PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LITAK ® 10 (solution for injection)

Cladribine, 10 mg

Read all of this leaflet carefully before you are given LITAK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

LITAK has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LITAK is and what it is used for.
2. What you need to know before you are given LITAK.
3. How to receive 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 has been prescribed by your doctor for the treatment of hairy cell leukaemia, a malignant disease of white blood cells.

2. What you need to know before receiving LITAK

Do not receive LITAK:

- if you are hypersensitive (allergic) to cladribine or to any of the other ingredients in LITAK;
- if you are pregnant or breastfeeding;
- 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

At any time during or after your treatment, tell your healthcare professional 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 LITAK, tell your doctor about any change in these symptoms.

Tell your doctor or if you have or had:

- liver disease;
- kidney disease;
- infection;
- fever.

You should know before receiving LITAK that your treatment with LITAK has been prescribed by a qualified doctor experienced in cancer chemotherapy. If you suffer from an infection, this will be treated before treatment with LITAK. If you notice any signs of fever or infections (such as flu-like symptoms) during or after treatment with LITAK, be sure to inform your doctor immediately.

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 blood transfusions or that you should receive an additional medicine containing the active substance allopurinol in order to reduce excess of uric acid.

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

Other medicines and LITAK

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Take special care with LITAK if you are using any other medicines that affect the production of blood cells (e.g. other anti-cancer medicines or steroids).

Tell your doctor if you are taking any of the following medicines:

- if you are using any other medicines which have been prescribed by a doctor for any other condition (e.g. antiviral medicines),
- if you are using corticosteroids, used to treat inflammation.

Pregnancy, ~~and~~ breastfeeding and fertility

If you are pregnant or breastfeeding you must inform your doctor, pharmacist or healthcare professional before being treated with LITAK.

Your doctor will decide whether you should be treated with LITAK.

- LITAK must not be used if you are pregnant or if you are planning to become pregnant since it may cause harm to the unborn baby.
- You must take adequate contraceptive precautions during therapy and for at least six months after LITAK is no longer administered to you.
- If pregnancy occurs during your treatment, you must immediately inform your doctor.
- You must not breastfeed while you are treated with LITAK, as LITAK may be excreted into breastmilk.

Driving and using machinery

LITAK may cause dwowsiness or dizziness and have a major effect onmental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment *(see section 4 'Possible side effects').*

It is not always possible to predict to what extent LITAK may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LITAK affects them.

3. How to use LITAK

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself LITAK. It will be given to you by a person who is qualified to do so.

The usual dose is:

- LITAK will be injected under your skin (subcutaneous use).

- LITAK should be injected at about the same time each day.
- The correct dosage will be calculated by your doctor and the treatment schedule will be explained to you in detail.
- The dosage depends on your body weight. The recommended dosage is a single course of LITAK at a dose of 0,14 mg per kg body weight per day for five consecutive days.
- LITAK is supplied as ready-to-use solution for subcutaneous injection. The recommended dose is directly withdrawn by a syringe and injected without dilution.
- Allow LITAK to warm up to room temperature before administration.
- Do not use vials which are damaged, or if the solution is not clear or if it contains any particles.
- LITAK 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 eyes, rinse the involved surface immediately with copious amounts of water.
- LITAK should not be mixed with other medicines.

Your doctor will tell you how long your treatment with LITAK will last.

If you have the impression that the effect of LITAK is too strong or too weak, tell your doctor or pharmacist.

If you use more LITAK than you should

Since a healthcare professional will administer LITAK, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of LITAK

Since a healthcare professional will administer LITAK, it is unlikely that the dose will be missed.

4. Possible side effects

LITAK can have side effects.

Not all side effects reported for LITAK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LITAK, please consult your healthcare professional for advice.

If any of the following happens, stop taking LITAK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- any signs of infections (such as flu-like symptoms);
- fever;
- serious allergic skin reaction (Stevens-Johnson syndrome or Lyell syndrome).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LITAK. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Abnormal breath sounds, abnormal chest sounds, cough.

- Skin eruption (rash), swelling, redness as well as soreness around the site of injection, sweating and skin pain. Skin reactions are mostly mild to moderate and usually resolve within a few days.
- Increased heart rate, abnormal heart sound, low blood pressure, decreased blood supply to the heart muscle.
- Shortness of breath, cough, swelling in lung tissue due to infection, inflammation of mouth and tongue.
- Sleepiness, numbness and tingling of the skin, feebleness, inactivity, disorder of peripheral nerves, confusion, impaired ability to coordinate movements.
- Depression, epileptic attack.
- Blood clot in the lung with symptoms such as shortness of breath, chest pain, cough, irregular heartbeat and dizziness.
- Reduced function of organs due to high amounts of a specific substance produced by the body (a glycoprotein).
- Stroke.
- Disturbances in speech and swallowing.
- Heart failure.
- Abnormal heart rhythm.
- Inability of the heart to maintain adequate blood circulation.
- Obstruction of the bowels.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Low numbers of certain white blood cells (neutrophils and lymphocytes) and platelets in blood tests. The lower number of platelets can cause unusual bleeding (for example nose or skin bleeds).
- 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.
- Feeling sick, vomiting, constipation and diarrhoea.
- Tiredness, chills, decreased appetite.
- Weakness.
- Sleeplessness, anxiety.
- 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.
- Swelling in tissues (oedema), not feeling well, pain (muscle pain, joint pain, and bone pain).

The following side effects have been reported less frequently:

- Anaemia (low red blood cell count), caused by destruction of red blood cells.
- Rejection response to blood transfusions.
- Eye inflammation.
- Swelling of the eyelid.
- Sore throat.
- Inflammation of the gallbladder.
- Reduced liver function.
- Reduced kidney function.

- Inflammation of a vein.
- Severe weight loss (malnutrition).
- Complications caused by cancer treatment due to break-down of cancer cells.
- Increased number of certain white blood cells (eosinophils).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LITAK.

5. How to store LITAK

- Store between +2 and +8 °C.
- Solutions prepared for I.V. administration may be stored refrigerated between 2 °C and 8 °C for not more than 8 hours prior to administration.
- Do not freeze.
- Any remaining solution after administration must be discarded.
- Do not store in a bathroom.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use LITAK after the expiry date stated on the vial label and the outer carton.
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What LITAK contains:

- The active substance is:

  Each 5 ml vial contains 10 mg of cladribine.

- The other ingredients are:

Sodium chloride

Water for injections

Sugar free

What LITAK looks like and contents of the pack

Clear colourless odourless solution.

5 ml solution in a 10 ml clear neutral Type I glass vial with a bromobutyl stopper and sealed with an aluminium cap. One or five vials are packed in a cardboard carton.

Holder of Certificate of Registration and Manufacturer

KEY ONCOLOGICS (PTY) LTD

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Can be obtained on the SAHPRA website

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