

Package leaflet: Information for the user
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 or pharmacist. 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 Calcium Folate Tablets are and what they are used for

Calcium folinate is one of the B group of vitamins.

Calcium folinate is used to reduce the harmful effects of certain types of medicines called folic acid antagonists. Examples of folic acid antagonists are:

- methotrexate (a medicine often used to treat cancer)
- trimetrexate (an antibiotic and anti-cancer medicine)
- trimethoprim (an antibiotic)
- pyrimethamine (a medicine often used to treat malaria)

It may also be used to treat an overdose of these medicines.

Calcium folinate 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.

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 Calcium Folate Tablets

Do not take Calcium Folate Tablets

- if you are allergic to calcium folinate or any of the other ingredients of this medicine (listed in section 6).
- if you have a type of anaemia caused by too little vitamin B₁₂.

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 Calcium Folate Tablets.

Take special care with Calcium Folate 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

Your bloods will be monitored to check the treatment is working. Additionally, your urine will be checked for signs of methotrexate toxicity.

Other medicines and Calcium Folate Tablets

Tell your doctor if you are using, have recently used or might use any other medicines. Special care is needed if you are taking/using other medicines as some could interact with calcium folinate, for example:

- folic acid antagonists (such as methotrexate, trimetrexate, trimethoprim and pyrimethamine) the effectiveness of these medicines will be reduced by calcium folinate
- taking the anti-cancer medicines capecitabine, fluorouracil, or medicines of the same family (fluoropyrimidines), and calcium folinate together may be linked to seizures (fits) and fainting
- the effectiveness of phenobarbitone, phenytoin and primidone (used to treat epilepsy) may be reduced by calcium folinate. Your doctor may check blood levels of these medicines and change your dose to prevent increased seizures (fits)
- chloramphenicol (antibiotic used to treat bacterial infections)

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.

Driving and using machines

Calcium folinate has no known effect on the ability to drive and use machines.

Calcium Folate 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 Calcium Folate Tablets

Always take Calcium Folate 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 calcium folinate is usually started 24 hours after the folic acid antagonist has been given. The dose is usually one 15 mg tablet every 6 hours for 2 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, calcium folinate treatment is usually given by injection.

Megaloblastic anaemia

In the treatment of megaloblastic anaemia the dose is one 15 mg tablet daily.

If you take more Calcium Folate Tablets than you should

Tell your doctor or pharmacist immediately.

If you forget to take Calcium Folate Tablets

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

4. Possible side effects

Like all medicines, calcium folinate can cause side effects, although not everybody gets them.

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)

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.

Not known: frequency cannot be estimated from the available data

- fainting

Serious skin reactions such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), sometimes life-threatening, have been reported in patients receiving calcium folinate in combination with other medicines known to cause these disorders.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcium Folate 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.

Disposal

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 Calcium Folate Tablets contain**

The active substance is folic acid. Each tablet contains 15 milligrams (mg) of folic acid in the form of calcium folinate hydrate.

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

What Calcium Folate 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.

It is supplied in a screw cap, plastic bottle containing 10 tablets.

Marketing Authorisation Holder

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