

For appropriate patients receiving myelosuppressive chemotherapy

Who could benefit from Neulasta® Onpro®?

Neulasta® Onpro® may be appropriate for all of your patients who:

- are adults¹
- are comfortable following the Patient Instructions for Use¹
- do not have allergies to acrylics¹

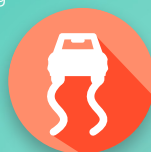
What do you consider when determining if Onpro® is right for your patients?

Struggle to get transportation

No caregiver and can't get back to the healthcare facility*

Weather Conditions

Such as a blizzard, could make driving hazardous



Multiple consecutive days of chemo

Chemo two days in a row and the patient doesn't want to come back a third day every cycle



Friday chemo

And the clinic is closed on Saturday



Scheduling conflicts

Family or work conflicts

Flu season

Immunosuppressed patients may want to stay away from those with the flu²



Requests Neulasta® Onpro®

Specific requests from patients who don't want to come back

Non-compliant

Missed prefilled syringe appointment last cycle and didn't get next day



Holiday

Chemo a day before holiday closings



Live far away

Total time spent includes more than just driving time

*For patients with Onpro® applied on the abdomen. The back of the arm may only be used if there is a caregiver available to monitor the status of the on-body injector for Neulasta®.

Indication

Neulasta® is 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 clinically significant incidence of febrile neutropenia. Neulasta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Contraindication

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

Please see full Important Safety Information on back cover.

 **Neulasta®** **Onpro®**
(pegfilgrastim) injection **kit**

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Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of Neulasta®
- Evaluate for an enlarged or ruptured spleen in patients who report left upper abdominal or shoulder pain

Acute Respiratory Distress Syndrome (ARDS)

- ARDS has occurred in patients receiving Neulasta®
- Evaluate patients who develop a fever and lung infiltrates or respiratory distress after receiving Neulasta®
- Discontinue Neulasta® in patients with ARDS

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis can occur in patients receiving Neulasta®
- Majority of events occurred upon initial exposure and can recur within days after discontinuation of initial anti-allergic treatment
- Permanently discontinue Neulasta® in patients with serious allergic reactions

Allergies to Acrylics

- On-body injector (OBI) for Neulasta® uses acrylic adhesives
- Patients who are allergic to acrylic adhesives may have a significant reaction

Use in Patients With Sickle Cell Disorders

- In patients with sickle cell trait or disease, sickle cell crisis, in some cases fatal, can occur in patients receiving Neulasta®
- Discontinue Neulasta® if sickle cell crisis occurs

Glomerulonephritis

- Has occurred in patients receiving Neulasta®
- Diagnoses based on azotemia, hematuria, proteinuria, and renal biopsy
- Generally events resolved after dose reduction or discontinuation of Neulasta®
- If suspected, evaluate for cause and if cause is likely, consider dose-reduction or interruption of Neulasta®

Leukocytosis

- Increased white blood cell counts of $100 \times 10^9/L$ have been observed
- Monitoring CBCs is recommended

Capillary Leak Syndrome (CLS)

- CLS has been reported after G-CSF administration, including Neulasta®
- Characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration
- Episodes vary in frequency, severity, and may be life-threatening if treatment is delayed
- Patients with symptoms should be closely monitored and receive standard symptomatic treatment, which may include intensive care

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- G-CSF receptor has been found on tumor cell lines
- The possibility that pegfilgrastim acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, cannot be excluded

Potential Device Failures

- Missed or partial doses have been reported in patients receiving pegfilgrastim via the on-body injector (OBI) due to the device not performing as intended
- In the event of a missed or partial dose, patients may be at increased risk of events such as neutropenia, febrile neutropenia and/or infection than if the dose had been correctly delivered
- Instruct patients to notify their healthcare professional immediately in order to determine the need for a replacement dose if they suspect that the device may not have performed as intended

Aortitis

- Aortitis has been reported in patients receiving Neulasta®. 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 Neulasta® 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

Please see accompanying Neulasta® full Prescribing Information.

Special Instructions for the on-body Injector (OBI) for Neulasta®

A healthcare provider must fill the on-body injector (OBI) with Neulasta® using the co-packaged prefilled syringe and then apply the OBI to the patient's skin (abdomen or back of arm). The back of the arm may only be used if there is a caregiver available to monitor the status of the OBI. Approximately 27 hours after the OBI is applied to the patient's skin, Neulasta® will be delivered over approximately 45 minutes. A healthcare provider may initiate administration with the OBI on the same day as the administration of cytotoxic chemotherapy, as long as the OBI delivers Neulasta® no less than 24 hours after the administration of cytotoxic chemotherapy.

The prefilled syringe co-packaged in the Neulasta® Onpro® kit contains additional solution to compensate for liquid loss during delivery through the OBI. If this syringe is used for manual subcutaneous injection, the patient will receive an overdose. If the prefilled syringe for manual use is used with the OBI, the patient may receive less than the recommended dose.

Do not use the OBI to deliver any other drug product except the Neulasta® prefilled syringe co-packaged with the OBI. Use of the OBI has not been studied in pediatric patients.

The OBI should be applied to intact, non-irritated skin on the arm or abdomen.

A missed dose could occur due to an OBI failure or leakage. Instruct patients using the OBI to notify their healthcare professional immediately in order to determine the need for a replacement dose of pegfilgrastim if they suspect that the device may not have performed as intended. If the patient misses a dose, a new dose should be administered by single prefilled syringe for manual use as soon as possible after detection.

Review the Patient Information and Patient Instructions for Use with the patient and provide the instructions to the patient.

Refer to the Healthcare Provider Instructions for Use for the OBI for full administration information.

For any OBI problems, call Amgen at 1-800-772-6436 or 1-844-MYNEULASTA (1-844-696-3852).

References:

1. Neulasta® (pegfilgrastim) Prescribing Information, Amgen.
2. American Cancer Society. Preventing Infections in People With Cancer. <https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/infections/preventing-infections-in-people-with-cancer>. Accessed November 9, 2018.



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