

EUROFOLIC 10 mg/ml Solution for Injection

folinic acid (as calcium folinate)

What is in this leaflet

This leaflet answers some common questions about EUROFOLIC. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using EUROFOLIC against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What EUROFOLIC 10 mg/ml Solution for Injection is used for

EUROFOLIC contains folinic acid (as calcium folinate). It is used in two main situations:

1. When your body does not have enough folic acid.

This occurs in conditions such as megaloblastic anaemia, where the level of red blood cells and iron in the blood is too low. Megaloblastic anaemia can happen during pregnancy or infancy, or due to liver disease, malnutrition, or a reduced ability to absorb folic acid from the diet.

2. As an antidote or “rescue” therapy to reduce the toxic side effects of some medications such as methotrexate.

EUROFOLIC may be used for the management of other conditions that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed EUROFOLIC.

EUROFOLIC is not addictive.

Ask your doctor if you have any questions about why EUROFOLIC has been prescribed for you.

Before you use EUROFOLIC 10 mg/ml Solution for Injection

When you must not use it

You must not be given EUROFOLIC if you have or have had an allergy to EUROFOLIC, folic acid, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to EUROFOLIC may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given EUROFOLIC if you have pernicious anaemia or any other megaloblastic anaemias which are due to a lack of Vitamin B12.

You must not be given EUROFOLIC after the expiry date (EXP) printed on the pack. If you are given this medicine after the expiry date has passed, it may not work as well.

You must not be given EUROFOLIC if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using EUROFOLIC, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if:

1. You have any allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

2. You are pregnant or intend to become pregnant.
3. You are breastfeeding or plan to breast feed
4. You have or have had any medical conditions especially the following:
 - fits or convulsions (epilepsy)
 - vitamin B12 deficiency
 - pernicious anaemia
 - cancer which has spread to other part of the body such as the brain

If you have not told your doctor about any of the above, tell them before you start using EUROFOLIC.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking EUROFOLIC.

Some medicines may interfere with EUROFOLIC. These include:

- some drugs used to treat epilepsy (fits), including phenytoin, phenobarbitone and primidone
- fluorouracil (5-FU), a medicine used to treat some cancers.

These medicines may be affected by EUROFOLIC, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking EUROFOLIC.

How to use EUROFOLIC 10 mg/ml Solution for Injection

How much is given

Your doctor will decide which strength of EUROFOLIC you need and how much you need to take. This will depend on any previous treatment you have had and any current treatment you are taking.

How it is given

EUROFOLIC can be given in three ways:

- as a slow injection into a vein
- as a continuous infusion (intravenous drip) into a vein
- as a deep injection into a large muscle.

EUROFOLIC must only be given by a doctor or nurse.

If you are being given EUROFOLIC as methotrexate “rescue therapy” treatment will usually be started 24 hours after treatment with methotrexate. You should not be given EUROFOLIC at the same time as cancer drugs such as methotrexate, as it may stop them from working properly.

You must not be given EUROFOLIC as an injection into your spine.

During your treatment your doctor may also give you other fluids, and take blood samples from you.

While you are using EUROFOLIC 10 mg/ml Solution for Injection

Things you must do

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of EUROFOLIC.

Tell all the doctors, dentists and pharmacists who are treating you that you are being given EUROFOLIC.

If you are about to be started on any new medicine tell your doctor, dentist or pharmacist that you are taking EUROFOLIC.

In case of overdose

If you take too much (overdose)

As EUROFOLIC is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given EUROFOLIC, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention.

Symptoms of a EUROFOLIC overdose include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using EUROFOLIC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

If the following effects occur you should report them to your doctor immediately.

- Seizures, fits or fainting
- Allergies: Some people develop an allergy to EUROFOLIC; this may appear as an itchy rash or high temperature after the injection. If you experience this, or a swelling of the face, lips, tongue or throat, and/or difficulty in breathing, you should inform the doctor or nurse immediately.

The following effects normally disappear after a few days, however, if they persist, you should contact your doctor:

- Nausea and vomiting may occur. If it persists you should consult your doctor.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Some side effects may only be seen by your doctor.

Even after you have finished being treated with EUROFOLIC, you should tell your doctor if you notice any side effects listed in this section.

After using EUROFOLIC 10 mg/ml Solution for Injection

Storage

EUROFOLIC will be stored in the pharmacy or in the ward.

The injections should be kept in a refrigerator where the temperature stays between 2-8°C and protected from light.

Product description

What it looks like

EUROFOLIC is a clear, pale yellow solution for injection.

Pack sizes

50 mg in 5 mL amber glass vial x 1
100 mg in 10 mL amber glass vial x 1
350 mg in 35 mL amber glass vial x 1
500 mg in 50 mL amber glass vial x 1
1000 mg in 100 mL amber glass vial x 1

Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- Folinic acid (as Calcium folinate)

Inactive ingredients:

- sodium chloride
- sodium hydroxide
- water for injections
- nitrogen as protective gas

Sponsor Details

EUROFOLIC 10 mg/ml Solution for Injection is supplied in New Zealand by:

ORSPEC Pharma Management Limited
PO BOX 59013
Mangere Bridge
Auckland 2151
NEW ZEALAND
Tel: +6421 054 3923

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