

DOSING AND ORDERING GUIDE

RELY ON RYLAZE

TWO IM DOSING OPTIONS:

MONDAY, WEDNESDAY, FRIDAY
OR EVERY 48 HOURS¹

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

IM=intramuscular.

Indication

RYLAZE is indicated as a component of a multi-agent chemotherapeutic regimen given by intramuscular injection for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase.

IMPORTANT SAFETY INFORMATION

Contraindications

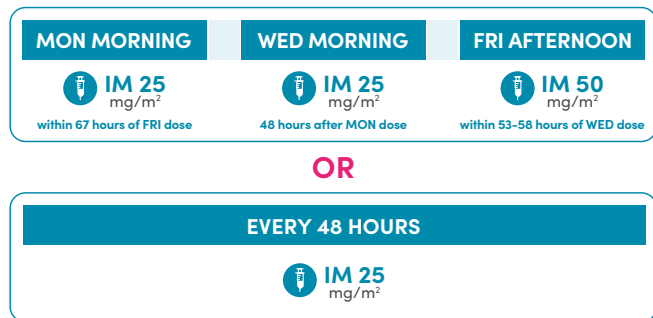
RYLAZE is contraindicated in patients with:

- History of serious hypersensitivity reactions to *Erwinia asparaginase*, including anaphylaxis
- History of serious pancreatitis during previous asparaginase therapy
- History of serious thrombosis during previous asparaginase therapy
- History of serious hemorrhagic events during previous asparaginase therapy
- Severe hepatic impairment

Please see pages 14 and 15 for additional Important Safety Information and full [Prescribing Information](#).

R_x DOSING

There are two RYLAZE regimens that can be used to replace a long-acting asparaginase product. The recommended dosages of RYLAZE are¹:



RYLAZE dosing example for 25/25/50 mg/m² IM schedule¹:

8 AM on Monday and Wednesday, and 1 PM to 6 PM on Friday

Recommended Premedication

Premedicate patients with acetaminophen, an H-1 receptor blocker (such as diphenhydramine), and an H-2 receptor blocker (such as famotidine) 30-60 minutes prior to administration of RYLAZE to decrease the risk and severity of hypersensitivity reactions.¹

IM=intramuscular.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hypersensitivity Reactions

Hypersensitivity reactions after the use of RYLAZE occurred in 29% of patients in clinical trials, and it was severe in 6% of patients. Anaphylaxis was observed in 2% of patients after intramuscular administration. Discontinuation of RYLAZE due to hypersensitivity reactions occurred in 5% of patients. Hypersensitivity reactions were higher in patients who received intravenous asparaginase erwinia chrysanthemi (recombinant)-rywn. The intravenous route of administration is not approved.

RECOMMENDED DURATION OF RYLAZE DOSING TO REPLACE ONE LONG-ACTING ASPARAGINASE DOSE¹

When RYLAZE is Administered	Recommended Duration of RYLAZE to Replace 3 Weeks of Asparaginase Coverage (Calaspargase Products)	Recommended Duration of RYLAZE to Replace 2 Weeks of Asparaginase Coverage (Pegaspargase Products)
25 mg/m ² intramuscular every 48 hours	Replace 1 dose of calaspargase pegol products with 11 doses of RYLAZE	Replace 1 dose of pegaspargase products with 7 doses of RYLAZE
25 mg/m ² intramuscular on Monday morning and Wednesday morning, and 50 mg/m ² intramuscular on Friday afternoon*	Replace 1 dose of calaspargase pegol products with 9 doses of RYLAZE	Replace 1 dose of pegaspargase products with 6 doses of RYLAZE

*Administer the Friday afternoon dose 53 to 58 hours after the Wednesday morning dose.¹

The table above shows the number of RYLAZE dosages recommended for the intended duration of treatment for replacement of¹:

- 3 weeks of asparaginase coverage (1 dose of calaspargase pegol products) or
- 2 weeks of asparaginase coverage (1 dose of pegaspargase products)

See the full prescribing information for the long-acting asparaginase product to determine the total duration of administration of RYLAZE as replacement therapy.¹

Please see pages 14 and 15 for additional Important Safety Information and full Prescribing Information.


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



FOR IM ADMINISTRATION¹

- Use aseptic technique
- Determine the dose, total volume of RYLAZE solution required, and the number of RYLAZE vials needed based on the individual patient's BSA. More than one vial may be needed for a full dose
- Withdraw the indicated injection volume of RYLAZE into the syringe for injection
 - Do not shake the vial
 - Limit the volume of RYLAZE at a single injection site to 2 mL
 - If the volume to be administered is greater than 2 mL, divide the dose equally into multiple syringes, one for each injection site
 - Discard the remaining unused RYLAZE in the single-dose vial
- Administer RYLAZE by intramuscular injection
 - Rotate injection sites
 - Do not inject RYLAZE into scar tissue or areas that are reddened, inflamed, or swollen
- If the prepared dose is not used immediately, store the syringe(s) at room temperature 59°F to 77°F for up to 8 hours or refrigerated at 36°F to 46°F for up to 24 hours. The syringe does not need to be protected from light during storage
- Ensure that medical support is available to appropriately manage anaphylactic reactions when administering RYLAZE

BSA=body surface area; IM=intramuscular.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Hypersensitivity Reactions (continued)

In patients administered RYLAZE intramuscularly in clinical trials, the median number of doses of RYLAZE that patients received prior to the onset of the first hypersensitivity reaction was 12 doses (range: 1-64 doses). The most commonly observed reaction was rash (19%), and 1 patient (1%) experienced a severe rash.

Hypersensitivity reactions observed with L-asparaginase class products include angioedema, urticaria, lip swelling, eye swelling, rash or erythema, blood pressure decreased, bronchospasm, dyspnea, and pruritus.



PREPARATION

- ✓ Ready-to-use vial²
 - No reconstitution required²
 - No filtration required^{1,2}
- ✓ Visually inspect RYLAZE for particulate matter and discoloration prior to administration, whenever solution and container permit. If particulate matter, cloudiness, or discoloration are present, discard the vial¹
- ✓ Discard partially used or empty vials of RYLAZE¹
- ✓ Do not shake the vial¹



STORAGE AND HANDLING

RYLAZE is supplied as a sterile, clear to opalescent, colorless to slightly yellow, preservative-free solution in single-dose vials. Each single-dose vial contains 10 mg/0.5 mL.¹

- Each carton of RYLAZE contains 3 single-dose vials¹
- Store RYLAZE refrigerated at 36°F to 46°F in the original carton to protect from light¹
- Do not shake or freeze¹

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Hypersensitivity Reactions (continued)

Premedicate patients prior to administration of RYLAZE as recommended. Because of the risk of serious allergic reactions (e.g., life-threatening anaphylaxis), administer RYLAZE in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis (e.g., epinephrine, oxygen, intravenous steroids, antihistamines). Discontinue RYLAZE in patients with serious hypersensitivity reactions.

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RECOMMENDED MONITORING AND DOSAGE MODIFICATIONS

Monitor patient's bilirubin, transaminase, and glucose levels, and clinical examinations prior to treatment every 2-3 weeks and as indicated clinically.¹

- If results are abnormal, monitor patients until recovery from the cycle of therapy¹
- If an adverse reaction occurs, modify treatment according to the table below¹

Adverse Reaction	Severity*	Action
Hypersensitivity Reaction	Grade 2	<ul style="list-style-type: none"> • Treat the symptoms
	Grade 3 to 4	<ul style="list-style-type: none"> • Discontinue RYLAZE permanently
Pancreatitis	Grade 2 to 4	<ul style="list-style-type: none"> • Hold RYLAZE for elevations in lipase or amylase >2 times the ULN, or for symptomatic pancreatitis • Resume treatment when lipase and amylase are <1.5 times the ULN and symptoms are resolved • Discontinue RYLAZE permanently if clinical necrotizing or hemorrhagic pancreatitis is confirmed
Thrombosis	Uncomplicated thrombosis	<ul style="list-style-type: none"> • Hold RYLAZE • Treat with appropriate antithrombotic therapy • Upon resolution of symptoms, consider resuming RYLAZE, while continuing antithrombotic therapy
	Severe or life-threatening thrombosis	<ul style="list-style-type: none"> • Discontinue RYLAZE permanently • Treat with appropriate antithrombotic therapy
Hemorrhage	Grade 3 to 4	<ul style="list-style-type: none"> • Hold RYLAZE • Evaluate for coagulopathy and consider clotting factor replacement as needed • Resume RYLAZE with the next scheduled dose if bleeding is controlled
Hepatotoxicity	Total bilirubin >3 times to ≤10 times the ULN	<ul style="list-style-type: none"> • Hold RYLAZE until total bilirubin levels decrease to ≤1.5 times the ULN
	Total bilirubin >10 times the ULN	<ul style="list-style-type: none"> • Discontinue RYLAZE and do not make up missed doses

*Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.¹
ULN=upper limit of normal.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Pancreatitis

Pancreatitis, including elevated amylase or lipase, was reported in 20% of patients in clinical trials of RYLAZE and was severe in 8%. Symptomatic pancreatitis occurred in 7% of patients, and it was severe in 6% of patients. Elevated amylase or lipase without symptomatic pancreatitis was observed in 13% of patients treated with RYLAZE. Hemorrhagic or necrotizing pancreatitis have been reported with L-asparaginase class products.

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HOW TO CALCULATE DOSE VOLUME

To calculate dose volume for 25 mg/m² on Monday and Wednesday, and 50 mg/m² on Friday:

- Each single-dose vial of RYLAZE contains 10 mg/0.5 mL¹
- Use the chart to determine the injection volume based on patient's body surface area (BSA)
 - Calculate the total volume of RYLAZE solution required for each dose:

$$\text{Volume (mL)} = \frac{\text{BSA (m}^2\text{)} \times \text{Individual dose (mg/m}^2\text{)}}{\text{Concentration (20 mg/mL)}}$$

- Injection volume should be rounded based on institutional standard of care
- It is solely the responsibility of the treating healthcare professional and/or institution to determine the appropriate dosage for each patient and to appropriately account for any unused drug or wastage in accordance with any applicable law, regulation, or policy
- Healthcare professionals should calculate all doses before administration. This vial dosage schedule is merely a guide and is not a substitute for, nor intended to influence, the independent judgment of healthcare professionals. Neither Jazz Pharmaceuticals nor its contractors accept any responsibility for the applicability of the information provided to any particular clinical situation or for any actions or decisions taken in calculating or administering the dose

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Pancreatitis (continued)

Inform patients of the signs and symptoms of pancreatitis, which, if left untreated, could be fatal. Evaluate patients with symptoms compatible with pancreatitis to establish a diagnosis. Assess serum amylase and lipase levels in patients with any signs or symptoms of pancreatitis. Discontinue RYLAZE in patients with severe or hemorrhagic pancreatitis. In the case of mild pancreatitis, withhold RYLAZE until the signs and symptoms subside and amylase and/or lipase levels return to 1.5 times the ULN. After resolution of mild pancreatitis, treatment with RYLAZE may be resumed.

Thrombosis

Serious thrombotic events, including sagittal sinus thrombosis and pulmonary embolism, have been reported in 1% of patients following treatment with RYLAZE. Discontinue RYLAZE for a thrombotic event, and administer appropriate antithrombotic therapy. Consider resumption of treatment with RYLAZE only if the patient had an uncomplicated thrombosis.

VIAL DOSAGE SCHEDULE

BSA (m ²)	Monday/Wednesday OR Q48 dose 25 mg/m ²		Friday dose 50 mg/m ²	
	Volume (mL)	Number of Vials	Volume (mL)	Number of Vials
0.4	0.50	1	1.00	2
0.5	0.63	2	1.25	3
0.6	0.75	2	1.50	3
0.7	0.88	2	1.75	4
0.8	1.00	2	2.00	4
0.9	1.13	3	2.25	5
1.0	1.25	3	2.50	5
1.1	1.38	3	2.75	6
1.2	1.50	3	3.00	6
1.3	1.63	4	3.25	7
1.4	1.75	4	3.50	7
1.5	1.88	4	3.75	8
1.6	2.00	4	4.00	8
1.7	2.13	5	4.25	9
1.8	2.25	5	4.50	9
1.9	2.38	5	4.75	10
2.0	2.50	5	5.00	10
2.1	2.63	6	5.25	11
2.2	2.75	6	5.50	11
2.3	2.88	6	5.75	12
2.4	3.00	6	6.00	12

Q48=every 48.

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RYLAZE ORDERING INFORMATION

Specialty Distribution Partners

RYLAZE is available for purchase from the authorized Specialty Distributors listed below. Verify that your facility has an account with their Specialty Distributor before ordering. If not, they should contact their Specialty Distributor. The facility should also contact their Specialty Distributor with questions regarding product returns.

AmerisourceBergen

ASD Healthcare

RYLAZE Item #: 10259717

Online: <https://www.asdhealthcare.com>

Phone: 1-800-746-6273

Fax: 1-800-547-9413

Email: asd.customerservice@asdhealthcare.com

- Orders can be placed Monday-Thursday, 7 AM-6:30 PM CT; Friday, 7 AM-6 PM CT
- For emergency orders after hours of service, call 1-800-746-6273

Oncology Supply

RYLAZE Item #: 10259764

Online: <https://www.oncologysupply.com>

Phone: 1-800-633-7555

Fax: 1-800-248-8205

Email: custserv@oncologysupply.com

- Orders can be placed Monday-Friday, 9 AM-8 PM CT
- Orders placed after hours via Oncology Supply's email address are processed the next business day

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Hemorrhage

Bleeding was reported in 25% of patients treated with RYLAZE, and it was severe in 2%. Most commonly observed reactions were bruising (12%) and nose bleed (9%).

In patients treated with L-asparaginase class products, hemorrhage may be associated with increased prothrombin time (PT), increased partial thromboplastin time (PTT), and hypofibrinogenemia. Consider appropriate replacement therapy in patients with severe or symptomatic coagulopathy.

Hepatotoxicity, including Hepatic Veneno-Occlusive Disease
Elevated bilirubin and/or transaminases occurred in 75% of patients treated with RYLAZE in clinical trials, and 26% had Grade ≥ 3 elevations. Elevated transaminases occurred in

Cardinal Health

Cardinal Specialty Pharmaceutical Distribution

RYLAZE Item #: 5731948

Online: Order Express

<https://orderexpress.cardinalhealth.com>

Specialty Online

<https://specialtyonline.cardinalhealth.com>

Phone: 1-877-453-3972

Fax: 1-877-274-9897

Email: SPDOncologyTeam@cardinalhealth.com

- Orders can be placed Monday-Friday, 8 AM-7 PM CT
- For emergency orders after hours of service, call 1-877-453-3972

McKesson Specialty Health

McKesson Plasma and Biologics

RYLAZE Item #: 2338747

Online: <https://connect.mckesson.com>

Phone: 1-877-625-2566

Fax: 1-888-752-7626

Email: MPBOrders@mckesson.com

- Orders can be placed Monday-Friday, 9 AM-7:30 PM ET
- Email for all other information requests: MPB@mckesson.com
- For emergency orders after hours of service, call 1-877-625-2566

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Hepatotoxicity, including Hepatic Veneno-Occlusive Disease (continued)

73% of patients treated with RYLAZE in clinical trials, and 25% had Grade ≥ 3 elevations.

Hepatotoxicity, including severe, life-threatening, and potential fatal cases of hepatic veneno-occlusive disease (VOD), have been observed in patients treated with asparaginase class products in combination with standard chemotherapy, including during the induction phase of multiphase chemotherapy. Do not administer RYLAZE to patients with severe hepatic impairment. Inform patients of the signs and symptoms of hepatotoxicity.

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RYLAZE CODING INFORMATION

Permanent J-code
J9021

Effective January 1, 2022

NDC		
10-digit	11-digit	
68727-900-03	68727-0900-03	Carton containing 3 vials of RYLAZE

Payers may require a 10-digit or 11-digit NDC. Both are provided for your convenience. These are sample codes based on publicly available information and are informational only and not a guarantee or promise of coverage. Appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements.



NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Hepatotoxicity, including Hepatic Veno-Occlusive Disease (continued)

Evaluate bilirubin and transaminases prior to each cycle of RYLAZE and at least weekly during cycles of treatment that include RYLAZE, through four weeks after the last dose of RYLAZE. Monitor frequently for signs and symptoms of hepatic VOD, which may include rapid weight gain, fluid retention with ascites, hepatomegaly (which may be painful), and rapid increase of bilirubin. For patients who develop abnormal liver tests after RYLAZE, more frequent monitoring for liver test abnormalities and clinical signs and symptoms of VOD is recommended. In the event of serious liver toxicity, including VOD, discontinue treatment with RYLAZE and provide supportive care.

PATIENT SUPPORT SERVICES

JazzCares® supports healthcare providers and office staff with coverage and reimbursement support^a so appropriate patients can get access to RYLAZE and reduce their out-of-pocket costs.^b



JazzCares

Assists you with benefits investigations, prior authorizations and appeals,^a and referrals to other financial assistance options for eligible patients



Savings Card

Eligible, commercially insured patients can pay as little as \$10 for their RYLAZE medication, subject to an annual maximum (restrictions apply)^a



Free Drug Program

Uninsured or underinsured patients who meet certain financial criteria may be eligible to receive RYLAZE at no cost^b

Learn more about JazzCares support offerings by calling 1-833-533-JAZZ (5299) Monday-Friday, 8 AM-8 PM ET, or visiting jazzcares.com/hcp/rylaze.

^aInsurance coverage and plans may vary. JazzCares provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional.

^bSubject to eligibility requirements and terms and conditions.

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IMPORTANT SAFETY INFORMATION

Contraindications

RYLAZE is contraindicated in patients with:

- History of serious hypersensitivity reactions to *Erwinia asparaginase*, including anaphylaxis
- History of serious pancreatitis during previous asparaginase therapy
- History of serious thrombosis during previous asparaginase therapy
- History of serious hemorrhagic events during previous asparaginase therapy
- Severe hepatic impairment

Warnings and Precautions

Hypersensitivity Reactions

Hypersensitivity reactions after the use of RYLAZE occurred in 29% of patients in clinical trials, and it was severe in 6% of patients. Anaphylaxis was observed in 2% of patients after intramuscular administration. Discontinuation of RYLAZE due to hypersensitivity reactions occurred in 5% of patients. Hypersensitivity reactions were higher in patients who received intravenous asparaginase *erwinia chrysanthemi* (recombinant)-rywn. The intravenous route of administration is not approved.

In patients administered RYLAZE intramuscularly in clinical trials, the median number of doses of RYLAZE that patients received prior to the onset of the first hypersensitivity reaction was 12 doses (range: 1-64 doses). The most commonly observed reaction was rash (19%), and 1 patient (1%) experienced a severe rash.

Hypersensitivity reactions observed with L-asparaginase class products include angioedema, urticaria, lip swelling, eye swelling, rash or erythema, blood pressure decreased, bronchospasm, dyspnea, and pruritus.

Premedicate patients prior to administration of RYLAZE as recommended. Because of the risk of serious allergic reactions (e.g., life-threatening anaphylaxis), administer RYLAZE in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis (e.g., epinephrine, oxygen, intravenous steroids, antihistamines). Discontinue RYLAZE in patients with serious hypersensitivity reactions.

Pancreatitis

Pancreatitis, including elevated amylase or lipase, was reported in 20% of patients in clinical trials of RYLAZE and was severe in 8%. Symptomatic pancreatitis occurred in 7% of patients, and it was severe in 6% of patients. Elevated amylase or lipase without symptomatic pancreatitis was observed in 13% of patients treated with RYLAZE. Hemorrhagic or necrotizing pancreatitis have been reported with L-asparaginase class products.

Inform patients of the signs and symptoms of pancreatitis, which, if left untreated, could be fatal. Evaluate patients with symptoms compatible with pancreatitis to establish a diagnosis. Assess serum amylase and lipase levels in patients with any signs or symptoms of pancreatitis. Discontinue RYLAZE in patients with severe or hemorrhagic pancreatitis. In the case of mild pancreatitis, withhold RYLAZE until the signs and symptoms subside and amylase and/or lipase levels return to 1.5 times the ULN. After resolution of mild pancreatitis, treatment with RYLAZE may be resumed.

Thrombosis

Serious thrombotic events, including sagittal sinus thrombosis and pulmonary embolism, have been reported in 1% of patients following treatment with RYLAZE. Discontinue RYLAZE for a thrombotic event, and administer appropriate antithrombotic therapy. Consider resumption of treatment with RYLAZE only if the patient had an uncomplicated thrombosis.

Hemorrhage

Bleeding was reported in 25% of patients treated with RYLAZE, and it was severe in 2%. Most commonly observed reactions were bruising (12%) and nose bleed (9%).

In patients treated with L-asparaginase class products, hemorrhage may be associated with increased prothrombin time (PT), increased partial thromboplastin time (PTT), and hypofibrinogenemia. Consider appropriate replacement therapy in patients with severe or symptomatic coagulopathy.

Hepatotoxicity, including Hepatic Veno-Occlusive Disease

Elevated bilirubin and/or transaminases occurred in 75% of patients treated with RYLAZE in clinical trials, and 26% had Grade ≥ 3 elevations. Elevated bilirubin occurred in 28% of patients treated with RYLAZE in clinical trials, and 2% had Grade ≥ 3 elevations. Elevated transaminases occurred in 73% of patients treated with RYLAZE in clinical trials, and 25% had Grade ≥ 3 elevations.

Hepatotoxicity, including severe, life-threatening, and potential fatal cases of hepatic veno-occlusive disease (VOD), have been observed in patients treated with asparaginase class products in combination with standard chemotherapy, including during the induction phase of multiphase chemotherapy. Do not administer RYLAZE to patients with severe hepatic impairment. Inform patients of the signs and symptoms of hepatotoxicity.

Evaluate bilirubin and transaminases prior to each cycle of RYLAZE and at least weekly during cycles of treatment that include RYLAZE, through four weeks after the last dose of RYLAZE. Monitor frequently for signs and symptoms of hepatic VOD, which may include rapid weight gain, fluid retention with ascites, hepatomegaly (which may be painful), and rapid increase of bilirubin. For patients who develop abnormal liver tests after RYLAZE, more frequent monitoring for liver test abnormalities and clinical signs and symptoms of VOD is recommended. In the event of serious liver toxicity, including VOD, discontinue treatment with RYLAZE and provide supportive care.

Adverse Reactions

The most common adverse reactions (incidence $>20\%$) with RYLAZE are abnormal liver test, nausea, musculoskeletal pain, infection, fatigue, headache, febrile neutropenia, pyrexia, hemorrhage, stomatitis, abdominal pain, decreased appetite, drug hypersensitivity, hyperglycemia, diarrhea, pancreatitis, and hypokalemia.

Use in Specific Populations

Pregnancy and Lactation

RYLAZE can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective non-hormonal contraceptive methods during treatment with RYLAZE and for 3 months after the last dose.

Advise women not to breastfeed during treatment with RYLAZE and for 1 week after the last dose.

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For more information about RYLAZE, visit [RYLAZE.com](https://www.rylaze.com).

Please see Important Safety Information throughout and full Prescribing Information.

References: 1. RYLAZE [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.
2. Maese L, Rizzari C, Coleman R, et al. Can recombinant technology address asparaginase *Erwinia chrysanthemi* shortages? *Pediatr Blood Cancer*. 2021;68(10):e29169.

