

CALCIUM FOLINATE 15 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 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.

IN THIS LEAFLET:

1. What Calcium Folate is and what it is used for
2. Before you take Calcium Folate
3. How to take Calcium Folate
4. Possible side effects
5. How to store Calcium Folate
6. Further information

1 WHAT CALCIUM FOLINATE IS AND WHAT IT IS USED FOR

Calcium Folate belongs to a group of drugs called antidotes. Antidotes prevent the damage caused by other substances. Calcium Folate increases the levels of folic acid in your body.

Methotrexate (a medicine used to treat cancer) can lower your body's level of folic acid. Calcium Folate is used to reverse this and help to maintain folic acid levels. This is known as 'leucovorin rescue'.

Calcium Folate is also used to treat a form of anaemia (megaloblastic) which results from low levels of folic acid.

Ask your doctor or pharmacist if you need further information.

2 BEFORE YOU TAKE CALCIUM FOLINATE

Do NOT take Calcium Folate if you:

- are allergic (hypersensitive) to calcium folinate or any of the other ingredients of this medicine
- suffer from anaemia due to lack of vitamin B₁₂ (pernicious anaemia or some megaloblastic anaemias).

Take special care with Calcium Folate

Tell your doctor before you start to take this medicine if you:

- are also being treated with methotrexate. Calcium Folate should only be used after treatment with methotrexate.

Taking other medicines

Talk to your doctor if you are taking any of the following:

- anti-epileptics e.g. phenobarbital, phenytoin or primidone
- methotrexate (see above, Tell your doctor before you start to take this medicine).
- antibiotic such as chloramphenicol
- other anticancer drugs such as fluorouracil.

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

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor for advice before taking this medicine.

Driving and using machines

Calcium Folate is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Calcium Folate

Patients who are intolerant to **lactose** should note that Calcium Folate tablets contain a small amount of 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 FOLINATE

Always take Calcium Folate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should be swallowed preferably with a glass of water. The usual dose is:

To reduce the harmful effects after certain anticancer treatments

- **Adults and Children:**
Following intravenous treatment: 15 mg (1 tablet) every 6 hours for 48 hours.

To treat anaemia due to low levels of folic acid

- **Adults:**
15 mg (1 tablet) a day.
- **Children up to 12 years:**
Your doctor will calculate the appropriate dose for your child.

If you see another doctor or go into hospital, let him or the staff know what medicines you are taking.

If you take more Calcium Folate than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital

casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Calcium Folate

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Calcium Folate can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (sudden wheeziness, swelling of the lips, eyelids, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Rarely, fever has been reported following intravenous or intramuscular injection with Calcium Folate.

If Calcium Folate is given with another drug called fluorouracil (to treat cancer) the following side effects have been reported:

- decreased white blood cell count or low platelets in the blood. Symptoms may include bruising, nose bleeds or rash. Your doctor will take regular blood tests to check these.
- sore and inflamed mouth (stomatitis) and/or diarrhoea.

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 the Yellow Card Scheme Website:

<http://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

Keep out of the reach and sight of children. Do not store above 25°C. Keep in the package or container supplied. Do not transfer to another container. Do not use Calcium Folate after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. 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 ingredient is calcium folinate (as pentahydrate).
- The other ingredients are lactose monohydrate, maize starch, pregelatinised maize starch, magnesium stearate (E572).

What Calcium Folate Tablets look like and contents of the pack:

- A standard convex tablet, almost white to cream with slight speckling
- The Calcium Folate tablets are available in blister packs of 10 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Teva Operations Poland Sp. z o.o, ul. Mogilska 80, 31-546 Krakow, Poland

This leaflet was last revised: April 2022

PL 00289/0468