PRODUCT FACT SHEET

Ryzneuta®
(efbemalenograstim alfa-vuxw)
20mg/mL for injection

Help Manage the Risk of Febrile Neutropenia With Ryzneuta®

THE FIRST AND ONLY PEG-FREE, LONG-ACTING G-CSF

Approved by the FDA

INDICATIONS

Ryzneuta® is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Limitations of Use

Ryzneuta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Ryzneuta® is contraindicated in patients with a history of serious allergic reactions to granulocyte stimulating factors such as efbemalenograstim alfa-vuxw, pegfilgrastim, or filgrastim products.

Presentation[1]	Ryzneuta® is a clear, colorless, preservative-free solution supplied in a prefilled, single-dose syringe with a 27-gauge, ½-inch needle and an UltraSafe Passive™ Needle Guard, containing 20 mg of efbemalenograstim alfa-vuxw
HCPCS code[2]	J9361
HCPCS description[2]	Injection, efbemalenograstim alfa-vuxw, Ryzneuta® for subcutaneous use, 20 mg
Billable units[2]	1 billable unit = 0.5 mg
WAC	$4600
NDC[1]	72893-0016-02
Unit of sale[1]	One (1) vial
How Ryzneuta® is supplied[1]	Dispensing pack containing one 20 mg/mL prefilled syringe Prefilled syringe does not bear graduation marks and is intended only to deliver the entire contents of the syringe for direct administration to adult patients
Storage information[1]	• Store refrigerated at 2°C to 8°C (36°F to 46°F) in the carton to protect from light • Do not shake • Discard syringes stored at room temperature for more than 48 hours • Do not freeze • Discard syringe if frozen

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

References: 1 Ryzneuta® [Prescribing Information], Acrotech Biopharma Inc. **2** Centers for Medicare & Medicaid Services (CMS). Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations: First Quarter, 2024 HCPCS Coding Cycle. Accessed June 10, 2025. https://www.cms.gov/files/ document/2024-hcpcs-application-summary-quarter-1-2024-drugs-and-biologicals.pdf.

Please see additional Important Safety Information on the next page.

Please see accompanying full Prescribing Information (PI) or visit ryzneuta.com/PI for full PI.

THE NEXT BRANCH IN

G-CSF EVOLUTION

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WARNINGS AND PRECAUTIONS

Splenic Rupture

Splenic rupture, including fatal cases, can occur following the administration of recombinant human granulocyte colony stimulating factor (rhG-CSF) products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome (ARDS)

ARDS can occur in patients receiving rhG-CSF products. Evaluate patients who develop fever and lung infiltrates or respiratory distress. Discontinue Ryzneuta® in patients with ARDS.

Serious Allergic Reactions

Serious allergic reactions, including anaphylaxis, can occur in patients receiving rhG-CSF products. Permanently discontinue Ryzneuta® in patients with serious allergic reactions. Ryzneuta® is contraindicated in patients with a history of serious allergic reactions to Ryzneuta® or other rhG-CSF products such as pegfilgrastim, eflapegrastim or filgrastim products.

Sickle Cell Crisis in Patients with Sickle Cell Disorders

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving rhG-CSF products. Discontinue Ryzneuta® if sickle cell crisis occurs.

Glomerulonephritis

Glomerulonephritis has occurred in patients receiving rhG-CSF products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation. Evaluate and consider dose-reduction or interruption of Ryzneuta® if causality is likely.

Leukocytosis

White blood cell (WBC) counts of 100×10^9/L or greater have been observed in patients receiving rhG-CSF products. Monitor complete blood count (CBC) during Ryzneuta® therapy. Discontinue Ryzneuta® treatment if WBC count of 100×10^9/L or greater occurs.

Thrombocytopenia

Thrombocytopenia has been reported in patients receiving rhG-CSF products. Thrombocytopenia occurred in 11% of Ryzneuta®-treated patients. One patient (0.4%) experienced severe thrombocytopenia. Monitor platelet counts.

Capillary Leak Syndrome

Capillary leak syndrome has been reported after administration of rhG-CSF products and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency and severity, and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor, and give standard symptomatic treatment, which may include a need for intensive care.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor through which Ryzneuta® acts has been found on tumor cell lines. The possibility that Ryzneuta® acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which Ryzneuta® is not approved, cannot be excluded.

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

MDS and AML have been associated with the use of rhG-CSF products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

Aortitis

Aortitis has been reported in patients receiving rhG-CSF products. It may occur as early as the first week after start of therapy. Consider aortitis in patients who develop generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count) without known etiology. Discontinue Ryzneuta® if aortitis is suspected.

Nuclear Imaging

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

ADVERSE REACTIONS

In study GC-627-04, the most common adverse reactions (≥10%) through cycle 1 were nausea (51%), anemia (15%), and thrombocytopenia (12%). Other adverse reactions reported by ≥ 20% of Ryzneuta®-treated patients with breast cancer receiving myelosuppressive chemotherapy in study GC-627-05 were fatigue and bone pain.

Please see additional Important Safety Information on previous page.

Please see accompanying full Prescribing Information (PI) or visit ryzneuta.com/PI for full PI.

RYZ-0157

ACROTECH® BIOPHARMA