Fylnetra®
(pegfilgrastim-pbbk)

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	70121-1627-01	70121-1627-01	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.

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

Contraindication: 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.
- 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.

Please see next page for additional Important Safety Information and visit Fylnetra.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 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.

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 (continued)

- Serious allergic reactions, including anaphylaxis: Permanently discontinue Fylnetra in patients with serious allergic reactions.
- 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 12/31/2023. **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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