PEMRYDI RTU®

(pemetrexed injection)

The first and only ready-to-use presentation of pemetrexed[1-3]

- Shares the same indications as Alimta® (pemetrexed)[1,2]
- Requires no reconstitution, dilution, or refrigeration[1]
- Approved via the FDA's 505(b)(2) regulatory pathway[4]
- Covered by the Amneal PATHways® Patient Support Program

Use the unique HCPCS code J9324 when billing for PEMRYDI RTU®.[5]

FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System.

Alimta® is a registered trademark of Eli Lilly and Company.

INDICATIONS

Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

PEMRYDI RTU® is a folate analog metabolic inhibitor indicated:

- in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic non-squamous NSCLC with no *EGFR* or *ALK* genomic tumor aberrations.
- in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic non-squamous NSCLC.
- as a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
- as a single agent for the treatment of patients with recurrent metastatic non-squamous NSCLC after prior chemotherapy.

Limitations of Use:

PEMRYDI RTU® is not indicated for treatment of squamous cell non-small cell lung cancer.

Mesothelioma

PEMRYDI RTU® is indicated in combination with cisplatin for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

Please see pages 6-7 for Important Safety Information and full Prescribing Information.

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The first and only ready-to-use presentation of pemetrexed[1-3]

	PEMRYDI RTU® (pemetrexed injection)[1]	Pemfexy® (pemetrexed injection)[3]	Alimta® (pemetrexed for injection)[2]
Does not require **RECONSTITUTION**	✓	✓	—
Does not require **DILUTION**	✓	—	—
STABLE AT ROOM TEMPERATURE in original packaging*	✓	—	✓

PEMRYDI RTU® may be stored in an infusion bag at controlled room temperature* for up to 24 hours prior to use. Discard the infusion bag if not used within 24 hours.[1]

PEMRYDI RTU® was approved via the FDA's 505(b)(2) regulatory pathway[4]

Products approved via the 505(b)(2) regulatory pathway[6-9]:

- **Contain full safety and effectiveness reports**, based at least in part on the originator product's data
- **Allow for changes in product characteristics that may support operational efficiency**, such as ready-to-use formulations or other differences in dosage form, strength, or route of administration

*Controlled room temperature is defined as 20°C to 25°C (68°F to 77°F).[1]

FDA, US Food and Drug Administration.

Alimta® is a registered trademark owned by or licensed to Eli Lilly and Company, its subsidiaries, or affiliates.

Pemfexy® is a registered trademark of Eagle Pharmaceuticals, LLC.

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PEMRYDI RTU®
(pemetrexed injection)

Ready-to-use formulation makes preparation more efficient

Withdraw the calculated dose of PEMRYDI RTU® from the vial(s) and transfer to an empty IV bag. Discard any unused drug remaining in the vial.[1]

No refrigeration[1]

Shelf stable at room temperature, in original packaging

No reconstitution[1]

Save time and resources without the need for a diluent

No dilution[1]

Presented at a dosable, ready-to-use concentration of 10 mg/mL

IV, intravenous.

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Dosed similarly to Alimta® (pemetrexed for injection)[1,2]

For patients with non-squamous non-small cell lung cancer (NSCLC)[1]

The recommended dose of PEMRYDI RTU® is 500 mg/m^2 as an IV infusion over 10 minutes. PEMRYDI RTU® should be used:

In combination with pembrolizumab and platinum chemotherapy for initial treatment of patients with **metastatic non-squamous NSCLC**	In combination with cisplatin chemotherapy for initial treatment of patients with **locally advanced or metastatic non-squamous NSCLC**	As a single agent for maintenance treatment of **locally advanced or metastatic non-squamous NSCLC**	As a single agent for treatment of **recurrent metastatic non-squamous NSCLC** following prior chemotherapy

For patients with mesothelioma[1]

The recommended dose of PEMRYDI RTU® is 500 mg/m^2 as an IV infusion over 10 minutes, in combination with cisplatin

Premedication and concomitant medications[1]

Medication	Dosage	Timing
Folic acid	400-1000 mcg orally, once daily	Daily starting 7 days before first dose of PEMRYDI RTU®. Continue until 21 days after last dose
Vitamin B_{12}	1 mg intramuscularly **Do not substitute oral vitamin B_{12} for intramuscular vitamin B_{12}**	1 week prior to first dose of PEMRYDI RTU® and every 3 cycles thereafter. Subsequent vitamin B_{12} injections may be given the same days as treatment with PEMRYDI RTU®
Dexamethasone	4 mg orally, twice daily	On the day before, day of, and the day after PEMRYDI RTU®

IV, intravenous.

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PEMRYDI RTU®
(pemetrexed injection)

The Amneal PATHways® Patient Support Program makes accessing and paying for medicine seamless

The Amneal PATHways® Patient Support Program offers services such as:

Amneal PATHways® Patient Access To Health

- Benefit investigation
- Prior authorization support
- Affordability options
- Claims assistance
- Co-pay assistance

The Amneal PATHways® Co-pay Assistance Card is available to eligible patients

- Eligible* commercially insured patients may pay as little as $0 per treatment with PEMRYDI RTU®

Questions? Call 1-866-4-AMNEAL (1-866-426-6325) with any questions or concerns Monday-Friday, 8:00 AM-8:00 PM ET.

*Limits, terms, and conditions apply. No income restrictions for patients to qualify. For information on enrollment, claims submissions, and reimbursement, log on to the PATHways provider portal at pathwaysproviderportal.com. Eligibility Criteria/Terms & Conditions: The PATHways Co-Pay Savings Program is NOT insurance. The Program is only available for residents of the US and Puerto Rico who have commercial health insurance with co-pay/co-insurance on each prescription fill per product. Uninsured and cash-pay individuals are NOT eligible for the Program nor are individuals with commercial insurance coverage that does not provide coverage for PEMRYDI RTU® (pemetrexed injection). Individuals with coverage for PEMRYDI RTU® (pemetrexed injection), in whole or in part, under any state or federally funded healthcare program, including but not limited to, Medicare, Medicare Advantage Plans, Medicare Part D (including Qualified Retiree Prescription Drug Plans), Medicaid, Medigap, VA, DoD, TRICARE, and the Puerto Rico Government Health Insurance Plan, are NOT eligible for the Program. Patients who move from commercial to state or federally funded insurance will no longer be eligible for the Program.

Patients may not combine this offer with any rebate, coupon, free trial, or similar offer. Patients must present a valid prescription for an eligible drug at a participating pharmacy. Federal and state laws and other factors may prevent or otherwise restrict eligibility. This offer is not valid where prohibited by law. Void if copied, transferred, purchased, altered, or traded. Amneal Pharmaceuticals LLC reserves the right to rescind, revoke or amend this offer or discontinue the Program at any time without notice. When submitting claims under the Program, patients are certifying that they understand the Program rules, regulations and terms and conditions, and will comply with the Program terms as set forth herein. Additionally, you are certifying that a claim has not been submitted under a state or federally funded healthcare program, including but not limited to, Medicare, Medicare Advantage Plans, Medicare Part D (including Qualified Retiree Prescription Drug Plans), Medicaid, Medigap, VA, DoD, TRICARE, and the Puerto Rico Government Health Insurance Plan. Limit one Program enrollment per individual.

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Indications and Important Safety Information

PEMRYDI RTU®
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INDICATIONS

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Limitations of Use:

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Mesothelioma

PEMRYDI RTU® is indicated in combination with cisplatin for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

IMPORTANT SAFETY INFORMATION

Contraindication

PEMRYDI RTU® is contraindicated in patients with a history of hypersensitivity reaction to pemetrexed.

Warnings and Precautions

- **Myelosuppression:** PEMRYDI RTU® may cause severe bone marrow suppression resulting in cytopenia and an increased risk of infection. Do not administer when the absolute neutrophil count is less than 1500 cells/mm^3 and platelets are less than 100,000 cells/mm^3. Initiate supplementation with oral folic acid and intramuscular vitamin B_{12} to reduce the severity of hematologic and gastrointestinal toxicity of PEMRYDI RTU®.
- **Renal Failure:** PEMRYDI RTU® may cause severe and sometimes fatal renal failure. Do not administer when creatinine clearance is less than 45 mL/min.
- **Bullous and Exfoliative Skin Toxicity:** Permanently discontinue PEMRYDI RTU® for severe and life-threatening bullous, blistering, or exfoliating skin toxicity.
- **Interstitial Pneumonitis:** Withhold PEMRYDI RTU® for acute onset of new or progressive unexplained pulmonary symptoms such as dyspnea, cough, or fever pending diagnostic evaluation. If pneumonitis is confirmed, permanently discontinue PEMRYDI RTU®.
- **Radiation Recall:** May occur in patients who received radiation weeks to years previously; permanently discontinue PEMRYDI RTU® for signs of radiation recall.
- **Embryo-Fetal Toxicity:** PEMRYDI RTU® can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Please see accompanying full Prescribing Information.

Adverse Reactions

- The most common adverse reactions (incidence ≥ 20%) of PEMRYDI RTU® when administered as a single agent are fatigue, nausea, and anorexia.
- The most common adverse reactions (incidence ≥ 20%) of PEMRYDI RTU® when administered with cisplatin are vomiting, neutropenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation.
- The most common adverse reactions (incidence ≥ 20%) of PEMRYDI RTU® when administered with pembrolizumab and platinum chemotherapy are fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.

Drug Interactions

- Ibuprofen increased the risk of PEMRYDI RTU® toxicity in patients with mild to moderate renal impairment. Modify the ibuprofen dosage for patients with a creatinine clearance between 45 mL/min and 79 mL/min.

Use in Specific Populations

- **Lactation:** Advise not to breastfeed.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Biosciences, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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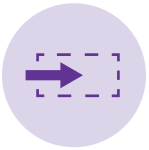
PEMRYDI RTU® is supplied as a ready-to-use solution[1]

PEMRYDI RTU® is available in 2 strengths to minimize waste

Unit of Sale[1]	Unit of Sale Quantity[1]	NDC[1]
100 mg/10 mL (10 mg/mL)	Single-dose vial	70121-2453-1
500 mg/50 mL (10 mg/mL)	Single-dose vial	70121-2461-1

PEMRYDI RTU® is supplied as a sterile clear, colorless to pale yellow to green-yellow ready-to-use solution packaged in a USP type-I glass vial with rubber stopper and aluminum flip-off cap.[1]



Unique HCPCS code for billing PEMRYDI RTU®: **J9324.**[5]

Order PEMRYDI RTU® from your wholesaler or contact Amneal: Toll free 866.525.7270 | CustomerRelations@amneal.com

HCPCS, Healthcare Common Procedure Coding System.

References: 1. PEMRYDI RTU. Prescribing information. Amneal Pharmaceuticals LLC; 2024. **2.** Alimta. Prescribing information. Eli Lilly and Company; 2004. **3.** Pemfexy. Prescribing information. Eagle Pharmaceuticals, Inc.; 2022. **4.** Amneal Pharmaceuticals. Amneal receives 505(b)(2) NDA approval from FDA for PEMRYDI RTU®, a ready-to-use oncology injectable. Accessed November 12, 2024. https://investors.amneal.com/news/press-releases/press-release-details/2023/Amneal-Receives-505b2-NDA-Approval-from-FDA-for-PEMRYDI-RTU-a-Ready-to-Use-Oncology-Injectable/default.aspx **5.** CMS. First quarter, 2024 HCPCS quarterly update. Updated March 21, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **6.** Lal R. Abbreviated approval pathways for drug product: 505(b)(2) or ANDA? Updated September 19, 2019. https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-anda **7.** GRP. Overview of FDA 505(b)(2) regulatory pathway. July 2017. https://globalregulatorypartners.com/white_papers/overview-of-fda-505b2-regulatory-pathway/ **8.** Goldstein B. Overview of the 505(b)(2) regulatory pathway for new drug applications. Food and Drug Administration. Accessed March 14, 2024. https://www.fda.gov/media/156350/download **9.** Freije I, Lamouche S, Tanguay M. Review of drugs approved via the 505(b)(2) pathway: uncovering drug development trends and regulatory requirements. *Ther Innov Regul Sci*. 2020;54(1):128-138.

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