

STARTING YOUR

Pr **RYLAZE**®

Treatment journey



For caregivers and patients

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.

Pr **RYLAZE**®
crisantaspase
recombinant solution for
intramuscular
injection, 10 mg/0.5 mL



ABOUT RYLAZE

GETTING STARTED WITH RYLAZE

Your healthcare professional has prescribed RYLAZE for you or a loved one to help treat ALL or LBL. This guide will allow you to learn more about RYLAZE. Inside, you will find:

- Information on how RYLAZE works, how to take RYLAZE, and possible side effects
- Tips for dealing with possible side effects
- Topics to discuss with your healthcare team
- A fillable appointment planner
- Helpful resources and a glossary of terms

THE RYLAZE TREATMENT JOURNEY

RYLAZE is used to treat acute ALL or LBL in patients 1 year of age and older. It is often used when patients have had to stop taking similar medicines because of a severe hypersensitivity reaction.

How RYLAZE works

RYLAZE contains asparaginase, an enzyme 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.



If you have any questions about RYLAZE or why your healthcare professional prescribed it for you or a loved one, talk to your healthcare team.



Scan the QR code to watch this animated video and learn about the RYLAZE treatment journey.

HOW TO TAKE RYLAZE

RYLAZE is provided as a solution for injection (10 mg/0.5 mL) in a single-dose vial.

Store RYLAZE refrigerated at **2 °C to 8 °C** in the original carton to protect it from light. Do not shake or freeze it. RYLAZE may be stored at room temperature in the provided syringe for up to 4 hours.

The RYLAZE dose, which is the amount of RYLAZE you or a loved one will be taking, is based on:

1. A person's age, and
2. A person's body surface area or body weight.

Your healthcare professional will decide the appropriate dose and will administer RYLAZE by intramuscular injection (an injection into the muscle) in a hospital setting where appropriate resuscitation equipment is available.

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.

Usual weekly dose of RYLAZE

Monday



25 mg/m²

Wednesday



25 mg/m²

Friday



50 mg/m²

Check out the back of this booklet for a resource to help you keep track of your upcoming treatment appointments.

ANSWERS TO OTHER QUESTIONS THAT YOU MAY HAVE



What should you do if you took too much RYLAZE?

If you think you or a loved one has taken too much RYLAZE, contact one of the following **immediately**, even if you have no symptoms:



Healthcare professional



Hospital emergency department



Regional poison control centre

What if you miss a scheduled dose?

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

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

IMPORTANT INFORMATION TO KNOW BEFORE STARTING RYLAZE

RYLAZE should not be taken if you or your loved one:

- Is hypersensitive to it or to any ingredient in the formulation, including any non-medicinal ingredient.
- Has ever had serious pancreatitis during previous asparaginase therapy.
- Has ever had blood clots during previous asparaginase therapy.
- Has ever had serious bleeding during previous asparaginase therapy.
- Has ever had a serious allergic reaction to *Erwinia* asparaginase, including anaphylaxis.

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

- Has had a serious allergic reaction to *Erwinia* asparaginase, including anaphylaxis. Your doctor may pause or stop treatment with RYLAZE if any allergic reactions occur.
- Currently has 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 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.
- Has 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 blood sugar levels during treatment.
- Suffers from bleeding or 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 breastfeeding, 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 breastfeeding due to the risk to the breastfeeding child. Ask your doctor when breastfeeding can resume after your last dose of RYLAZE.
- In males, the 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 your health before your treatment. In addition, let them know about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines. If you or your partner can become pregnant, tell your doctor about this too.

IMPORTANT SAFETY INFORMATION

Serious side effects and what to do about them			
Symptom/effect	Talk to your doctor		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Abdominal pain		X	
Vomiting	X		
Abnormal liver function values		X	
Diarrhea	X		
Abnormal laboratory values, including decreased potassium or increased triglycerides		X	
Increased blood sugar levels		X	
Fever		X	X
Infection, including in the blood: fever, increased heart rate, rapid breathing		X	
Allergic reactions: rash, itching, swelling, shortness of breath, injection site reaction		X	X
Bleeding: bleeding from gums, nose, or other sites, abnormal bruising	X		X

Serious side effects and what to do about them

Symptom/effect	Talk to your doctor		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Inflammation of the pancreas (pancreatitis): pain in the upper abdomen, nausea, vomiting		X	X
Severe allergic reaction (anaphylactic shock) that may cause loss of consciousness, difficulty in breathing, decreased blood pressure, and could be life-threatening		X	X
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 the body		X	X

This is not a complete list of possible side effects. Please consult your Patient Information Brochure for the complete safety information.

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-healthproducts/medeffect-canada.html>) for information on how to report online, by mail, or by fax



Calling toll-free at **1-866-234-2345**

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



TOOLS AND RESOURCES

DISCUSSION GUIDE

Many questions may arise for you or your loved one during treatment with RYLAZE. Here are a few that you can use to begin discussing your treatment with your healthcare professional.

- ? How often will I receive doses?
- ? What signs or symptoms should I tell you about right away?
- ? How many visits to the hospital will I need to plan for my RYLAZE treatments?
- ? How long will I be undergoing treatment with RYLAZE?
- ? How do I talk to my child about ALL or LBL?
- ? How can I help my child or loved one feel more comfortable with their treatment?

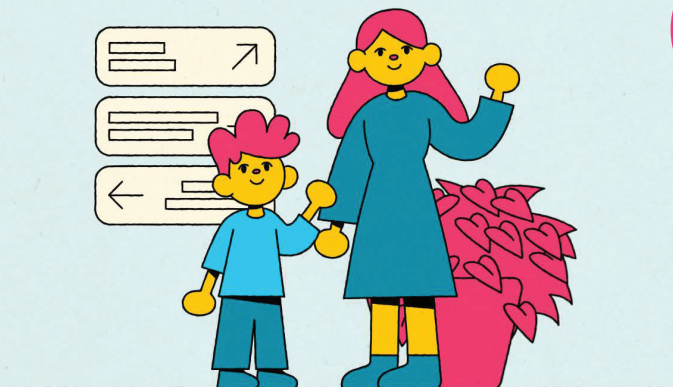
Notes or other questions to ask:

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>), by visiting www.jazzpharma.com, or by calling 1-800-520-5568.



Scan the QR code to watch this animated video and learn about the RYLAZE treatment journey.



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HELPFUL RESOURCES



Canadian Cancer Society

cancer.ca

Leukemia & Lymphoma Society of Canada

bloodcancers.ca

Childhood Cancer Canada

childhoodcancer.ca

For caregivers

Cancer Connection

cancerconnection.ca

Carers Canada

carerscanada.ca

GLOSSARY



Anaphylaxis: A severe, potentially life-threatening allergic reaction. It can occur within seconds or minutes of exposure to something you're allergic to.

Asparaginase: An enzyme that breaks down asparagine and may block the growth of tumour cells that need asparagine to grow.

Asparagine: A chemical compound.

Enzyme: A protein that speeds up chemical reactions in the body.

Hypersensitivity: An exaggerated response by the immune system to a medication or other substance.

Acute lymphoblastic leukemia (ALL): A type of leukemia (blood cancer) that comes on quickly and is fast growing. In ALL, there are too many lymphoblasts (immature white blood cells) in the blood and bone marrow.

Lymphoblastic lymphoma (LBL): A fast-growing type of lymphoma in which too many lymphoblasts are found in the lymph nodes and the thymus gland. These lymphoblasts may spread to other places in the body.

This planner is based on the recommended dosing schedule for RYLAZE.

The usual dose of RYLAZE is **25 mg/m² on Monday and Wednesday** and **50 mg/m² on Friday**, by intramuscular injection, for a total of six doses for each treatment course.



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