

Biosimilar to Neulasta®



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

Product Information

Dosage Strength	Inner NDC	Unit of Sale NDC	Unit of Sale Pack Size	List (WAC) ¹
6 mg/0.6 mL	70121-1627-1	70121-1627-1	1 x 0.6 mL Prefilled Syringe	\$2,500.00
HCPCS Code ²	Descriptor			
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg			

IMPORTANT SAFETY INFORMATION

Indications and Usage

FYLNETRA® is a leukocyte growth factor indicated to

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome).

Limitations of Use: FYLNETRA® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

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

Before taking FYLNETRA®, 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 FYLNETRA® in patients with ARDS.
- Serious allergic reactions, including anaphylaxis: Permanently discontinue FYLNETRA® in patients with serious allergic reactions.

Please see next page for additional Important Safety Information and visit <u>Fylnetra.us</u> for full <u>Prescribing Information</u>.



Storage & Handling

Store refrigerated between 36°F to 46°F (2°C to 8°C) in the carton to protect from light. Do not shake. Discard syringes stored at room temperature for more than 72 hours.

Avoid freezing; if frozen, thaw in the refrigerator before administration.

Discard syringe if frozen more than once.



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)

- Fatal sickle cell crises: Serious sickle cell crises have been reported in patients with sickle cell disorders receiving FYLNETRA®. Discontinue FYLNETRA® if sickle cell crisis occurs.
- Kidney injury (Glomerulonephritis): Kidney injury have been reported in patients on FYLNETRA®. Consider dose-reduction or interruption of FYLNETRA® in patients with kidney injury.
- 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.
- Capillary leak syndrome has been reported after G-CSF administration, including pegfilgrastim products, and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration.
- The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using FYLNETRA® in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.
- Aortitis has been reported in patients receiving pegfilgrastim products.
- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes.

Adverse Reactions: Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity.

Visit Fylnetra.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.



