

PACKAGE LEAFLET: INFORMATION FOR THE USER

Leustat[®] Subcutaneous 2 mg/ml solution for injection Cladribine

Leustat is a registered trademark.

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again. It may be helpful to ask your partner or carer to read it as well
- If you have any further questions, ask your doctor or nurse
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse

What is in this leaflet:

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

1. What Leustat Subcutaneous is and what it is used for

Leustat Subcutaneous contains a medicine called cladribine. This belongs to a group of medicines used to treat cancer (called 'cytotoxic drugs').

Leustat Subcutaneous is for:

- An illness caused by the abnormal growth of white blood cells. This is called 'hairy cell leukaemia'
- An illness caused by the abnormal growth of a type of white blood cell called 'lymphocytes'. This illness is called 'B-cell chronic lymphocytic leukaemia'. In this case, Leustat Subcutaneous is used when the first treatment (called an 'alkylating agent') has not worked or has stopped working.

Leustat Subcutaneous works by killing abnormal white blood cells.

2. What you need to know before Leustat Subcutaneous is given

Do not have Leustat Subcutaneous if:

- You are allergic to anything in Leustat Subcutaneous (listed in section 6).

Take special care

Talk to your doctor before you are given Leustat Subcutaneous if:

- You are suffering from any infection or fever
- You have ever had kidney or liver problems
- You have ever had bone marrow or blood problems

You may still be able to have Leustat Subcutaneous, but you should discuss this with your doctor first.

Warnings and precautions

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular tell your doctor if you are already taking or are to be given:

- Medicines which reduce blood cell formation in the bone marrow (known as myelosuppression)
- A live vaccine while being treated with Leustat Subcutaneous
- Other medicines for the treatment of leukaemia, such as fludarabine or pentostatin (also known as deoxycytosine)
- Medicines to treat viral infections including HIV (such as didanosine, tenofovir, adefovir)

Blood tests

- Your doctor will arrange regular blood tests before and during your treatment. The blood tests check that your liver and kidneys are working properly. They also check how the Leustat Subcutaneous treatment is working
- If you visit another hospital or your family doctor for a blood test, tell them that you have been given Leustat Subcutaneous. This is because Leustat Subcutaneous may affect the result of blood tests

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant, think you may be pregnant or might become pregnant. This is because it may affect the baby.

You must use effective contraception while you are being treated with Leustat Subcutaneous and for 6 months after your treatment ends. Ask your doctor or pharmacist for advice.

You must not breast-feed while you are being treated with Leustat Subcutaneous, or for 6 months after your treatment ends.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Family planning

Men should not father a child until at least 3 months after the last dose of Leustat Subcutaneous.

Driving or using machines

Your illness and its treatment may affect you being able to drive. Do not drive or use any tools or machines without discussing this with your doctor first.

3. How Leustat Subcutaneous is given

Always use Leustat Subcutaneous in 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.

Hairy-cell leukaemia

The recommended daily dose is 0.14 mg per kg body weight for five consecutive days (single treatment course).

B-cell chronic lymphocytic leukaemia

The recommended daily dose is 0.1 mg per kg body weight for five consecutive days (single treatment course).

Leustat Subcutaneous in has to be injected under your skin (subcutaneous injection), at about the same time each day. If you are injecting Leustat Subcutaneous in 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.

Children

Leustat Subcutaneous has not been fully tested for use in children.

If you use more Leustat Subcutaneous than you should

In case you inject an incorrect dose, tell your doctor immediately.

If you forget to use Leustat Subcutaneous

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, Leustat Subcutaneous can cause side effects, although not everybody gets them. Some side effects may be the same as symptoms of the illness. Your doctor may decide to delay or stop using Leustat Subcutaneous if you get side effects.

Tell your doctor or nurse straight away if you notice any of the following serious side effects. You may need urgent medical treatment.

- The sudden appearance of rash, itching, hives (also known as nettle rash or urticaria), swollen face or lips, or shortness of breath. These may be signs of an allergic reaction.
- Fever and chills (affects more than 1 in 10 people). These may be the first signs that you have an infection. The infection may happen because of a fall in the number of white blood cells (neutropenia). Some infections are more common than others. Infection can happen anywhere in your body including:
 - Your chest (cough, shortness of breath or difficulty breathing, noisy breathing, pneumonia)
 - Your urinary system (pain or discomfort on passing water)
 - Your skin (bacterial, fungal or viral infections that may leave the skin tender, hot or red)
 - Your mouth (a fungal infection called thrush)
 - Your gut (infection or inflammation of the intestines)
 - Your blood (septicaemia)
- Easier bruising and bleeding under the skin (thrombocytopenia) or red or purple spots under the skin (petechiae), or more bleeding than usual after injury. This can be caused by a fall in the number of small blood cells called platelets (affects more than 1 in 10 people) or problems with blood clotting.
- Feeling weak or breathless. This can be caused by a fall in the number of red blood cells (anaemia). The anaemia may be severe (affects more than 1 in 10 people)
- Build-up of fluid under the skin called oedema (affects more than 1 in 10 people)
- Swelling and clotting in a vein called phlebitis (affects less than 1 in 10 people)

- Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals) (affects less than 1 in 100 people)
- Tumour lysis syndrome (a serious condition resulting from breakdown of tumour cells. This can lead to heart and kidney problems, weakness and fits) (affects less than 1 in 100 people)
- Leustat Subcutaneous may increase the risk of developing another cancer in the future

Tell your doctor or nurse at your next appointment if you notice any of the following side effects:

Very common (affects more than 1 in 10 people)

- Feeling dizzy or tired
- Headache
- Rash, sweating
- Feeling sick (nausea), being sick (vomiting)
- Redness, swelling or pain where the injection was given

Common (affects less than 1 in 10 people)

- Faster heart beat
- Reduced blood flow to the heart muscle
- Stomach pain or wind (flatulence)
- Having less appetite
- Constipation or diarrhoea
- Joint pain, muscle pains or weakness
- Generalised pain
- Anxiety or difficulty sleeping (insomnia)
- Itching (pruritus)
- Conjunctivitis
- Generally feeling unwell

Uncommon (affects less than 1 in 100 people)

- A problem that affects the body being able to produce white blood cells, red blood cells and small blood cells (platelets). The effects may need further treatment
- An increase in a particular type of white blood cell (eosinophil)
- A decrease in the ability of your kidneys being able to get rid of waste products from the blood, and a decrease in urine production
- Serious nerve damage. The effects include partial or complete paralysis and may be permanent
- An increase in liver enzymes (shown in blood tests)
- Confusion, reduced consciousness, co-ordination problems (ataxia)
- A red, irritated and painful eye
- Shingles

Rare (affects less than 1 in 1,000 people)

- Heart failure
- Irregular heart beat

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 at: 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 Leustat Subcutaneous

- Keep out of the sight and reach of children.
- Store in a refrigerator (2°C-8°C). Do not freeze.
- Do not use Leustat Subcutaneous 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 Leustat Subcutaneous 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 Leustat Subcutaneous 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 Leustat Subcutaneous looks like and contents of the pack

Leustat Subcutaneous 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

Atnahs Pharma UK Limited,
Sovereign House,
Miles Gray Road, Basildon,
Essex, SS14 3FR,
United Kingdom.

Manufacturer

Pharma Pack Hungary Kft.
Building B, Raktarvarosi Ut 9 Torokbalint, 2045
Hungary

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INSTRUCTIONS FOR INJECTION

This section contains information on how to give an injection of Leustat Subcutaneous. 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 Leustat Subcutaneous you need and how often and when you have to inject yourself. Leustat Subcutaneous 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.

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

What do I need for the injection?

To give yourself a subcutaneous injection, you will need:

- one vial of Leustat Subcutaneous (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 3/4''),
- 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 Leustat Subcutaneous?

1. Before injection, allow Leustat Subcutaneous 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.

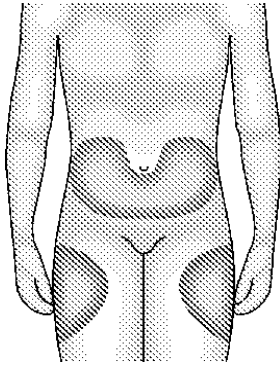
How do I prepare the injection?

Before you inject Leustat Subcutaneous, you must do the following:

1. Remove the red protective cap from the Leustat Subcutaneous 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.

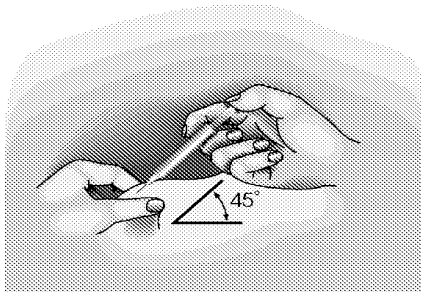
2. Push the needle through the rubber stopper of the vial and turn the vial and the syringe upside down. Be sure that the tip of the needle is in the solution.
3. Draw the correct volume of Leustat Subcutaneous into the syringe by pulling back the plunger (your doctor will inform you how many ml of Leustat Subcutaneous 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.