PACKAGE LEAFLET: INFORMATION FOR THE USER

LITAK 2 mg/ml solution for injection
cladribine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LITAK is and what it is used for
2. What you need to know before you use LITAK
3. How to use LITAK
4. Possible side effects
5. How to store LITAK
6. Contents of the pack and other information

1. What LITAK is and what it is used for

LITAK contains the active substance cladribine. Cladribine is a cytostatic agent. It affects the growth of malignant (cancerous) white blood cells which play a role in hairy cell leukaemia. LITAK is used to treat this disease.

2. What you need to know before you use LITAK

Do not use LITAK
- if you are allergic to cladribine or any of the other ingredients of LITAK (listed in section 6)
- if you are pregnant or breast-feeding
- if you are less than 18 years of age
- if you have moderate to severe kidney or liver impairment
- if you are using other medicines which affect the production of blood cells in the bone marrow (myelosuppression).

Warnings and precautions
Talk to your doctor or pharmacist before using LITAK.

At any time during or after your treatment, **tell your doctor or nurse immediately** if you:
experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a **serious and potentially fatal brain condition** known as progressive multifocal leukoencephalopathy **(PML)**.

If you had these symptoms prior to treatment with cladribine, **tell your doctor** about any change in these symptoms.

Tell your doctor if you have or have had:
- liver or kidney problems
- **infections**
  - if you suffer from an infection, this will be treated before you start using LITAK.
  - if you notice any signs of infections (such as flu-like symptoms or fever) during or after treatment with LITAK, inform your doctor immediately.
- fever

Before and during treatment with LITAK, you will have regular blood tests to check whether it is safe for you to continue with your treatment. Your doctor may decide that you should receive blood transfusions to improve your level of blood cells. In addition, the proper function of your liver and your kidneys will be checked.

If you want to father a child, please tell your doctor before treatment with LITAK is started. You should not father a child during treatment and up to 6 months after treatment with LITAK. Your doctor may advise you about the possibility to store deep-frozen sperm (cryoconservation).

Other medicines and LITAK
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell your doctor if you are using any medicines containing:
- corticosteroids, commonly used to treat inflammation
- antiviral agents, used to treat viral infections

You must not use LITAK with other medicines that affect the production of blood cells in the bone marrow (myelosuppression).

Pregnancy and breast-feeding
You must not use LITAK if you are pregnant. You must take adequate contraceptive precautions during therapy and for at least six months after your last LITAK dose. If pregnancy occurs during your treatment, you must immediately inform your doctor.

You must not breast-feed while you are treated with LITAK and for at least six months after your last LITAK dose.

Driving and using machines
LITAK has a major effect on the ability to drive and use machines. If you feel drowsy, which may occur due to a low number of red blood cells caused by LITAK treatment, or dizzy, you should not drive or use machines.

3. How to use LITAK

Always use LITAK as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will calculate your dose according to your body weight and explain the treatment schedule in detail. The recommended daily dose is 0.14 mg per kg body weight for five consecutive days (single treatment course).

LITAK has to be injected under your skin (subcutaneous injection), at about the same time each day. If you are injecting LITAK yourself, first you must receive adequate training by your doctor or nurse. You will find detailed instructions for injection at the end of this leaflet.

You may also receive an additional medicine containing the active substance allopurinol in order to reduce excess of uric acid.

If you use more LITAK than you should
In case you inject an incorrect dose, tell your doctor immediately.

If you forget to use LITAK
Do not inject a double dose to make up for a forgotten dose. In case you miss an injection of a dose, tell your doctor immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, LITAK can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have any of the following during or after treatment with LITAK:
- any signs of infections (such as flu-like symptoms)
- fever

Repeated occurrence of malignant (cancerous) disease cannot be excluded. This means that the risk that you develop a malignant disease in the future is slightly higher than for healthy people. This slightly increased risk can be due to hairy cell leukaemia or to therapies used to treat the disease including LITAK.

The following side effects may occur:

Very common side effects (may affect more than 1 in 10 people)
- Infections.
- Fever.
- Low numbers of certain white blood cells (neutrophils and lymphocytes) and platelets in blood tests.
- Low number of red blood cells, which may result in anaemia, with symptoms such as tiredness and drowsiness.
- Reduced function of your body's immune system.
- Headache, dizziness.
- Abnormal breath sounds, abnormal chest sounds, cough.
- Feeling sick, vomiting, constipation and diarrhoea.
- Skin eruption (rash), swelling, redness as well as soreness around the site of injection, sweating. Skin reactions are mostly mild to moderate and usually resolve within a few days.
- Tiredness, chills, decreased appetite.
- Weakness.

Common side effects (may affect up to 1 in 10 people)
- Repeated occurrence of malignant (cancerous) disease.
- Low number of platelets, which can cause unusual bleeding (for example nose or skin bleeds).
- Sleeplessness, anxiety.
- Increased heart rate, abnormal heart sound, low blood pressure, decreased blood supply to the heart muscle.
- Shortness of breath, swelling in lung tissue due to infection, inflammation of mouth and tongue.
- Abdominal pain and presence of excessive amount of gas in the stomach or bowels, mostly mild increases in liver laboratory values (bilirubin, transaminases) which will return to normal values once treatment is over.
- Itching, itching skin eruption (urticaria), redness of the skin and skin pain.
- Swelling in tissues (oedema), not feeling well, pain (muscle pain, joint pain, and bone pain).

Uncommon side effects (may affect up to 1 in 100 people)
- Anaemia caused by destruction of red blood cells.
- Sleepiness, numbness and tingling of the skin, feebleness, inactivity, disorder of peripheral nerves, confusion, impaired ability to coordinate movements.
- Eye inflammation.
- Sore throat.
- Inflammation of a vein.
- Severe weight loss.

Rare side effects (may affect up to 1 in 1.000 people)
- Reduced liver function.
- Reduced kidney function.
- Complications caused by cancer treatment due to break-down of cancer cells.
- Rejection response to blood transfusions.
- Increased number of certain white blood cells (eosinophils).
- Stroke.
- Disturbances in speech and swallowing.
- Heart failure.
- Abnormal heart rhythm.
- Inability of the heart to maintain adequate blood circulation.
- Obstruction of the bowels.
- Serious allergic skin reaction (Stevens-Johnson syndrome or Lyell syndrome).

Very rare side effects (may affect up to 1 in 10.000 people)
- Depression, epileptic attack.
- Swelling of the eyelid.
- Blood clot in the lung.
- Inflammation of the gallbladder.
- Reduced function of organs due to high amounts of a specific substance produced by the body (a glycoprotein).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LITAK

Keep out of the sight and reach of children.

Store in a refrigerator (2°C-8°C). Do not freeze.

Do not use LITAK after the expiry date which is stated on the vial label and the outer carton after EXP. The expiry date refers to the last day of that month.

From a microbiological point of view, unless the opening precludes the risk of microbiological contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use LITAK if you notice that the vial is damaged or that the solution is not clear or contains any particles.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What LITAK contains
- The active substance is cladribine. Each ml solution contains 2 mg cladribine. Each vial contains 10 mg cladribine in 5 ml solution.
- The other ingredients are sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

What LITAK looks like and contents of the pack
LITAK is available in glass vials containing 5 ml of clear, colourless solution for injection.
Pack size of 1 or 5 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Lipomed GmbH
Hegenheimer Strasse 2
79576 Weil am Rhein
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last revised in November 2022.

INSTRUCTIONS FOR INJECTION

This section contains information on how to give an injection of LITAK. It is important that you do not try to give yourself the injection unless you have been instructed by your doctor or nurse. Your doctor will tell you how much LITAK you need and how often and when you have to inject yourself. LITAK should be injected into the tissue just under the skin (subcutaneous injection). If you have any question with regard to giving the injection, please ask your doctor or nurse for help.

LITAK is a cytotoxic and should therefore be handled with caution. When LITAK is not self-administered by the patient, the use of disposable gloves and protective garments is recommended when handling and administering LITAK. If LITAK contacts the skin or eyes, rinse the involved surface immediately with copious amounts of water. Pregnant women must avoid contact with LITAK.

What do I need for the injection?

To give yourself a subcutaneous injection, you will need:

- one vial of LITAK (or two vials if you need to inject more than 5 ml).

Do not use vials which are damaged, or if the solution is not clear or if it contains any particles.

- one sterile syringe (e.g. 10 ml LUER syringe),
- one sterile injection needle (e.g. 0.5 x 19 mm, 25 G x ¾’’),
- alcohol wipes,
- a puncture-proof container for safe disposal of the used syringe.

What should I do before I give myself a subcutaneous injection of LITAK?

1. Before injection, allow LITAK to warm up to room temperature.

2. Wash your hands thoroughly.

3. Find a comfortable, well-lit place and put everything you need where you can reach it.

How do I prepare the injection?

Before you inject LITAK, you must do the following:

1. Remove the red protective cap from the LITAK vial. Do not remove the rubber stopper of the vial. Clean the rubber top of the vial with an alcohol wipe. Remove the syringe from the wrapping without touching the tip of the syringe. Remove the injection needle from the wrapping and place it firmly on the tip of the syringe. Remove the needle guard without touching the needle.

2. Push the needle through the rubber stopper of the vial and turn the vial and the syringe upside down. Be sure that the tip of the needle is in the solution.

3. Draw the correct volume of LITAK into the syringe by pulling back the plunger (your doctor will inform you how many ml of LITAK you need to inject).

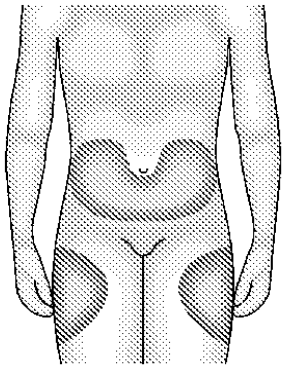
4. Pull the needle out of the vial.

5. Make sure there is no air left in the syringe: point the needle upwards and push the air out.

6. Check you have the right volume.

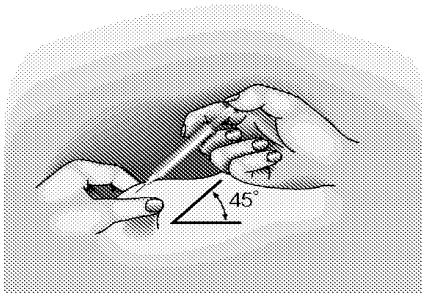
7. Inject straight away.

Where should I give my injection?



The most suitable places to inject yourself are shown here: the top of your thighs and the abdomen, except for the area around the navel. If someone else is injecting you, they can also use the outer surface of the upper arms or the buttocks.

How do I give my injection?



1. Disinfect your skin by using an alcohol wipe, wait for the area to dry and pinch the skin between your thumb and forefinger, without squeezing it.

2. Put the needle fully into the skin at an angle of about 45°, as shown in the picture.

3. Pull slightly on the plunger to check that no blood vessel has been punctured. If you see blood in the syringe, remove the needle and re-insert it in another place.

4. Inject the liquid slowly and evenly for approximately one minute, always keeping the skin pinched.

5. After injecting the liquid, remove the needle.

6. Put the used syringe in the puncture-proof container. Use a new syringe and injection needle for each injection. The vials are for single use only. Return any portion of the contents remaining after use to your doctor or pharmacist for proper disposal.

Disposing of used syringes

Put used syringes into a puncture-proof container and keep it out of the reach and sight of children.

Dispose the puncture-proof container as instructed by your doctor, nurse or pharmacist.

Do not put used syringes into the normal household garbage bin.