PACKAGE LEAFLET: INFORMATION FOR THE USER

Leustat® 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

In this leaflet

1. What Leustat is and what it is used for

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

Leustat 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 is used when the first treatment (called an 'alkylating agent') has not worked or has stopped working

Leustat works by killing abnormal white blood cells.

2. Before you are given Leustat

Do not have Leustat if:
- You are allergic to anything in Leustat (listed in section 6).

Take special care
Talk to your doctor before you are given Leustat 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, 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
- Other medicines for the treatment of leukaemia, such as fludarabine or pentostatin (also known as deoxycoformycin)
- 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 treatment is working
- If you visit another hospital or your family doctor for a blood test, tell them that you have been given Leustat. This is because Leustat 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 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, 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 6 months after the last dose of Leustat.

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.

Important information about an ingredient of Leustat
If you need to control your salt intake (controlled sodium diet) be aware that:
- This medicine contains 38.2 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.91% of the recommended maximum daily dietary intake of sodium for an adult.
- The contents of the vial are diluted in a salt solution (called 'saline') before being given to you. This salt solution also contains sodium

3. How Leustat is used

Leustat is put in a drip and given slowly into a vein. It is normally diluted in a salt solution (called 'saline'). A doctor experienced in using this type of medicine will give it to you. Check with your doctor or nurse if you are not sure about anything.

Adults and the elderly
The dose of Leustat is based on your body weight in kilograms.

For abnormal growth of hairy white blood cells:
- The usual dose is 0.09 mg per kilogram each day
- The dose is given over 24 hours every day for 7 days, without a break

For abnormal growth of lymphocyte white blood cells:
- The usual dose is 0.12 mg per kilogram each day
- The dose is given every day for 5 days
- Each dose is normally given over 2 hours
- The 5 day course is repeated every 28 days
- You can receive a maximum of 6 of these courses

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

If you have too much Leustat
Tell your doctor or nurse straight away if you think you have been given too much Leustat.

4. Possible side effects

Like all medicines, Leustat 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 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 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 Leustat is stored

The vials are stored unopened in a hospital refrigerator where children can't see or reach them. Vials should be protected from light.

Do not use Leustat after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not use Leustat if:
- The seal is broken or a dose has already been taken from the vial
- The liquid is coloured or you can see particles floating in it
- It has been diluted and refrigerated for more than 8 hours
- It has been diluted with a solution of 5% dextrose

6. Further information

The active substance in Leustat is cladribine (1 mg/ml).

The other ingredients are sodium chloride, phosphoric acid, dibasic sodium phosphate heptahydrate and water for injection.

What Leustat looks like and contents of the pack

Leustat is supplied in a clear glass vial containing 10 ml of a clear, colourless liquid.

The product licence is held by:
Atnahs Pharma UK Limited., Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom.

Leustat is made by:
Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

Eurofins Analytical Services Hungary Kft., Kerulet, Anonymus utca 6/IV, IV Kerulet, Budapest, 1045, Hungary.

For information in large print, tape, CD or Braille, telephone 0800 198 5000 (UK only).

This leaflet was last revised in June 2023