

LEUSTATIN® Injection

Cladribine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LEUSTATIN 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 risks and benefits. Your doctor has weighed the risks of you taking LEUSTATIN Injection against the benefits this medicine is expected to have for you.

If you have any concerns about using LEUSTATIN Injection ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What LEUSTATIN Injection is used for

LEUSTATIN is used to treat

- Chronic Lymphocytic Leukaemia where treatment with alkylating agents has failed.
- Hairy Cell Leukaemia

LEUSTATIN Injection belongs to a group of medicines known as antimetabolites. It interferes with the production of, and kills, abnormal white blood cells that are causing the leukaemia.

Your doctor may have prescribed LEUSTATIN Injection for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

LEUSTATIN should only be used by a doctor experienced in using this type of medicine.

Before you use LEUSTATIN Injection

LEUSTATIN Injection is only available on a doctor's prescription.

When you must not use it

Do not use LEUSTATIN Injection if

- you have an allergy to LEUSTATIN Injection, or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- you are pregnant
- you are breastfeeding

Do not use LEUSTATIN Injection if the packaging is torn or shows signs of tampering. Do not use LEUSTATIN Injection beyond the expiry date (month and year) printed on the pack.

Before you start to use it

You must tell your doctor if

- you are pregnant or planning to become pregnant
- you are breast feeding or wish to breastfeed
- you are trying to make your partner pregnant

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given LEUSTATIN Injection.

Your doctor will advise you whether or not to have LEUSTATIN Injection or if you need to adjust the dose or adapt your treatment.

Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Do not take vaccines prepared from live microorganisms or functional viruses, because they may increase your risk of infections.

Effects on driving and operating machinery

- You should be careful if you drive or operate machinery

Using LEUSTATIN Injection

How much to use:

Adults

- The usual dose for hairy cell leukaemia is 0.09 mg/kg of your body weight daily for 7 days.
- The usual dose for chronic lymphocytic leukaemia is 0.12 mg/kg of your body weight daily for 5 days.

How to use it:

- LEUSTATIN Injection is given as an infusion into a vein by a doctor or a nurse. The contents of the vial are added to a large volume of a sterile solution of sodium chloride. This diluted solution needs to be prepared under special conditions which your doctor or pharmacist can explain. Once diluted, the solution may be stored at 2-8°C for no more than 8 hours before use.
- For Hairy Cell Leukaemia the diluted solution is infused usually over 24 hours. This is repeated daily for 7 days, to complete the treatment.
- For Chronic Lymphocytic Leukaemia the diluted solution is infused over 2 hours. This is repeated daily for a total of 5 days. Further courses are then usually given at monthly intervals.
- LEUSTATIN Injection is a cytotoxic agent and precautions are necessary when handling, preparing and administering it. The use of disposable gloves and protective garments is recommended. If LEUSTATIN contacts the skin or mucous membranes, wash the involved surface immediately with copious amounts of water.

If you have used too much (overdose)

As LEUSTATIN is being given to you under the supervision of your doctor it is very unlikely you will receive too much. Your doctor or nurse will be closely observing you during this time. If at some later time you feel really unwell and you think LEUSTATIN may be responsible immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: (03) 474 7000

Keep these telephone numbers handy.

While you are using LEUSTATIN Injection

Things you must do

- Always follow your doctor's instructions carefully
- Tell your doctor if you become pregnant while being given LEUSTATIN Injection.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are receiving LEUSTATIN Injection.
- Use effective contraception during treatment with LEUSTATIN, and for 6 months after the last dose of LEUSTATIN.

Things you must not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side Effects

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

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

Because of your condition, your blood may already be weakened so that you are more susceptible to infections, you may be tired because of anaemia and any cuts may take longer to clot and heal. Although LEUSTATIN Injection is selective and kills mainly the leukaemia cells, it may further weaken your blood before strengthening it.

Tell your doctor if you experience any of the following:

- serious bacterial infection of the blood (blood poisoning)
- allergic reactions
- anaemia (illness resulting from the destruction of red blood cells)
- confusion, including disorientation
- liver disease
- swollen runny eyes
- lung disease
- itchy rash
- renal failure

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- symptoms suggestive of infections; numbness and tingling, usually of the hands and feet.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

- Because of the prolonged action of this drug on the body some side effects may occur after the treatment has been completed.

After using LEUSTATIN Injection

Remember to tell your doctor that you are receiving or have received LEUSTATIN, if you have to visit a hospital or your family doctor for any treatment, or to visit a clinic for a blood test. LEUSTATIN may affect the results.

Storage

Keep LEUSTATIN Injection in the pack until it is time to use it.

Keep LEUSTATIN Injection in a cool dry place where the temperature is below 8°C and protect from light.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5m) above the ground is a good place to store medicines.

Do not store LEUSTATIN Injection, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking LEUSTATIN Injection, or your medicine has passed its expiry date, give the medicine to your pharmacist who is experienced in disposing of it.

Product Description

What it looks like

LEUSTATIN Injection is presented as a clear colourless solution in a single dose boxed vial. Each pack contains 1 vial [AUST R 48000].

Ingredients

LEUSTATIN Injection contains cladribine as the entire ingredient, 10 mg in each 10 mL vial.

The product also contains sodium chloride, phosphoric acid and/or dibasic sodium phosphate. It does not contain lactose.

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road Macquarie Park
NSW 2113
Australia
Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

This leaflet was prepared in October 2010.