

RYLAZE[®]
asparaginase erwinia chrysanthemi
(recombinant)-rywn for injection
10mg/0.5mL per vial

Leighton & Her Family
(Actual Patient & Family)

After an allergic reaction to *E. coli*-derived asparaginase

RELY ON RYLAZE

(asparaginase erwinia chrysanthemi
(recombinant)-rywn)

to continue the asparaginase journey

What is RYLAZE?

RYLAZE is a prescription medicine, given by intramuscular injection, that is part of a chemotherapy regimen used to treat adults and children 1 month or older who have acute lymphoblastic leukemia (ALL), a type of blood cancer that affects the white blood cells that help fight infection, and lymphoblastic lymphoma (LBL), a type of non-Hodgkin lymphoma that also affects white blood cells. RYLAZE is used in patients who have had an allergic reaction to *E. coli* asparaginase.

IMPORTANT SAFETY INFORMATION

RYLAZE should not be given to people who have:

- History of serious allergic reactions to RYLAZE
- History of serious swelling of the pancreas (stomach pain), serious blood clots, or serious bleeding during previous asparaginase treatment
- Severe damage to the liver

Please see [page 13](#) for additional Important Safety Information and full [Prescribing Information](#).

Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL)

ALL and LBL are both cancers that affect the white blood cells.

ALL and LBL are caused when lymphoblasts, which are immature white blood cells, fail to mature into white blood cells called lymphocytes. The immature lymphoblasts malfunction and grow out of control, leading to blood cancer. One of 2 types of lymphocytes may be affected in ALL and LBL: B-cell or T-cell.

Quick facts: ALL and LBL

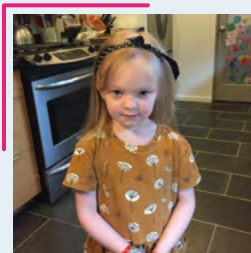
ALL

An estimated
6,540
people in the US will be diagnosed with **ALL** in 2023, which is
less than 1%
of all new cancer cases

ALL is the most common type of cancer in children;
more than 53%
of patients are 19 years old or younger

LBL

An estimated
1,600
people in the US will be diagnosed with **LBL** in 2023



“Here we are sitting in this little, tiny room in the emergency department discussing treatment for our daughter’s leukemia.”

—Leighton’s Mother (Actual Patient Family)

Asparaginase therapy is a key component in treatment plans for ALL and LBL

What is asparagine (uh-speh-ruh-jeen)?

Asparagine is an amino acid used to create important proteins and cells in the body. Both healthy cells and cancer cells need asparagine to survive.

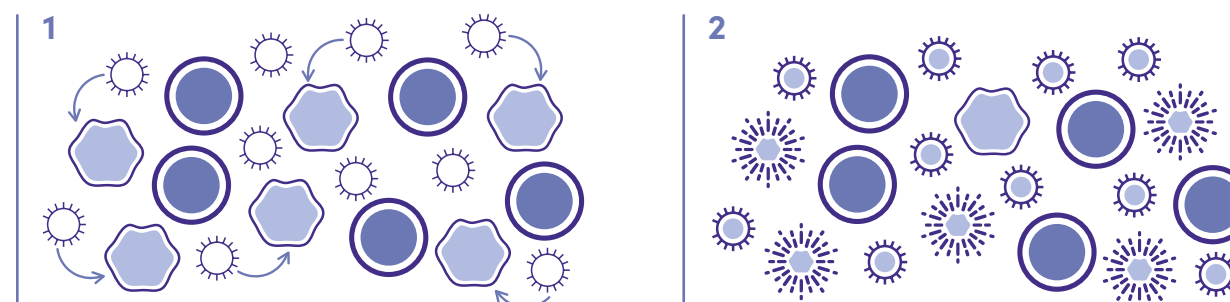
What is asparaginase (uh-speh-ruh-jen-ace)?

Asparaginase is a naturally occurring enzyme used to help break down asparagine in the blood. Enzymes are proteins that speed up chemical reactions in the body.

Asparaginase does the critical job of breaking down asparagine.

Doctors use asparaginase therapy as a key component in ALL and LBL treatment plans because it helps prevent cancer cells from accessing the asparagine they need to survive, causing cancer cells to die.

How asparaginase targets cancer cells



Healthy cells can create their own asparagine, but cancer cells cannot. Cancer cells need to get asparagine from blood to survive.

Asparaginase helps break down asparagine in the blood, causing cancer cells to die.



Healthy cell



Cancer cell



Asparagine

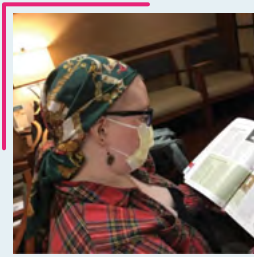


Asparaginase



Cell death

Allergic reactions can sometimes occur as a result of asparaginase therapy



“I had my first allergic reaction 4 months into treatment [with *E. coli*-derived asparaginase therapy]. It started with an itchy feeling, and it progressed to my throat closing. I knew we needed to find an alternative asparaginase.”

—Caroline (Actual Patient)

Patients with acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) receive asparaginase therapy that is derived by extracting the asparaginase enzyme from a bacteria called *Escherichia coli*, or *E. coli* (ee KOH-lie).

Allergic reactions to asparaginase derived from *E. coli* trigger an immune response throughout the body. The healthcare team may call this an allergic reaction or hypersensitivity reaction.

An immune response is when the body’s immune system (the part of the body that fights infection and illness) recognizes something as foreign or harmful and attacks it in an attempt to destroy it.

An allergic reaction can affect the body in different ways. Signs and symptoms of an allergic reaction may include one or more of the following:

Mouth: swelling of lips, itchy throat, tongue



General: headache, nasal congestion, watery eyes, sweating, feeling of impending doom, loss of consciousness

Respiratory: shortness of breath, wheezing, coughing, chest pain and/or tightness



Heart: drop in blood pressure, dizziness, faintness

Stomach: vomiting, diarrhea, cramps

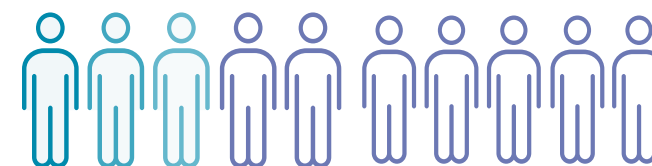


Skin: itching, redness, swelling, hives

More about allergic reactions and asparaginase therapy

- Allergic reactions usually happen after repeated administration of asparaginase because the immune system starts to react more quickly to the therapy than it did after the first treatment
- Most allergic reactions occur quickly, but some can occur **up to 6 hours after treatment**
- Being treated again with the same asparaginase therapy that triggered an allergic reaction can cause a **similar or even worse reaction**
- An allergic reaction may signal that the asparaginase therapy isn’t working as it should

Up to 3 out of 10



patients may experience an allergic reaction after *E. coli*-derived asparaginase therapy

Allergic reactions may cause missed asparaginase doses, which put patients at greater risk of negative outcomes such as relapse. It’s important for asparaginase therapy to continue after an allergic reaction.

Switching to another form of asparaginase therapy that is not derived from *E. coli* can help ensure treatment continues uninterrupted.

Please see [page 13](#) for additional Important Safety Information and full [Prescribing Information](#).

Switching to RYLAZE after an allergic reaction to *E. coli*-derived asparaginase

RYLAZE is an asparaginase therapy derived from *Erwinia chrysanthemi* instead of *E. coli*. It was developed by medical scientists to help ensure asparaginase therapy could continue for patients who experienced an allergic reaction from asparaginase derived from *E. coli*.

What is RYLAZE?

RYLAZE is the only *Erwinia* asparaginase approved by the Food and Drug Administration (FDA) to treat acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in patients who have had an allergic reaction to asparaginase derived from *E. coli*.

RYLAZE is a prescription medicine that is part of a chemotherapy regimen used to treat adults and children 1 month or older who have ALL or LBL after an allergic reaction to *E. coli* asparaginase.

May prevent missed doses

RYLAZE allows the body to continue using asparaginase to fight ALL and LBL by preventing or limiting missed doses and maintaining the effectiveness of treatment. Patients who miss asparaginase doses are at greater risk of negative outcomes such as relapse, so it's important for asparaginase therapy to continue after an allergic reaction. Switching to RYLAZE can help asparaginase therapy finish uninterrupted.



Visit [RYLAZE.com](https://rylaze.com) to learn more about why RYLAZE is part of treatment after an allergic reaction to *E. coli*-derived asparaginase.

IMPORTANT SAFETY INFORMATION (CONTINUED)

RYLAZE may cause serious side effects, including:

- Allergic reactions (a feeling of tightness in your throat, unusual swelling/redness in your throat and/or tongue, rash, or trouble breathing), some of which may be life-threatening
- Swelling of the pancreas (stomach pain), which, if left untreated, may be fatal
- Blood clots (may be experienced as headache, arm or leg swelling, shortness of breath, or chest pain), which may be life-threatening
- Bleeding, which may be life-threatening
- Liver problems (may result in abnormal laboratory values) or, in severe cases, hepatic veno-occlusive disease (reduced blood flow in the liver)

6 Contact your doctor immediately if any of these side effects occur.



Caroline (Actual Patient)

How was RYLAZE studied?

RYLAZE was studied in a clinical trial of 167 patients (ages 1-25) receiving an injection into the muscle. All patients had ALL or LBL and experienced an allergic reaction while receiving asparaginase therapy derived from *E. coli*, along with their chemotherapy regimen.

The FDA approved RYLAZE for treatment of ALL and LBL as part of a multiagent chemotherapy regimen after an allergic reaction to *E. coli* asparaginase.

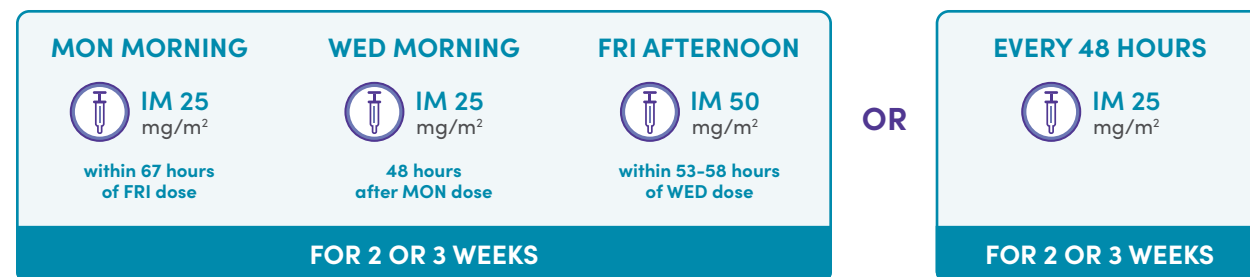
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How RYLAZE is given

Two dosing options: Monday, Wednesday, Friday or every 48 hours

The healthcare team will choose 1 of 2 possible dosing options for RYLAZE, both administered with an injection into the muscle. One option involves receiving the injection 3 times a week over the course of approximately 2 or 3 weeks on Monday, Wednesday, and Friday. Another option involves receiving the injection approximately every 48 hours over the course of 2 or 3 weeks.



Before beginning asparaginase therapy with RYLAZE, the doctor will monitor the patient's health. The doctor may first administer other medications to decrease the risk and severity of an allergic reaction, in case one occurs.

On the day RYLAZE is given, the doctor will determine the individualized dose and monitor for any negative reactions. If an allergic or adverse reaction occurs, alert the healthcare team immediately and treatment with RYLAZE should be paused or stopped.

Work with the healthcare team to understand the treatment schedule.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Some of the most common side effects with RYLAZE include:

- Liver problems
- Nausea and vomiting
- Bone and muscle pain
- Infection
- Tiredness
- Headache
- Fever with low white blood cell count
- Fever
- Bleeding
- Mouth swelling (sometimes with sores)
- Pain in the abdomen
- Decreased appetite
- Allergic reactions
- High blood sugar levels
- Diarrhea
- Swelling of the pancreas
- Low levels of potassium in your blood

Frequently asked questions

? How are acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) different?

While ALL and LBL are both cancers of the white blood cells, they originate in different parts of the body. ALL is a cancer of the white blood cells in the bone marrow that can also impact red blood cells and platelets. LBL affects white blood cells but does not start in the bone marrow, like ALL does. In LBL, abnormal white blood cells usually build up in the lymph nodes or thymus (located in the chest), but can also easily spread to the rest of the body.

? Can RYLAZE cause allergic reactions?

Like other asparaginase therapies, RYLAZE may cause an allergic reaction. Seek medical advice immediately if symptoms of an allergic reaction occur.

? Why is the RYLAZE treatment schedule different than other asparaginase therapies?

RYLAZE is short-acting. As such, RYLAZE is given more frequently to help ensure patients can maintain effective levels of asparaginase in their blood.

? How can caregivers best support children with ALL or LBL?

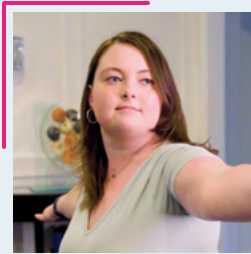
Children should be able to have wide-ranging conversations about their illness. The following suggestions can encourage open conversations:

- Listen attentively and address their questions and concerns
- Be aware that children process information at their own pace
- Provide age-appropriate information about the illness
- Introduce them to the treatment team for additional support
- Encourage open communication about fears and concerns
- Be present, and help reassure children they have support
- Help children understand medical procedures and treatments

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Navigating the treatment journey as a teen or young adult



“It meant all the world to be able to finish my treatment and know that I did everything that I possibly could ... so that I would be healthy and hopefully not have a relapse; and I was able to do that because of RYLAZE.”

—Caroline (Actual Patient)

The healthcare team may recommend a treatment plan for teens and young adults that is similar to what is used to treat children with acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL). It's called a **pediatric-inspired regimen**.

A pivotal study, CALGB 10403, looked at how well treatment worked in teens and young adults (ages 17-39) with ALL. The results showed that **patients who received a pediatric-inspired regimen were able to stay healthier longer** than patients who received non-pediatric regimens in earlier studies. Other results showed that pediatric-inspired regimens that include asparaginase have **more than doubled the length of time teens and young adults with ALL stay cancer-free** compared to patients who received non-pediatric regimens in earlier studies.

Another study showed **more than 1 in 5 patients with high-risk B-cell ALL who missed at least one prescribed asparaginase dose had their disease come back**.

After an ALL or LBL diagnosis, **scheduling all treatments and going to all appointments is important to help ensure asparaginase doses are not missed**.

As a reminder, various medications will be needed as part of a larger treatment plan. Healthcare team members are there to help during this challenging time. **Work closely with them to get the most out of treatment**.

IMPORTANT SAFETY INFORMATION (CONTINUED)

RYLAZE can harm your unborn baby. Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Females of reproductive potential should use effective contraception (other than hormonal contraceptives) during treatment and for 3 months following the final dose. Do not breastfeed while receiving RYLAZE and for 1 week after the final dose.

Tell your healthcare provider if there are any side effects that are bothersome or that do not go away.

These are not all the possible side effects of RYLAZE. For more information, ask your healthcare provider.

Call your doctor for medical advice about any side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

Learn how to feel in control of your treatment journey

Tips for teens and young adults living with ALL or LBL

4 tips to keep in mind:

Ask for information

If uncertain about anything, ask the healthcare team for clarity. Listen to their answers, and make sure they provide enough information for comfort and confidence in the treatment plan. Take notes during appointments to reference later.

Report allergic reactions

If signs and symptoms of an allergic reaction occur, reach out to the healthcare team immediately so appropriate treatment can be provided. It is extremely important to inform the healthcare team of a potential allergic reaction to asparaginase therapy as there can be serious side effects.

Speak up

One important way to manage concerns/fears about an ALL or LBL diagnosis and treatment plan is by self-advocating and speaking up. Writing down thoughts and questions before an appointment can be helpful when it comes to remembering what to ask.

Reach out for support

Taking care of one's mental health is critical. Consider mindfulness or meditation to manage anxiety, and lean on friends and family for help. Meet with local or online organizations or cancer advocacy/support groups. Ask the healthcare team for referrals to support groups.

Talk with the healthcare team about asparaginase therapy with RYLAZE.

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- Liver problems (may result in abnormal laboratory values) or, in severe cases, hepatic veno-occlusive disease (reduced blood flow in the liver)

Some of the most common side effects with RYLAZE include:

Liver problems, nausea and vomiting, bone and muscle pain, infection, tiredness, headache, fever with low white blood cell count, fever, bleeding, mouth swelling (sometimes with sores), pain in the abdomen, decreased appetite, allergic reactions, high blood sugar levels, diarrhea, swelling of the pancreas, and low levels of potassium in your blood.

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Patients are also encouraged to report negative side effects of prescription drugs to the Food and Drug Administration (FDA). Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. Patients may also report side effects to Jazz Pharmaceuticals at 1-800-520-5568.

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Caroline (Actual Patient)



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