LEUNASE(R)

asparaginase (colaspase)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LEUNASE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given LEUNASE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

What LEUNASE is used for

LEUNASE is used to treat leukaemia and some types of cancer.

LEUNASE works by slowing or stopping the growth of cancer.

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

Your doctor may have prescribed LEUNASE for another reason.

LEUNASE is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given LEUNASE

When you must not be given LEUNASE

You must not be given LEUNASE if you have an allergy to:

* Asparaginase (colaspase), the drug known as LEUNASE

Symptoms of an allergic reaction to LEUNASE may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You must not be given LEUNASE if you have or have had pancreatitis, an infection or inflammation of the pancreas.

You must not be given LEUNASE if you are pregnant or intend to become pregnant.

LEUNASE may affect your developing baby if you take it during pregnancy.

Do not breast-feed while you are being given LEUNASE.

If you are not sure whether you should start being given LEUNASE, talk to your doctor.

Before you are given LEUNASE

Tell your doctor if you have had LEUNASE before.

Your doctor may test you for an allergic reaction to LEUNASE. A small test dose is injected under the skin and observed for several hours to see if you have a reaction to

LEUNASE.

Tell your doctor if you have allergies to:

- any other medicines
- * any other substances, such as foods, preservatives or dyes

Tell your doctor if you have or have had any medical conditions, especially the following:

- * pancreatitis, an infection or inflammation of the pancreas
- * liver problems (cirrhosis)
- * Gout (high levels of uric acid in the blood)
- * diabetes
- * if you have been vaccinated recently
- * AIDS or HIV positive
- * are suffering from any type of infection

Tell your doctor if you are breast-feeding or plan to breast-feed.

If you have not told your doctor about any of the above, tell them before you are given LEUNASE.

Taking other medicines

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

Some medicines and LEUNASE may interfere with each other. These include:

- * other medicines used to treat leukaemia or cancer
- prednisone, a steroid used to treat infections

 * allopurinol or probenecid, drugs used to treat gout or high levels of uric acid in the blood

These medicines may be affected by LEUNASE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given LEUNASE.

How LEUNASE is given

LEUNASE is diluted and given intravenously.

LEUNASE must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive LEUNASE.

Overdose

As LEUNASE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given LEUNASE, tell your doctor immediately.

You may need urgent medical attention.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given LEUNASE.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if any of the following happen.

* sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

- * fever
- * nausea, vomiting, loss of appetite, diarrhoea, stomach cramps and weight loss.
- depression, irritability and feeling generally unwell
- * urination disturbances
- pain in the joints or uncontrolled shaking
- * disorientation
- * loss of consciousness
- * sleeping disturbances
- headache, seizures, altered mental status, any signs or symptoms of high blood pressures and visual disturbance

After receiving LEUNASE

Tell your doctor that you have been given LEUNASE if you are undergoing a thyroid function test. LEUNASE may interfere with this test

Storage

LEUNASE should be stored in the pharmacy or in the ward. The powder for injection should be stored in a refrigerator between 2 degrees and 8 degrees C. It should not be frozen.

Product description

What it looks like

White powder for injection in a vial. Each vial contains 10,000 K.U. (Kyowa Unit) of asparaginase (colaspase).

Distributor/ Supplier

sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113 Australia Aust R 27513

Distributed in New Zealand by: sanofi-aventis new zealand limited Auckland

New Zealand

This leaflet was prepared in October 2016