

Consumer Medicine Information

What is this leaflet

This leaflet answers some common questions about LITAK solution for injection. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of you being given LITAK against the benefits they expect it will have for you.

If you have any concerns about being given LITAK, ask your doctor or pharmacist.

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

What is LITAK used for

LITAK solution for injection is used to treat certain types of cancers; hairy cell leukaemia and lymphoplasmacytic lymphoma (also known as Waldenström's Macroglobulinaemia).

LITAK contains the active ingredient, cladribine. Cladribine belongs to a group of medicines called antineoplastic (cytotoxic, or chemotherapy agents). These agents are used to treat cancer.

LITAK helps to stop the uncontrolled increase and abnormal growth of cancer cells.

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

Your doctor may have prescribed LITAK for another use.

LITAK is not addictive.

Before you are given it

LITAK solution for injection is not suitable for everyone.

When you must not be given it

Do not use LITAK if you are:

- allergic to cladribine or any of the other ingredients listed at the end of this leaflet.
Symptoms of an allergic reaction to LITAK may include shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest; swelling of the face, lips tongue or other parts of the body; rash, itching, hives or flushed, red skin; dizziness or light headedness.

Do not use LITAK if you are pregnant or intend to become pregnant.

If there is any need to consider LITAK during pregnancy, your doctor will discuss with you the benefits and risks of using it.

Do not use LITAK if you are breastfeeding or intend to breastfeed.

LITAK is not recommended for use in children.

Before you are given it

Tell your doctor if you:

- have any allergies.
- are pregnant or intend to become pregnant
- are breastfeeding or planning to breastfeed

- have or have had any of the following medical conditions:
 - infections
 - fever
 - liver disease
 - kidney disease.

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 proper 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.

Taking other medicines

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

Medicines that interfere with the process of production of blood cells in the bone marrow should not be used together with LITAK unless advised by your doctor.

How LITAK is given

Therapy with LITAK solution for injection 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 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 kg body weight per day for five consecutive days.

Intravenous infusion

A single course of LITAK is given by 0.10 mg per kg body weight per day for seven consecutive days.

Lymphoplasmacytic lymphoma

Subcutaneous bolus injection

A dose of 0.10 mg per kg body weight per day of LITAK for five consecutive days is given by subcutaneous bolus injection 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 given by a doctor or nurse.

It should be handled with caution.

Avoid contact by pregnant women.

The use of disposable gloves and protective garments is recommended when handling and administering LITAK. If LITAK contacts the skin or mucous membrane, rinse

the involved surface immediately with copious amounts of water.

For subcutaneous bolus injection

The recommended dose is directly withdrawn by a syringe and injected without dilution.

For intravenous infusion

The fresh infusion is prepared daily. The recommended dose is diluted in 500 mL of 0.9% sodium chloride. The ready-to-use solution may be stored refrigerated between 2°C and 8°C for not more than 8 hours prior to administration.

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 immediately or go to Accident and Emergency at your nearest hospital.

Symptoms of a LITAK overdose include the side effects listed below in the Side Effects section, but are usually of a more severe nature.

While you are being given it

Things you must do

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

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and to check for any unwanted side effects.

Tell all doctors, dentists and pharmacists who are treating you that you are having treatment with LITAK.

Remind them if any new medicines are about to be started, or if you are about to have a medical or dental procedure.

If pregnancy occurs during your treatment, you must immediately inform your doctor.

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

LITAK can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- 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 cutters.
- avoid contact sports or other situations where you may bruise or get injured.

Things that you must not do

Do not use 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.

Things to be careful of

Be careful driving or operating machinery until you know how LITAK affects you.

This medicine may cause dizziness, drowsiness or tiredness 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, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with LITAK.

Like 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 the side effects.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- 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.

These are the more common side effects of LITAK. They are usually mild.

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

- bleeding, bruising more easily than normal
- 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.

These may be serious side effects. You may need medical attention.

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 heart beat.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

LITAK solution for injection will be stored in the pharmacy or on the hospital ward.

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

Store LITAK at 2°C to 8°C (Refrigerate. Do not freeze).

Keep LITAK where children cannot reach it.

Product description

What LITAK looks like

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

LITAK is packaged in a 10 mL neutral glass type I vial with a teflonised rubber closure and flip-off aluminium cap, for single-use only.

It is available in pack sizes of 1 single vial.

Ingredients

LITAK contains 10 mg of cladribine in 5 mL of solution (2 mg/mL).

It also contains sodium chloride and water for injections.

Sponsor

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