

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **RYLAZE™**

crisantaspase recombinant solution

Read this carefully before you start taking **RYLAZE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RYLAZE**.

What is RYLAZE used for?

RYLAZE is used to treat acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) in adults and pediatric patients 1 year of age and older where a reduction in a substance called asparagine may be useful. Most commonly it is used when patients have had a severe hypersensitivity reaction to similar medicines and, therefore, had to stop using them.

How does RYLAZE work?

RYLAZE contains an enzyme asparaginase that breaks down asparagine, an important component for cell survival. Unlike normal cells, cancer cells are unable to make their own asparagine, which is required for DNA synthesis and cell survival. Therefore, the depletion of asparagine by asparaginase kills cancer cells, while healthy cells are not affected.

What are the ingredients in RYLAZE?

Medicinal ingredient:

crisantaspase recombinant

Non-medicinal ingredients:

- polysorbate 80
- sodium chloride
- sodium hydroxide
- sodium phosphate dibasic anhydrous
- sodium phosphate monobasic monohydrate
- trehalose dihydrate

RYLAZE comes in the following dosage forms:

Solution for Injection: 10 mg/0.5 mL in a single-dose vial.

Do not use RYLAZE if you:

- are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient.
- have ever had serious pancreatitis during previous asparaginase therapy.
- have ever had blood clots during previous asparaginase therapy.
- have ever had serious bleeding during previous asparaginase therapy.
- have ever had serious allergic reaction to *Erwinia asparaginase*, including anaphylaxis.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RYLAZE. Talk about any health conditions or problems you may have, including if you:

- have had serious allergic reactions to *Erwinia asparaginase*, including anaphylaxis. Your doctor may pause or stop treatment with RYLAZE, if any allergic reactions occur.
- currently have or had pancreatitis. RYLAZE can cause pancreatitis, which may become life-threatening or lead to other problems. In case of severe pancreatitis, your doctor may stop the treatment with RYLAZE. In the case of mild pancreatitis, your doctor may withhold RYLAZE until the signs and symptoms subside. After resolution of mild pancreatitis, treatment with RYLAZE may be resumed.
- have or had diabetes mellitus or high blood sugar. RYLAZE can cause high blood sugar levels, which may need to be treated. RYLAZE may have to be stopped until the blood sugar is lowered. Your doctor will monitor your glucose levels during treatment.
- suffer from bleeding and blood clot disorders. During treatment your body's ability to prevent excessive bleeding may be affected. In the case you experience any significant bleeding your treatment will be stopped. Your doctor will determine if, and when, treatment can be restarted.

Other warnings you should know about:

- If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. RYLAZE can cause embryonic and fetal harm when given to a pregnant woman.
- It is unknown whether RYLAZE is present in human breast milk. Therefore, RYLAZE must not be used during breast-feeding due to the risk to a breast-feeding child. Ask your doctor about when breast-feeding can resume after your last dose of RYLAZE.
- In males, potential for a decrease in sperm count cannot be ruled out. Talk to your healthcare professional if you have questions about this.
- If you are sexually mature you must use contraceptives or remain abstinent during treatment with RYLAZE and for 3 months after the end of treatment. Since an indirect interaction between components of oral contraceptives and asparaginase cannot be ruled out, oral contraceptives are not considered sufficiently safe. Ask your healthcare professional for advice on the best contraceptive method that you can use.
- Do not drive or use machines when taking this medicine because it may make you feel drowsy, tired, or confused.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take RYLAZE:

RYLAZE is given by injection into a muscle (intramuscular injection). This product should be administered by your healthcare professional in a hospital setting where appropriate resuscitation equipment is available.

Usual dose:

Your healthcare professional will determine the dose of RYLAZE you will receive. The dose you receive will be based on your age, and body surface area or body weight.

The recommended dosage of RYLAZE is 25 mg/m² on Monday and Wednesday and 50 mg/m² on Friday, administered intramuscularly, for a total of six doses for each treatment course.

Overdose:

If you think you, or a person you are caring for, have taken too much **RYLAZE**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your scheduled treatment, contact your healthcare professional as soon as possible to schedule your next treatment.

What are possible side effects from using RYLAZE?

These are not all the possible side effects you may have when taking RYLAZE. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects were observed in patients receiving RYLAZE: fatigue, decreased appetite, nausea, headache, pain in extremity, increased blood pressure, decrease in weight, increased heart rate, constipation, mouth sores, dehydration, back pain, anxiety, cough, pain in mouth or throat, and dry skin.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Abdominal pain		✓	
Vomiting	✓		
Abnormal liver function values		✓	
Diarrhea	✓		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Abnormal laboratory values including decreased potassium or increased triglycerides		✓	
Increased blood sugar levels		✓	
Fever		✓	✓
Infection, including in the blood: fever, increased heart rate, rapid breathing		✓	
Allergic reactions: rash, itching, swelling, shortness of breath, injection site reaction		✓	✓
Bleeding: bleeding from gums, nose or other sites, abnormal bruising	✓		✓
COMMON			
Inflammation of the pancreas: Pain in the upper abdomen, nausea, vomiting (pancreatitis)		✓	✓
Severe allergic reaction that may cause loss of consciousness, difficulty in breathing, decreased blood pressure, and could be life-threatening (anaphylactic shock)		✓	✓
Blood clot, including in the lung or brain: chest pain, shortness of breath, blurred vision, loss of consciousness, or pain/numbness/spasm in other parts of body		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store RYLAZE refrigerated at 2°C to 8°C in the original carton to protect from light. Do not shake or freeze product.

Keep out of reach and sight of children.

If you want more information about RYLAZE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.jazzpharma.com, or by calling 1-800-520-5568.

This leaflet was prepared by: Jazz Pharmaceuticals Ireland Limited.

Imported by: Jazz Pharmaceuticals Canada Inc.
4080 Confederation Parkway, Suite 602
Mississauga, Ontario L5B 0G1

Last Revised: SEP 02, 2022