NYVEPRIA™ (pegfilgrastim-apgf)

Product Information

NYVEPRIA is an FDA-approved biosimilar* for Neulasta (pegfilgrastim) available as an SC injection[1]

Not actual size.

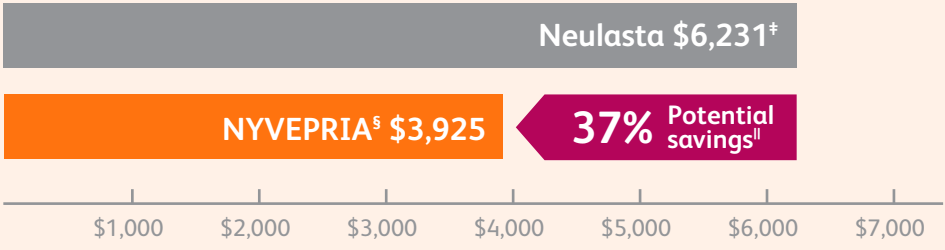
Ordering NYVEPRIA: What to know

NYVEPRIA PRODUCT INFORMATION

	6 mg/0.6 mL prefilled syringe
Individual unit	NDC 0069-0324-01
Unit list price	$3,925
Q-code	Q5122 Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg

POTENTIAL COST SAVINGS WITH NYVEPRIA

Wholesale acquisition cost (WAC)† represents a 37% discount vs Neulasta per 6 mg prefilled syringe[2,3]



*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of NYVEPRIA has been demonstrated for the condition(s) of use (eg, indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its full Prescribing Information.

†WAC is a manufacturer's undiscounted list price to wholesalers/direct purchasers and, therefore, is not inclusive of discounts to payers, providers, distributors, and other purchasing organizations.

‡As of 2019.

§NYVEPRIA does not have a designation of interchangeability with Neulasta.

‖There are no head-to-head studies between Neulasta and NYVEPRIA, and no clinical comparisons can be made between the products.

Learn more at www.NYVEPRIAHCP.com

Please see Important Safety Information on pages 2-3 and full Prescribing Information, including Patient Information and Instructions for Use.

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Indication and Important Safety Information

Indication

NYVEPRIA is 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

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

Important Safety Information

Contraindications

- NYVEPRIA is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products
- Reactions have included anaphylaxis

Warnings and Precautions

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products
- Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving NYVEPRIA

Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving pegfilgrastim products
- Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving NYVEPRIA
- Discontinue NYVEPRIA in patients with ARDS

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products
- The majority of reported events occurred upon initial exposure
- Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment
- Permanently discontinue NYVEPRIA in patients with serious allergic reactions
- Do not administer NYVEPRIA to patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products

Use in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products
- Discontinue NYVEPRIA if sickle cell crisis occurs

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving pegfilgrastim products
- The diagnoses were based on azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy
- Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation of pegfilgrastim products
- If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of NYVEPRIA

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Important Safety Information (continued)

Leukocytosis

- White blood cell counts of 100 x 10^9/L or greater have been observed in patients receiving pegfilgrastim products
- Monitoring of complete blood count (CBC) during NYVEPRIA therapy is recommended

Capillary Leak Syndrome (CLS)

- CLS has been reported after granulocyte-colony stimulating factor (G-CSF) administration, including pegfilgrastim 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
- Patients who develop symptoms of CLS should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- The G-CSF receptor through which pegfilgrastim and filgrastim products act has been found on tumor cell lines
- 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

Aortitis

- Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy
- Manifestations may include 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)
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue NYVEPRIA 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

Most Common Adverse Reactions

- Bone pain
- Pain in extremity

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Making your patients' support needs a priority. Together.

Pfizer Oncology Together is a personalized support program to help patients and their loved ones throughout NYVEPRIA treatment. We can assist with the access and reimbursement process and help identify financial assistance options for your patients' prescribed NYVEPRIA. And when your patients need support for their day-to-day challenges, we can provide them with a dedicated Care Champion who has social work experience and can connect them to resources that may help. Because when it comes to support, we're in this together.

FOR LIVE, PERSONALIZED SUPPORT
Call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET)

VISIT
PfizerOncologyTogether.com

References: 1. NYVEPRIA [prescribing information]. New York, NY: Pfizer Inc., June 2020. **2.** Data on file. Pfizer Inc., New York, NY. **3.** Neulasta.com. Neulasta® (pegfilgrastim) cost assistance, tools, and resources. https://www.neulasta.com/support/#panel1. Accessed July 28, 2020.

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