

LEUSTATIN[®] Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LEUSTATIN Injection?

LEUSTATIN Injection contains the active ingredient cladribine. LEUSTATIN Injection is used to treat Chronic Lymphocytic Leukaemia where treatment with alkylating agents has failed and Hairy Cell Leukaemia. For more information, see Section [1. Why am I using LEUSTATIN Injection?](#) in the full CMI.

2. What should I know before I use LEUSTATIN Injection?

Do not use if you have ever had an allergic reaction to LEUSTATIN Injection or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use LEUSTATIN Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LEUSTATIN Injection and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LEUSTATIN Injection?

- 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.
- LEUSTATIN Injection is given as an infusion into a vein by a doctor or a nurse.

More instructions can be found in Section [4. How do I use LEUSTATIN Injection?](#) in the full CMI.

5. What should I know while using LEUSTATIN Injection?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using LEUSTATIN Injection• If you are about to start taking a new medicine, tell your doctor and pharmacist you are taking LEUSTATIN Injection• Tell your doctor if you become pregnant while being given LEUSTATIN Injection• Use effective contraception during treatment with LEUSTATIN Injection and for 6 months after your last dose
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem similar to yours
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how LEUSTATIN Injection affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store LEUSTATIN Injection in a cool dry place where the temperature is below 8°C and protected from light• Keep LEUSTATIN Injection in a place where children cannot reach

For more information, see Section [5. What should I know while using LEUSTATIN Injection?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details.) Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any very serious side effects which suggest infection; numbness and tingling, usually in the hands and feet. Tell your doctor if you experience blood poisoning, anaemia, allergic reactions, swollen runny eyes, itchy rash, skin rashes, confusion (including disorientation), liver disease, lung disease, or renal failure.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LEUSTATIN[®] Injection

Active ingredient: *Cladribine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LEUSTATIN Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LEUSTATIN Injection.**

Where to find information in this leaflet:

- [1. Why am I using LEUSTATIN Injection?](#)
- [2. What should I know before I use LEUSTATIN Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LEUSTATIN Injection?](#)
- [5. What should I know while using LEUSTATIN Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using LEUSTATIN Injection?

LEUSTATIN Injection contains the active ingredient cladribine. LEUSTATIN 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.

LEUSTATIN Injection is used to treat Chronic Lymphocytic Leukaemia where treatment with alkylating agents has failed and Hairy Cell Leukaemia.

2. What should I know before I use LEUSTATIN Injection?

Warnings

Do not use LEUSTATIN Injection if:

- you are allergic to cladribine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Talk to your doctor if you are trying to make you 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

Some medicines may interfere with LEUSTATIN Injection and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LEUSTATIN Injection.

4. How do I use 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.
- Follow the instructions provided and use LEUSTATIN Injection until your doctor tells you to stop.

How to use LEUSTATIN Injection

- 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.
- 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 Injection contacts the skin or mucous membranes, wash the involved surface immediately with copious amounts of water.

If you use too much LEUSTATIN Injection

As LEUSTATIN Injection 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 Injection may be responsible, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **by calling:**
Australia: 13 11 26
New Zealand: 0800 764 766
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LEUSTATIN Injection?

Things you must do

- Always follow our doctor's instructions carefully
- Tell you 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 Injection, and for 6 months after the last dose of LEUSTATIN Injection.

Remind any doctor, dentist or pharmacist you visit that you are using LEUSTATIN Injection.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LEUSTATIN Injection affects you.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Serious side effects

Serious side effects	What to do
<p>Blood related:</p> <ul style="list-style-type: none">serious bacterial infection of the blood (blood poisoning)anaemia (illness resulting from the destruction of red blood cells) <p>Immune system related:</p> <ul style="list-style-type: none">allergic reactionsswollen runny eyesitchy rash <p>Brain related:</p> <ul style="list-style-type: none">confusion, including disorientation <p>Organ related:</p> <ul style="list-style-type: none">liver diseaselung diseaserenal failure <p>Skin related:</p> <ul style="list-style-type: none">red scaly widespread rash with bumps under the skin (including your skin folds, chest, abdomen, back and arms) and blisters accompanied by feverblistering of the skin, mouth, eyes or genitalssudden red patches and blisters, usually on the palms of hands, soles of feet, and face, with flat, round red 'targets'flu-like symptoms and a rash on the face followed by an extended rash with a high temperature and enlarged lymph nodes	<p>Tell your doctor if you experience any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do
<p>Infection related</p> <ul style="list-style-type: none">symptoms suggestive of infections; numbness and tingling, usually of the hands and feet	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed above may also occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LEUSTATIN Injection contains

Active ingredient (main ingredient)	cladribine, 10 mg in each 10 mL vial
Other ingredients (inactive ingredients)	sodium chloride phosphoric acid and/or dibasic sodium phosphate
Potential allergens	-

Do not take this medicine if you are allergic to any of these ingredients.

What LEUSTATIN Injection 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).

Who distributes LEUSTATIN Injection

Sponsor:

Atnahs Pharma Australia Pty Ltd

Level 10 / 10 Shelley Street, SYDNEY, NSW, 2000

Australia

Distributed in Australia by:

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173

Australia

Free call Australia: 1800 899 005

Distributed in New Zealand by:

Clinect NZ Pty Limited

C/- Ebos Group Limited
108 Wrights Road
Christchurch 8024
New Zealand

Free call New Zealand: 0800 138 803

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