Releuko®
(filgrastim-ayow)

Biosimilar to Neupogen®

- Made in the U.S.A.
- Preservative free
- Covered by the Amneal PATHways® patient support program

Product Information

Unit of Sale	Presentation	Pack Size	Unit of Sale NDC	List (WAC) Price[1]
300 mcg/0.5 mL Prefilled Syringe	Prefilled Syringe	1	70121-1568-1	$159.00
		10	70121-1568-7	$1,590.00
480 mcg/0.8 mL Prefilled Syringe	Prefilled Syringe	1	70121-1570-1	$254.40
		10	70121-1570-7	$2,544.00

HCPCS Code[2]	Descriptor
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram

IMPORTANT SAFETY INFORMATION

Indications and Usage

RELEUKO® is a leukocyte growth factor indicated to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- Reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

Contraindications

Patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim products.

Please see next page for additional Important Safety Information and visit Releuko.us for full Prescribing Information.

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

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Storage & Handling

Store RELEUKO® refrigerated at 2°C to 8°C (36°F to 46°F) in the original pack to protect from light.
Do not leave RELEUKO® in the direct sunlight. DO NOT freeze RELEUKO®.
Avoid shaking. Transport via pneumatic tube has not been studied.

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.

IMPORTANT SAFETY INFORMATION (continued)

Before you take RELEUKO® (filgrastim-ayow) injection, tell your healthcare provider if you are pregnant or plan to breast feed, and if you have sickle cell disorder, kidney problems or receiving radiation therapy.

Warnings and Precautions

- Fatal splenic rupture: Patients may experience enlarged spleen which can rupture and cause death.
- Acute respiratory distress syndrome (ARDS): Patients may develop fever and lung infiltrates or respiratory distress for ARDS. Discontinue RELEUKO® in patients with ARDS.
- Fatal sickle cell crises: Serious sickle cell crises have been reported in patients with sickle cell disorders receiving RELEUKO®. Discontinue RELEUKO® if sickle cell crisis occurs.
- Serious allergic reactions, including anaphylaxis: Permanently discontinue RELEUKO® in patients with serious allergic reactions.
- Kidney injury (Glomerulonephritis): Kidney injury have been reported in patients on RELEUKO®. Consider dose-reduction or interruption of RELEUKO® in patients with kidney injury.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using RELEUKO® in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.
- Decreased platelet count (thrombocytopenia); increased white blood cell count (leukocytosis) and inflammation of your blood vessels (cutaneous vasculitis) have been reported. Monitor platelet counts and white blood cell count.
- Aortitis has been reported in patients receiving filgrastim products. Discontinue treatment if aortitis is suspected.

Adverse Reactions

Most common adverse reactions in patients:

- With nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs are pyrexia, pain, rash, cough, and dyspnea.
- With AML are pain, epistaxis and rash.
- With nonmyeloid malignancies undergoing myeloablative chemotherapy followed by Bone Marrow Transplant is rash.
- Undergoing peripheral blood progenitor cell mobilization and collection are bone pain, pyrexia and headache.
- With severe chronic neutropenia are pain, anemia, epistaxis, diarrhea, hypoesthesia and alopecia.

Visit Releuko.us for full Prescribing Information.

References: 1. Wholesale acquisition cost (WAC) as of 5/12/2025. **2.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations; second quarter, 2024 HCPCS coding cycle.

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