETS

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

Expiry

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

Storage

Do not store above 25°C

Keep tablet bottle in the outer carton in order to protect from light.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Folinic Acid Tablets contain

The active substance is folinic acid. Each tablet contains calcium folinate equivalent to folinic acid 15 mg.

The other ingredients are microcrystalline cellulose, magnesium stearate and lactose.

What Folinic Acid Tablets look like and contents of the pack

The tablets are round and light yellow in colour. They are scored and marked "CF" on one side.

Folinic Acid Tablets are supplied in a screw cap, plastic bottle containing 10 tablets.

Marketing authorisation holder

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

Manufacturer

Pfizer Service Company BVBA, Hoge Wei 10, 1930 Zaventem, Belgium
or
Orion Corporation, Orion Pharma, Joensuukatu 7, Salo, 24100, Finland.

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