

PACKAGE LEAFLET: INFORMATION FOR THE USER

Calcium Folate 15 mg Tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Calcium Folate is and what it is used for
2. Before you take Calcium Folate Tablets
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1. WHAT CALCIUM FOLINATE IS AND WHAT IT IS 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, e.g. methotrexate.

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.

2. BEFORE YOU TAKE CALCIUM FOLINATE TABLETS

Do not take Calcium Folate Tablets

- if you have shown signs of hypersensitivity (severe allergy) to calcium folinate or any of the other ingredients (see section 6) in the past
- if you have a type of 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.

Taking/using other medicines

Special care is needed if you are taking/using other medicines as some could interact with calcium folinate, for example:

- 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)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will advise you whether you should take this medicine whilst pregnant or breast-feeding.

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

Important information about one of the ingredients of Calcium Folate Tablets

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 TAKE CALCIUM FOLINATE TABLETS

Always take Calcium Folate exactly as your doctor has instructed you. You should always check with your doctor or pharmacist if you are unsure.

The tablets should be swallowed whole with a drink of water.

Your doctor may also ask you to drink more than usual.

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

If you forget to take your tablet, take it as soon as you can, but do not take a double dose to make up for forgotten tablet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, calcium folinate 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)

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 FOLINATE TABLETS

Keep out of the reach and sight of children

Expiry

This medicine must not be used after the expiry date which is stated on the tablet bottle and carton after 'EXP'. Where only a month and year is stated, 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

Medicines should not be disposed of 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. FURTHER 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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