Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Leucovorin Calcium Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Leucovorin Calcium Injection against the benefits this medicine is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases, this leaflet may be given to you after the medicine has been used.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet.

You may need to read it again.

What Leucovorin Calcium Injection is used for

Leucovorin Calcium Injection contains calcium folinate. It belongs to a group of vitamins used as an antidote to the harmful effects of methotrexate therapy. Calcium folinate acts in the same way as folic acid which may be low in these patients.

Leucovorin Calcium Injection 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 Leucovorin Calcium Injection.

Before you are given Leucovorin Calcium Injection

When you must not be given it Do not have Leucovorin Calcium Injection if you have an allergy to:

- any medicine containing leucovorin calcium (calcium folinate or folinic acid)
- any of the ingredients listed at the end of this leaflet
- · any similar medicines.

You must not be given Leucovorin Calcium if you have or have had any of the following medical conditions:

- pernicious anaemia
- any other megaloblastic anaemias which are due to a lack of Vitamin B12.

Before you are given it

Tell your doctor if:

- 1. you have any allergies to:
- · any other medicine
- 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 breastfeed
- 4. you have or have had any medical conditions, especially the following:
- fits or convulsions (epilepsy)
- Vitamin B12 deficiency

 cancer which has spread to other parts of the body such as the brain

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop

Some medicines may be affected by Leucovorin Calcium Injection, 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 will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat cancer, such as fluorouracil
- medicines to treat epilepsy (fits), such as phenobarbitone, phenytoin, primidone, succinimides.
- medicines such as co-trimoxazole, pyrimethamine, methotrexate and antibiotic with antifolate effect.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Leucovorin Calcium Injection is given

Leucovorin Calcium Injection is given by injection into the veins or muscle, usually 24 hours after the methotrexate was given. Leucovorin Calcium Injection must only be given by a doctor or nurse.

Your doctor will decide which strength of Leucovorin Calcium Injection you need and how much you need to be given. This will depend on any previous treatment you have had and any current treatment you are taking.

If you are given too much (overdose)

If you are given too much folinic acid, you may experience some of the effects listed under "Side Effects" below.

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

While you are having Leucovorin Calcium Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Leucovorin Calcium Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you have been given this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests on your blood and urine to make sure the medicine is working.

Things you must not do

Do not have Leucovorin Calcium Injection to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Leucovorin Calcium Injection affects you.

This medicine may cause fainting or seizures in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having Leucovorin Calcium Injection.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of being given Leucovorin Calcium Injection, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them

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

Tell your doctor if...

Tell your doctor if you notice any of the following and they worry you:

- skin rash
- diarrhoea
- nausea and vomiting

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- persistent or severe diarrhoea
- sore mouth, throat or stomach
- fever

 redness, pain or peeling of skin on the hands or feet

The above list includes serious side effects that may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- · seizures, fits or fainting
- allergies

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Some people develop an allergy to Leucovorin Calcium Injection; 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.

Tell your doctor if you notice anything else that is making you feel unwell.

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Product description

What it looks like

Leucovorin Calcium Injection is a clear, yellowish solution.

Steriluer ampoule:

Leucovorin Calcium Injection 50 mg (folinic acid) in 5 mL (sterile) AUST R 61885 Leucovorin Calcium Injection 100 mg (folinic acid) in 10 mL (sterile) AUST R 61887

Ingredients

Leucovorin Calcium Injection contains calcium folinate in water for injections containing sodium chloride. It does not contain any preservatives.

Supplier

Leucovorin Calcium Injection is supplied in Australia by:

Pfizer Australia Pty Ltd Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

Date of preparation

This leaflet was revised in December 2019