PEMRYDI RTU®

(pemetrexed injection)

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

- Approved via the FDA's 505(b)(2) regulatory pathway
- No reconstitution, dilution, or refrigeration needed[1]
- Supplied in 2 dosage strengths, 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL)[1]
- Covered by the Amneal PATHways® Patient Support Program

PEMRYDI RTU® is available through most major wholesaler and distributor partners

PEMRYDI RTU® is available as follows:

Unit of Sale[1]	Unit of Sale Quantity[1]	NDC[1]	List (WAC)[4]
100 mg/10 mL (10 mg/mL)	Single-dose vial	NDC 70121-2453-1	$799.00
500 mg/50 mL (10 mg/mL)	Single-dose vial	NDC 70121-2461-1	$3,995.00

HCPCS Code[5]	Descriptor
J9324	Injection, pemetrexed (pemrydi rtu), 10 mg

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 next page for Important Safety Information and full Prescribing Information.

FDA, Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; WAC, wholesale acquisition cost.

References: 1. PEMRYDI RTU. Prescribing information. Amneal Pharmaceuticals LLC; 2024. **2.** Pemfexy. Prescribing information. Eagle Pharmaceuticals, Inc.; 2022. **3.** Alimta. Prescribing information. Eli Lilly and Company; 2004. **4.** Wholesale Acquisition Cost (WAC) as of 03/01/2024. **5.** CMS. First quarter, 2025 HCPCS quarterly update. November 4, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update

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READY-TO-USE FORMULATION MAKES PREPARATION MORE EFFICIENT

No Refrigeration	No Reconstitution	No Dilution
Stable for storage at room temperature in original packaging.[1]	Save time and resources without the need for diluent.[1]	Presented at a dosable, ready-to-use concentration of 10 mg/mL.[1]

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]

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

Amneal PATHways® Patient Access To Health

1-866-4AMNEAL (426-6325)

Amneal is pleased to offer reimbursement access and patient support services through the PATHways program.

PATHways Patient Access Specialists are available to assist healthcare providers and patients with:

- Benefit investigation
- Prior authorization support
- Affordability options like co-pay savings
- Claims assistance

Call toll-free Monday through Friday, 8 AM to 8 PM ET.

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.

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.

Please see full Prescribing Information.

Order from your wholesaler or contact Amneal: Toll Free 866.525.7270 | CustomerRelations@amneal.com

amnealbiosciences.com | amneal.com

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