

## 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.

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### 1. Why am I using LITAK?

LITAK contains the active ingredient cladribine. LITAK is used to treat hairy cell leukaemia and lymphoplasmacytic lymphoma (also known as Waldenström's Macroglobulinaemia).

For more information, see Section [1. Why am I using LITAK?](#) in the full CMI.

### 2. What should I know before I use LITAK?

Do not use if you have ever had an allergic reaction to LITAK 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 LITAK?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with LITAK 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 LITAK?

- LITAK should only be administered by a doctor or nurse.

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

### 5. What should I know while using LITAK?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using LITAK.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>• Keep all of your doctor's appointments so that</li></ul>
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	<p>your progress can be checked.</p> <ul style="list-style-type: none"> <li>• Avoid people who have infections.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take any other medicines while using LITAK unless you have discussed this with your doctor or pharmacist.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how LITAK affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep LITAK in its original packaging until it is time to use it.</li> <li>• Store LITAK between 2°C and 8°C.</li> </ul>

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

## 6. Are there any side effects?

**Tell your doctor or nurse if you experience any of the following:** serious bacterial infection of the blood (blood poisoning), allergic reactions, anaemia, confusion, including disorientation, liver disease, swollen runny eyes, lung disease, itchy rash, renal failure, fatigue, headache, dizziness, decreased appetite, weakness/feebleness, and chills, feeling sick,

upset stomach, vomiting, stomach pain, flatulence, constipation, diarrhoea, painful joints, muscle or bone, sleeplessness, anxiety.

**Tell your doctor or nurse as soon as possible if you notice any of the following:** bleeding, bruising more easily than normal, symptoms suggestive of infections; numbness and tingling, usually of the hands and feet, signs of an infection (such as fever, severe chills, sore throat, cough or mouth ulcers), shortness of breath, tiredness, weakness, dizziness, looking pale, difficulty or changes to breathing, yellowing of the skin and/or eyes, skin rash, itchiness, swelling in hands, ankles or feet, any unexplained changes in your behaviour or in your mental and emotional states, any neurological changes such as eye & speech problems or walking.

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.

# LITAK<sup>®</sup>

**Active ingredient:** *cladribine*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using LITAK. **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 LITAK.**

**Where to find information in this leaflet:**

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

## 1. Why am I using LITAK?

**LITAK contains the active ingredient cladribine.** LITAK belongs to a group of medicines called antineoplastic medicines (cytotoxic or chemotherapy agents). This medicine works by helping to stop the uncontrolled increase and abnormal growth of cancer cells.

**LITAK is used to treat:**

- hairy cell leukaemia
- lymphoplasmacytic lymphoma (also known as Waldenström's Macroglobulinaemia)

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

LITAK is only available on a doctor's prescription.

## **2. What should I know before I use LITAK?**

### **Warnings**

#### **Do not use LITAK if:**

- you are allergic to any medicine containing cladribine, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction 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

Always check the ingredients to make sure you can use this medicine.

- you have kidney or liver disease
- you are using other chemotherapy drugs

**Do not give this medicine to a child under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established.

**Check with your doctor if you:**

- are pregnant or planning to become pregnant
- are breastfeeding or wish to breastfeed
- are trying to make your partner pregnant
- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - any allergies
  - any infections
  - kidney disease
  - liver disease
  - a fever

**If you suffer from an infection, this will be treated before treatment with LITAK.**

**Before you start treatment with LITAK and during treatment, you will have regular blood tests to check whether it is safe for you to continue with your treatment.**

**In addition, the function of your liver and your kidneys will be checked.**

**Your doctor may decide that you should receive an additional medicine containing the active substance allopurinol in order to reduce excess of uric acid.**

**If you have not told your doctor about any of the above, tell them before you start receiving LITAK.**

**Your doctor will advise you whether or not to have the LITAK injection or if you need to adjust the dose or adapt your treatment.**

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**

**Do not receive this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking this medicine.**

## **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 and LITAK may interfere with each other. These include:

- medicines which interfere with the process of production of blood cells in the bone marrow
- corticosteroids, medicines used to reduce inflammation or to suppress the immune system

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

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

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

## **4. How do I use LITAK?**

Therapy with LITAK should be initiated by a qualified doctor with experience in cancer chemotherapy.

## How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight. The recommended dosages for the following conditions are:

### Hairy Cell Leukaemia

- **Subcutaneous bolus injection:**

A single course of LITAK is given by subcutaneous bolus injection at a dose of 0.14 mg per kilogram of body weight, per day, for five consecutive days.

- **Intravenous infusion:**

A single course of LITAK is given at a dose of 0.10 mg per kilogram of body weight, per day, for seven consecutive days.

### Lymphoplasmacytic lymphoma

- **Subcutaneous bolus injection:**

A dose of 0.10 mg per kilogram of body weight, per day, for five consecutive days at monthly intervals.

## How it is given

LITAK is injected under your skin (subcutaneous injection) or directly into the veins (intravenous infusion).

LITAK should only be administered by a doctor or nurse.

For subcutaneous bolus injection: the recommended dose is directly withdrawn by a syringe and injected without dilution.

For intravenous infusion: the infusion is prepared daily. The recommended dose is diluted in 500 mL of a 0.9% sodium chloride solution.

LITAK 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 LITAK contacts the skin or mucous membrane, rinse the involved surface immediately with copious amounts of water.

## **How long it is given**

Your doctor will decide how long to continue your treatment with LITAK.

## **If you use too much LITAK**

As LITAK is given to you in hospital under the supervision of your doctor, it is unlikely that you will receive an overdose.

**However, if you experience any side effects after being given LITAK, you should immediately:**

- Tell your doctor or nurse
- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- go to the Emergency Department at your nearest hospital.

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

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea

## **5. What should I know while using LITAK?**

### **Things you should do**

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LITAK.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**
- **If you become pregnant while taking this medicine, tell your doctor immediately.**

You must take adequate contraceptive precautions during therapy and for at least six months after LITAK is no longer being given to you.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

- **Using LITAK can increase your chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk:**
  - avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain, or find it painful or difficult to urinate
  - be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse, or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work
  - be careful not to cut yourself when you are using sharp objects such as a razor or nail clippers
  - avoid contact sports or other situations where you may bruise or get injured

## **Things you should not do**

- **Do not take any other medicines while using LITAK unless you have discussed this with your doctor or pharmacist.**
- This includes medicines you can buy without a prescription from a pharmacy, supermarket, or health food shop.
- 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 LITAK affects you.**

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

## **Looking after your medicine**

**Keep LITAK in its original packaging until it is time to use it.**

**Store LITAK between 2°C and 8°C. Do not store it:**

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

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Getting rid of any unwanted medicine**

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

## 6. Are there any side effects?

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with LITAK.**

As with other medicines that treat cancer, LITAK may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of these side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or nurse 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 LITAK is selective and kills mainly leukaemia cells, it may further weaken your blood before strengthening it.

### **Less serious to Serious side effects**

<b>Less serious to Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• serious bacterial infection of the blood (blood poisoning)</li><li>• allergic reactions</li></ul>	<b>Tell your doctor or nurse if you experience any of the following.</b>

<b>Less serious to Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● anaemia (illness resulting from the destruction of red blood cells)</li> <li>● confusion, including disorientation</li> <li>● liver disease</li> <li>● swollen runny eyes</li> <li>● lung disease</li> <li>● itchy rash</li> <li>● renal failure</li> <li>● fatigue, headache, dizziness, decreased appetite, weakness/ feebleness, and chills</li> <li>● feeling sick, upset stomach</li> <li>● vomiting</li> <li>● stomach pain, flatulence</li> <li>● constipation, diarrhoea</li> <li>● painful joints, muscle or bone</li> <li>● sleeplessness, anxiety</li> </ul>	



## More serious side effects

<b>More serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● bleeding, bruising more easily than normal</li><li>● symptoms suggestive of infections; numbness and tingling, usually of the hands and feet.</li><li>● signs of an infection (such as fever, severe chills, sore throat, cough or mouth ulcers)</li><li>● shortness of breath, tiredness, weakness, dizziness, looking pale</li><li>● difficulty or changes to breathing</li><li>● yellowing of the skin and/or eyes</li><li>● skin rash, itchiness</li><li>● swelling in hands, ankles or feet.</li><li>● any unexplained changes in your behaviour or in your mental and emotional states</li></ul>	<p><b>Tell your doctor or nurse as soon as possible if you notice any of the following.</b></p>

<b>More serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● any neurological changes such as eye &amp; speech problems or walking</li> </ul>	
<ul style="list-style-type: none"> <li>● signs of an allergic reaction (such as those listed at the start of this leaflet)</li> <li>● swelling and burning at site of injection</li> <li>● chest pain</li> <li>● fast heart rate, palpitations, altered heartbeat</li> <li>● You may need urgent medical attention or hospitalisation.</li> </ul>	<p><b>If any of the following happen, tell your doctor or nurse immediately or go to Emergency Department at your nearest hospital.</b></p>

**Tell your doctor or nurse if you notice anything that is 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](http://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 LITAK contains

<b>Active ingredient (main ingredient)</b>	10 mg of cladribine in each 10 mL vial
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium chloride</li><li>• sodium hydroxide or hydrochloric acid to adjust the pH</li><li>• water for injections</li></ul>

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

## **What LITAK looks like**

LITAK is a clear, colourless, odourless solution, preservative-free, isotonic solution.

LITAK is packaged in a 10 mL clear type I glass vial with a grey bromobutyl rubber stopper with a red flip-off aluminium polypropylene cap.

It is available in a pack size of 1 single use vial.

(AUST R 104283).

## **Sponsor**

### **Viatrix Pty Ltd**

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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