

PACKAGE LEAFLET: INFORMATION FOR THE USER

Calcium Folate 10 mg/ml Injection

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

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

1. WHAT CALCIUM FOLINATE INJECTION IS AND WHAT IT IS USED FOR

Calcium folinate is one of the B group of vitamins.

Calcium Folate Injection is used to reduce the side effects of other medicines (a group 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 Folate Injection may also be used to increase the effectiveness of the anti-cancer medicine fluorouracil.

2. BEFORE YOU USE CALCIUM FOLINATE INJECTION

Calcium Folate Injection must not be injected intrathecally (into the spine).

Do not use Calcium Folate Injection

- if you have shown signs of hypersensitivity (severe allergy) to calcium folinate in the past
- if you have a type of anaemia caused by too little vitamin B₁₂

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

Take special care with Calcium Folate Injection

If you are to receive calcium folinate and fluorouracil treatment at the same time take special care if:

- you have had radiotherapy
- you have stomach or bowel trouble

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

Special care is also needed if you are elderly and you are to receive calcium folinate and fluorouracil treatment at the same time.

Taking/using other medicines

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

- folic acid antagonists (see section 1 ‘What Calcium Folate is and what it is used for’ for examples of these medicines) - the effectiveness of these medicines will be reduced by calcium folinate
- fluorouracil (anti-cancer medicine) – the effectiveness and side effects of this medicine will be increased by calcium folinate
- medicines used to treat epilepsy (phenobarbitone, phenytoin, primidone or succinimides) – the effectiveness of these medicines may be reduced by calcium folinate. Your doctor may check blood levels of these medicines and change your dose to prevent increased convulsions (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.

It is unlikely that your doctor will ask you to take/use a folic acid antagonist or fluorouracil whilst you are pregnant or breast-feeding. However, if you have taken/used a folic acid antagonist whilst pregnant or breast-feeding, this medicine (calcium folinate) may be used to reduce its side effects.

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

Important information about one of the ingredients of Calcium Folate Injection

This medicinal product contains 12.5 mmol (287 mg) sodium per 850 mg dose. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE CALCIUM FOLINATE INJECTION

This medicine may be given by injection (using a syringe) into muscle. Alternatively it may be given by injection or infusion (drip) into a vein. If it is given by infusion Calcium Folate Injection will be diluted first.

Dose

Your doctor will work out the correct dose of Calcium Folate Injection for you and how often it must be given. It will depend upon the medical condition which is being treated.

If you are given too much or too little Calcium Folate Injection

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Calcium Folate Injection 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)

Combination therapy with 5-fluorouracil only:

If you receive calcium folinate in combination with an anticancer medicine containing fluoropyrimidines, it is more likely that you experience the following side effects of this other medicine:

Very common: may affect more than 1 in 10 people

- nausea
- vomiting
- severe diarrhea
- drying out which may be due to diarrhea
- inflammation of the lining of the intestine and mouth (life-threatening conditions have occurred)
- reduction in the number of blood cells (including life-threatening conditions)

Common: may affect up to 1 in 10 people

- redness and swelling of the palms of the hands or the soles of the feet which may cause the skin to peel (hand-foot syndrome)

Not known: frequency cannot be estimated from the available data

- elevated ammonia level in the blood

Your doctor may do tests to check for low levels of calcium in your blood.

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:

Yellow Card Scheme

Website: 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 INJECTION

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 vial and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

The vials should be stored in the outer carton, in order to protect from light, in a refrigerator.

Visible signs of deterioration

Only clear, pale yellow solutions should be used. If cloudy in appearance or particles can be seen, the solution should be discarded.

6. FURTHER INFORMATION

What Calcium Folate Injection contains

The active substance is folic acid. Each millilitre (ml) of solution contains 10 milligrams (mg) of folic acid in the form of calcium folinate.

The other ingredients are sodium chloride and Water for Injections. See section 2 'Important information about one of the ingredients of Calcium Folate Injection' for further information about the sodium content.

What Calcium Folate Injection looks like and contents of the pack

Calcium Folate Injection is a clear, pale yellow solution for injection which comes in glass containers called vials.

It is supplied in packs containing:

- 1 x 50 mg/5 ml vial
- 1 x 100 mg/10 ml vial
- 1 x 300 mg/30 ml vial

Marketing authorisation holder and manufacturer

Hospira UK Ltd, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK

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Calcium Folate 10 mg/ml Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Incompatibilities have been reported between injectable forms of calcium folinate and injectable forms of droperidol, fluorouracil, foscarnet and methotrexate.

Droperidol

1. Droperidol 1.25 mg/0.5 ml with calcium folinate 5 mg/0.5 ml, immediate precipitation in direct admixture in syringe for 5 minutes at 25° C followed by 8 minutes of centrifugation.
2. Droperidol 2.5 mg/0.5 ml with calcium folinate 10 mg/0.5 ml, immediate precipitation when the drugs were injected sequentially into a Y-site without flushing the Y-side arm between injections.

Fluorouracil

Calcium folinate must not be mixed in the same infusion as 5-fluorouracil because a precipitate may form. Fluorouracil 50 mg/ml with calcium folinate 20 mg/ml, with or without dextrose 5% in water, has been shown to be incompatible when mixed in different amounts and stored at 4°C, 23°C, or 32° C in polyvinyl chloride containers.

Foscarnet

Foscarnet 24 mg/ml with calcium folinate 20 mg/ml; formation of a cloudy yellow solution reported.

Instructions for use and handling, and disposal

Calcium Folate Injection is intended only for single use. Any unused portion of the solution should be disposed of in accordance with the local requirements.

For intravenous infusion, Calcium Folate Injection may be diluted with 0.9 % sodium chloride or 5% glucose solution before use.

From a microbial point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C.

Prior to administration, calcium folinate should be inspected visually. The solution for injection or infusion should be a clear and yellowish solution. If cloudy in appearance or particles are observed, the solution should be discarded.