

LITAK

cladribine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LITAK. 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 LITAK against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What LITAK is used for

This medicine is used to treat:

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

This medicine 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.

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

Before you are given

LITAKLITAK is only available on a doctor's prescription.

When you must not use it

Do not take LITAK if you have an allergy to:

- any medicine containing cladribine
- 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

Do not take this medicine if you have kidney or liver disease.

Do not take this medicine if you are using other chemotherapy drugs.

Do not receive this medicine if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

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.

Before you start to use it

You must tell your doctor if

- you are pregnant or planning to become pregnant
- you are breastfeeding or wish to breastfeed

- you are trying to make your partner pregnant

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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.

How LITAK is given

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 are given too much (overdose)

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, tell your doctor or nurse immediately or telephone to Poisons Information centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital.

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

While you are being given LITAK

Things you must 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 must 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.

Things to be careful of

Be careful driving or operating machinery 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.

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.

Tell your doctor or nurse 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
- 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 behavior or in your mental and emotional states
- any neurological changes such as eye & speech problems or walking

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- signs of an allergic reaction (such as those listed at the start of this leaflet)
- swelling and burning at site of injection
- chest pain
- fast heart rate, palpitations, altered heartbeat

You may need urgent medical attention or hospitalisation.

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.

After using LITAK

Storage

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

Store LITAK between 2°C and 8°C. Do not store LITAK or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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.

Product description

What it looks like

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

LITAK is packaged in a 10 mL glass vial with a teflonised rubber closure and flip-off aluminium cap.

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

Ingredients

LITAK contains cladribine as the active ingredient, 10 mg in each 10 mL vial.

It also contains the following inactive ingredients:

- sodium chloride
- sodium hydroxide or hydrochloric acid to adjust the pH
- water for injections

Distributor

LITAK is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

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