HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NEULASTA safely and effectively. See full prescribing information for NEULASTA.

NEULASTA® (pegfilgrastim) injection, for subcutaneous use
Initial U.S. Approval: 2002

----------RECENT MAJOR CHANGES----------
Dosage and Administration (2) 08/2025
Warnings and Precautions, Large and Medium Vessel Arteritis (5.13) 08/2026

----------INDICATIONS AND USAGE----------
Neulasta is a leukocyte growth factor indicated in adult and pediatric patients 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. (1.1)
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome). (1.2)

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

----------DOSAGE AND ADMINISTRATION----------

- Patients with cancer receiving myelosuppressive chemotherapy
  - For adult patients of any weight and pediatric patients weighing 45 kg and greater, the recommended dosage is 6 mg subcutaneously once per chemotherapy cycle. (2.1)
  - For pediatric patients weighing less than 45 kg, use weight-based dosing; refer to Table 1. (2.1)
  - Do not administer between 14 days before and 24 hours after administration of chemotherapy. (2.1)
- Patients acutely exposed to myelosuppressive doses of radiation
  - For adults of any weight and pediatric patients weighing 45 kg and greater, the recommended dosage is two doses, 6 mg each, subcutaneously one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation, and a second dose one week after. (2.2)
  - For pediatric patients weighing less than 45 kg, use weight-based dosing; refer to Table 1. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------

- Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only. (3)
- Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe co-packaged with the on-body injector for Neulasta. (3)
- Injection: 4 mg/0.4 mL solution in a single-dose vial. (3)

----------CONTRAINDICATIONS----------
In patients with a history of serious hypersensitivity reaction to pegfilgrastim or filgrastim. (4)

----------WARNINGS AND PRECAUTIONS----------

- Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture. (5.1)
- Acute respiratory distress syndrome (ARDS): Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue Neulasta in patients with ARDS. (5.2)
- Serious hypersensitivity reactions, including anaphylaxis: Permanently discontinue Neulasta in patients with serious hypersensitivity reactions. (5.3)
- The on-body injector for Neulasta uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction. (5.4)
- Fatal sickle cell crises: Discontinue Neulasta if sickle cell crisis occurs. (5.5)
- Glomerulonephritis: Evaluate and consider dose-reduction or interruption of Neulasta if causality is likely. (5.6)
- Thrombocytopenia: Monitor platelet counts. (5.8)
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using Neulasta in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML. (5.11)
- Potential device failures: Instruct patients to notify their healthcare provider if they suspect the on-body injector may not have performed as intended. (5.12)
- Large and Medium Vessel Arteritis: Discontinue Neulasta if arteritis is suspected. (5.13)

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Amgen Inc. at 1-800-77-AMGEN (1-800-772-6436) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 08/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
1.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy
1.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome
2 DOSAGE AND ADMINISTRATION
2.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy
2.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome
2.3 Preparation and Administration
2.4 Special Healthcare Provider Instructions for the On-body Injector for Neulasta
2.5 Advice to Give to Patients Regarding Administration via the On-body Injector for Neulasta
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Splenic Rupture
5.2 Acute Respiratory Distress Syndrome
5.3 Serious Hypersensitivity Reactions
5.4 Allergies to Acrylics
5.5 Use in Patients with Sickle Cell Disorders
5.6 Glomerulonephritis
5.7 Leukocytosis
5.8 Thrombocytopenia
5.9 Capillary Leak Syndrome
5.10 Potential for Tumor Growth Stimulatory Effects on Malignant Cells
5.11 Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer
5.12 Potential Device Failures
5.13 Large and Medium Vessel Arteritis
5.14 Nuclear Imaging
6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
6.2 Postmarketing Experience
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.4 Pediatric Use
8.5 Geriatric Use
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics

12.6 Immunogenicity
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
14.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy
14.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy

Neulasta is indicated in adult and pediatric patients 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 *[see Clinical Studies (14.1)]*.

Limitations of Use

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

1.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

Neulasta is indicated to increase survival in adults and pediatric patients acutely exposed to myelosuppressive doses of radiation *[see Dosage and Administration (2.2) and Clinical Studies (14.2)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy

The recommended dosage of Neulasta for adults of any weight and pediatric patients weighing at least 45 kg with cancer receiving myelosuppressive chemotherapy is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. For dosing in pediatric patients weighing less than 45 kg, refer to Table 1. Do not administer Neulasta between 14 days before and 24 hours after administration of chemotherapy.

Table 1. Dosing of Neulasta for Pediatric Patients Weighing Less Than 45 kg

Body Weight	Neulasta Dose	Volume to Administer
Less than 10 kg*	See below*	See below*
10 kg to 20 kg	1.5 mg	0.15 mL
21 kg to 30 kg	2.5 mg	0.25 mL
31 kg to 44 kg	4 mg	0.4 mL

* For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of Neulasta.

2.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

The recommended dosage of Neulasta for adults of any weight and pediatric patients weighing at least 45 kg with hematopoietic subsyndrome of acute radiation syndrome is two doses, 6 mg each, administered subcutaneously one week apart. For dosing in pediatric patients weighing less than 45 kg, refer to Table 1 *[see Dosage and Administration (2.1)]*. Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy). Administer the second dose one week after the first dose.

Obtain a baseline complete blood count (CBC). Do not delay administration of Neulasta if a CBC is not readily available. Estimate a patient's absorbed radiation dose (i.e., level of radiation exposure) based on information from public health authorities, biodosimetry if available, or clinical findings such as time to onset of vomiting or lymphocyte depletion kinetics.

2.3 Preparation and Administration

Neulasta is supplied in single-dose prefilled syringes for manual use or for use with the on-body injector (OBI) for Neulasta, which is co-packaged with a single-dose prefilled syringe for the OBI, and in single-dose vials *[see Dosage Forms and Strengths (3)]*.

Before using any of the Neulasta presentations:

- Remove the carton from the refrigerator and allow the Neulasta prefilled syringe or vial to reach room temperature, 20°C to 25°C (68°F to 77°F), for a minimum of 30 minutes. Do not warm in any other way. Discard any prefilled syringe or vial left at room temperature for greater than 48 hours.
- Neulasta is a clear, colorless, preservative-free solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer Neulasta if discoloration or particulates are observed.

Prefilled Syringe for Manual Use

For adult patients of any weight and pediatric patients weighing 45 kg and greater, the single-dose prefilled syringe for manual use is intended for subcutaneous administration of a single 6 mg/0.6 mL dose of Neulasta. The syringe does not bear graduation marks and therefore does not allow for direct administration of doses less than 6 mg/0.6 mL.

The needle cap on the prefilled syringe contains dry natural rubber (derived from latex); persons with latex allergies should not administer this product.

Prefilled Syringe for Use with OBI

For adult patients of any weight, the single-dose prefilled syringe for use with the OBI for Neulasta, is intended for subcutaneous administration of a single 6 mg/0.6 mL dose of Neulasta. The prefilled syringe co-packaged in the Neulasta Onpro® kit must only be used with the OBI for Neulasta *[see Dosage and Administration (2.4)]*.

Use of the OBI for Neulasta is not recommended for patients with hematopoietic subsyndrome of acute radiation syndrome. Use of the OBI for Neulasta has not been studied in pediatric patients.

The needle cap on the prefilled syringe contains dry natural rubber (derived from latex); persons with latex allergies should not administer this product.

Vial

For pediatric patients weighing less than 45 kg, the dose is prepared by withdrawing the required volume from the 4 mg/0.4 mL single-dose vial. A 0.5 mL staked tuberculin syringe with 0.01 mL graduation marks is recommended for preparation and administration for dose accuracy. Only healthcare providers should prepare and administer doses from the vials.

Administer Neulasta subcutaneously.

Discard unused portion of Neulasta in vials. Do not save unused drug for later administration.

2.4 Special Healthcare Provider Instructions for the On-body Injector for Neulasta

A healthcare provider must fill the on-body injector (OBI) with Neulasta using the prefilled syringe and then apply the OBI for Neulasta 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 for Neulasta. Approximately 27 hours after the OBI for Neulasta is applied to the patient's skin, Neulasta will be delivered over approximately 45 minutes. A healthcare provider may initiate administration with the OBI for Neulasta on the same day as the administration of chemotherapy, as long as the OBI for Neulasta delivers Neulasta no less than 24 hours after administration of chemotherapy.

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

Do not use the OBI for Neulasta to deliver any other drug product except the Neulasta prefilled syringe co-packaged with the OBI for Neulasta.

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

A missed dose could occur due to an OBI for Neulasta failure or leakage. If the patient misses a dose, a new dose should be administered by prefilled syringe for manual use, as soon as possible after detection.

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

2.5 Advice to Give to Patients Regarding Administration via the On-body Injector for Neulasta

Advise patients to avoid activities such as traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector (OBI) for Neulasta (this includes the 45-minute delivery period plus an hour post-delivery). Patients should have a caregiver nearby for the first use.

Refer the patient to the dose delivery information written on the Patient Instructions for Use. Provide training to patients to ensure they understand when the dose delivery of Neulasta will begin and how to monitor the OBI for Neulasta for completed delivery. Ensure patients understand how to identify signs of malfunction of OBI for Neulasta *[see Warnings and Precautions (5.12) and Patient Counseling Information (17)]*. Instruct patients using the OBI to notify their healthcare professional immediately in order to determine the need for a replacement dose of Neulasta if they suspect that the device may not have performed as intended *[see Warnings and Precautions (5.12)]*.

3 DOSAGE FORMS AND STRENGTHS

Neulasta is a clear, colorless, preservative-free solution available as:

- Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.

- Injection: 6 mg/0.6 mL in a single-dose prefilled syringe co-packaged with the on-body injector (OBI) for Neulasta (Neulasta Onpro kit).
- Injection: 4 mg/0.4 mL in a single-dose vial.

4 CONTRAINDICATIONS

Neulasta is contraindicated in patients with a history of a serious hypersensitivity reaction to pegfilgrastim or filgrastim. Reactions have included anaphylaxis *[see Warnings and Precautions (5.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

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

5.2 Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Neulasta, for ARDS. Discontinue Neulasta in patients with ARDS.

5.3 Serious Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, can occur in patients receiving Neulasta. The majority of reported events occurred upon initial exposure. Hypersensitivity reactions, including anaphylaxis, can recur within days after the discontinuation of initial therapies to manage the reaction. Permanently discontinue Neulasta in patients with serious hypersensitivity reactions. Neulasta is contraindicated in patients with a history of a serious hypersensitivity reaction to pegfilgrastim or filgrastim.

5.4 Allergies to Acrylics

The on-body injector (OBI) for Neulasta uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction.

5.5 Use in Patients with Sickle Cell Disorders

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving Neulasta. Discontinue Neulasta if sickle cell crisis occurs.

5.6 Glomerulonephritis

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

5.7 Leukocytosis

White blood cell (WBC) counts of 100×10^9/L or greater have been observed in patients receiving Neulasta. Monitoring of complete blood count (CBC) during Neulasta therapy is recommended.

5.8 Thrombocytopenia

Neulasta can cause thrombocytopenia. Monitor platelet counts during Neulasta therapy.

5.9 Capillary Leak Syndrome

Capillary leak syndrome has been reported after G-CSF administration, including Neulasta, and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.

5.10 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor through which pegfilgrastim and filgrastim act has been found on tumor cell lines. The possibility that Neulasta acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim is not approved, cannot be excluded.

5.11 Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

MDS and AML have been associated with the use of Neulasta in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

5.12 Potential Device Failures

Missed or partial doses have been reported in patients receiving Neulasta 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 using the OBI to notify their healthcare professional immediately in order to determine the need for a replacement dose of Neulasta if they suspect that the device may not have performed as intended.

5.13 Large and Medium Vessel Arteritis

Serious large and medium vessel arteritis, including 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, headache, neck pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count). Consider arteritis in patients who develop these signs and symptoms without known etiology. Consider appropriate clinical management and discontinue Neulasta as needed if arteritis is suspected.

5.14 Nuclear Imaging

Increased hematopoietic activity of the bone marrow in response to growth factor therapy, including Neulasta, has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Splenic Rupture *[see Warnings and Precautions (5.1)]*
- Acute Respiratory Distress Syndrome *[see Warnings and Precautions (5.2)]*
- Serious Hypersensitivity Reactions *[see Warnings and Precautions (5.3)]*
- Allergies to Acrylics *[see Warnings and Precautions (5.4)]*
- Use in Patients with Sickle Cell Disorders *[see Warnings and Precautions (5.5)]*
- Glomerulonephritis *[see Warnings and Precautions (5.6)]*
- Leukocytosis *[see Warnings and Precautions (5.7)]*
- Thrombocytopenia *[see Warnings and Precautions (5.8)]*
- Capillary Leak Syndrome *[see Warnings and Precautions (5.9)]*
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells *[see Warnings and Precautions (5.10)]*
- Myelodysplastic syndrome *[see Warnings and Precautions (5.11)]*
- Acute myeloid leukemia *[see Warnings and Precautions (5.11)]*
- Large and Medium Vessel Arteritis *[see Warnings and Precautions (5.13)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Neulasta clinical trials safety data are based upon 932 patients receiving Neulasta in seven randomized clinical trials. The population was 21 to 88 years of age and 92% female. The ethnicity was 75% Caucasian, 18% Hispanic, 5% Black, and 1% Asian. Patients with breast (n = 823), lung and thoracic tumors (n = 53) and lymphoma (n = 56) received Neulasta after nonmyeloablative cytotoxic chemotherapy. Most patients received a single 100 mcg/kg (n = 259) or a single 6 mg (n = 546) dose per chemotherapy cycle over 4 cycles.

The following adverse reaction data in Table 2 are from a randomized, double-blind, placebo-controlled study in patients with metastatic or non-metastatic breast cancer receiving docetaxel 100 mg/m^2 every 21 days (Study 3). A total of 928 patients were randomized to receive either 6 mg Neulasta (n = 467) or placebo (n = 461). The patients were 21 to 88 years of age and 99% female. The ethnicity was 66% Caucasian, 31% Hispanic, 2% Black, and < 1% Asian, Native American, or other.

The most common adverse reactions occurring in ≥ 5% of patients and with a between-group difference of ≥ 5% higher in the pegfilgrastim arm in placebo-controlled clinical trials are bone pain and pain in extremity.

Table 2. Adverse Reactions with ≥ 5% Higher Incidence in Neulasta Patients Compared to Placebo in Study 3

Body System Adverse Reaction	Placebo (N = 461)	Neulasta 6 mg SC on Day 2 (N = 467)
Musculoskeletal and connective tissue disorders		
Bone pain	26%	31%
Pain in extremity	4%	9%

Leukocytosis
In clinical studies, leukocytosis (WBC counts > 100 × 10^9/L) was observed in less than 1% of 932 patients with non-myeloid malignancies receiving Neulasta. No complications attributable to leukocytosis were reported in clinical studies.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of Neulasta. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Splenic rupture and splenomegaly (enlarged spleen) *[see Warnings and Precautions (5.1)]*
- Acute respiratory distress syndrome (ARDS) *[see Warnings and Precautions (5.2)]*
- Allergic reactions/hypersensitivity, including anaphylaxis, skin rash, urticaria, generalized erythema, and flushing *[see Warnings and Precautions (5.3)]*
- Sickle cell crisis *[see Warnings and Precautions (5.5)]*
- Glomerulonephritis *[see Warnings and Precautions (5.6)]*
- Leukocytosis *[see Warnings and Precautions (5.7)]*
- Thrombocytopenia *[see Warnings and Precautions (5.8)]*
- Capillary Leak Syndrome *[see Warnings and Precautions (5.9)]*
- Injection site reactions
- Sweet's syndrome (acute febrile neutrophilic dermatosis), cutaneous vasculitis
- Application site reactions (including events such as application site hemorrhage, application site pain, application site discomfort, application site bruise, and application site erythema) have been reported with the use of the on-body injector for Neulasta.
- Contact dermatitis and local skin reactions such as rash, pruritus, and urticaria have been reported with the use of the on-body injector for Neulasta, possibly indicating a hypersensitivity reaction to the adhesive.
- Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) in patients with breast and lung cancer receiving chemotherapy and/or radiotherapy *[see Warnings and Precautions (5.11)]*
- Large and medium vessel arteritis, including aortitis *[see Warnings and Precautions (5.13)]*
- Alveolar hemorrhage

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Although available data with Neulasta use in pregnant women are insufficient to establish whether there is a drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes, there

are available data from published studies in pregnant women exposed to filgrastim products. These studies have not established an association of filgrastim product use during pregnancy with major birth defects, miscarriage, or adverse maternal or fetal outcomes.

In animal studies, no evidence of reproductive/developmental toxicity occurred in the offspring of pregnant rats that received cumulative doses of pegfilgrastim approximately 10 times the recommended human dose (based on body surface area). In pregnant rabbits, increased embryolethality and spontaneous abortions occurred at 4 times the maximum recommended human dose simultaneously with signs of maternal toxicity *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

Pregnant rabbits were dosed with pegfilgrastim subcutaneously every other day during the period of organogenesis. At cumulative doses ranging from the approximate human dose to approximately 4 times the recommended human dose (based on body surface area), the treated rabbits exhibited decreased maternal food consumption, maternal weight loss, as well as reduced fetal body weights and delayed ossification of the fetal skull; however, no structural anomalies were observed in the offspring from either study. Increased incidences of post-implantation losses and spontaneous abortions (more than half the pregnancies) were observed at cumulative doses approximately 4 times the recommended human dose, which were not seen when pregnant rabbits were exposed to the recommended human dose.

Three studies were conducted in pregnant rats dosed with pegfilgrastim at cumulative doses up to approximately 10 times the recommended human dose at the following stages of gestation: during the period of organogenesis, from mating through the first half of pregnancy, and from the first trimester through delivery and lactation. No evidence of fetal loss or structural malformations was observed in any study. Cumulative doses equivalent to approximately 3 and 10 times the recommended human dose resulted in transient evidence of wavy ribs in fetuses of treated mothers (detected at the end of gestation but no longer present in pups evaluated at the end of lactation).

8.2 Lactation

Risk Summary

There are no data on the presence of pegfilgrastim in human milk, the effects on the breastfed child, or the effects on milk production. Other filgrastim products are secreted poorly into breast milk, and filgrastim products are not absorbed orally by neonates. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Neulasta and any potential adverse effects on the breastfed child from Neulasta or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of Neulasta for chemotherapy-induced neutropenia and hematopoietic subsyndrome of acute radiation syndrome have been established in pediatric patients.

Use of Neulasta in pediatric patients for chemotherapy-induced neutropenia is based on adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients aged 8 months and older with sarcoma *[see Clinical Pharmacology (12.3) and Clinical Studies (14.1)]*.

The use of Neulasta to increase survival in pediatric patients acutely exposed to myelosuppressive doses of radiation is based on efficacy studies conducted in animals and clinical data supporting the use of Neulasta in patients with cancer receiving myelosuppressive chemotherapy. Efficacy studies of Neulasta could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. Results from population modeling and simulation indicate that two doses of Neulasta (Table 1), administered one week apart provide pediatric patients with exposures comparable to that in adults receiving two 6 mg doses one week apart *[see Dosage and Administration (2.1, 2.2), Clinical Pharmacology (12.3) and Clinical Studies (14.2)]*.

8.5 Geriatric Use

Of the 932 patients with cancer who received Neulasta in clinical studies, 139 (15%) were aged 65 and over, and 18 (2%) were aged 75 and over. No overall differences in safety or effectiveness were observed between patients aged 65 and older and younger patients.

10 OVERDOSAGE

Overdosage of Neulasta may result in leukocytosis and bone pain. Events of edema, dyspnea, and pleural effusion have been reported in a single patient who administered Neulasta on 8 consecutive days in error. In the event of overdose, the patient should be monitored for adverse reactions *[see Adverse Reactions (6)]*. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11 DESCRIPTION

Pegfilgrastim is a covalent conjugate of recombinant methionyl human G-CSF (filgrastim) and monomethoxypolyethylene glycol. Filgrastim is a water-soluble 175 amino acid protein with a molecular weight of approximately 19 kilodaltons (kD). Filgrastim is obtained from the bacterial fermentation of a strain of *E. coli* transformed with a genetically engineered plasmid containing the human G-CSF gene. To produce pegfilgrastim, a 20 kD monomethoxypolyethylene glycol molecule is covalently bound to the N-terminal methionyl residue of filgrastim. The average molecular weight of pegfilgrastim is approximately 39 kD.

Neulasta (pegfilgrastim) is a sterile, clear, colorless, preservative-free solution with a pH of 4.0, supplied in single-dose prefilled syringes for manual use or for use with the on-body injector (OBI) for Neulasta, which is co-packaged with a single-dose prefilled syringe, or in single-dose vials.

<u>Prefilled Syringe for Manual Use or for Use with OBI</u>

- Neulasta for manual subcutaneous injection is supplied in 0.6 mL prefilled syringes. The prefilled syringe does not bear graduation marks and is designed to deliver the entire contents of the syringe (6 mg/0.6 mL).
- On-body injector (OBI) for Neulasta is supplied with a prefilled syringe containing 0.64 mL of Neulasta in solution that delivers 0.6 mL of Neulasta in solution when used with the OBI for Neulasta. The syringe does not bear graduation marks and is only to be used with the OBI for Neulasta.

The delivered 0.6 mL dose from either the prefilled syringe for manual subcutaneous injection or the OBI for Neulasta contains pegfilgrastim (6 mg based on protein weight), acetate (0.35 mg), polysorbate 20 (0.02 mg), sodium (0.02 mg), and sorbitol (30 mg) in Water for Injection, USP.

Vial

Neulasta for subcutaneous injection is supplied in 4 mg/0.4 mL single-dose vials. Each 0.4 mL vial contains pegfilgrastim (4 mg based on protein weight), acetate (0.24 mg), polysorbate 20 (0.02 mg), sodium (0.01 mg), and sorbitol (20 mg) in Water for Injection, USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Pegfilgrastim is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

12.2 Pharmacodynamics

Animal data and clinical data in humans suggest a correlation between pegfilgrastim exposure and the duration of severe neutropenia as a predictor of efficacy. Selection of the dosing regimen of Neulasta is based on reducing the duration of severe neutropenia.

12.3 Pharmacokinetics

The pharmacokinetics of pegfilgrastim was studied in 379 patients with cancer. The pharmacokinetics of pegfilgrastim was nonlinear, and clearance decreased with increases in dose. Neutrophil receptor binding is an important component of the clearance of pegfilgrastim, and serum clearance is directly related to the number of neutrophils. In addition to numbers of neutrophils, body weight appeared to be a factor. Patients with higher body weights experienced higher systemic exposure to pegfilgrastim after receiving a dose normalized for body weight. A large variability in the pharmacokinetics of pegfilgrastim was observed. The half-life of Neulasta ranged from 15 to 80 hours after subcutaneous injection. In healthy volunteers, the pharmacokinetics of pegfilgrastim were comparable when delivered subcutaneously via a manual prefilled syringe versus via the on-body injector (OBI) for Neulasta.

Specific Populations

No gender-related differences were observed in the pharmacokinetics of pegfilgrastim, and no differences were observed in the pharmacokinetics of geriatric patients (≥ 65 years of age) compared with younger patients (< 65 years of age) *[see Use in Specific Populations (8.5)]*.

Renal Impairment

In a study of 30 subjects with varying degrees of renal dysfunction, including end stage renal disease, renal dysfunction had no effect on the pharmacokinetics of pegfilgrastim.

Pediatric Patients with Cancer Receiving Myelosuppressive Chemotherapy

The pharmacokinetics and safety of pegfilgrastim were studied in 37 pediatric patients with sarcoma in Study 4 *[see Clinical Studies (14.1)]*. The mean (± standard deviation [SD]) systemic exposure ($AUC_{0\text{-}inf}$) of Neulasta after subcutaneous administration at 100 mcg/kg was 47.9 (± 22.5) mcg·hr/mL in the youngest age group (0 to 5 years, n = 11), 22.0 (± 13.1) mcg·hr/mL in the 6 to 11 years age group (n = 10), and 29.3 (± 23.2) mcg·hr/mL in the 12 to 21 years age group (n = 13). The terminal elimination half-lives of the corresponding age groups were 30.1 (± 38.2) hours, 20.2 (± 11.3) hours, and 21.2 (± 16.0) hours, respectively.

Patients Acutely Exposed to Myelosuppressive Doses of Radiation

The pharmacokinetics of pegfilgrastim is not available in patients acutely exposed to myelosuppressive doses of radiation. Based on limited pharmacokinetic data in irradiated non-human primates, the area under the concentration-time curve (AUC), reflecting the exposure to pegfilgrastim in non-human primates following a 300 mcg/kg dose of Neulasta, appears to be greater than in humans receiving a 6 mg dose. Results from population modeling and simulation indicate that two 6 mg doses of Neulasta administered one week apart in adults result in clinically relevant effects on duration of grade 3 and 4 neutropenia. In addition, weight-based dosing in pediatric patients weighing less than 45 kg *[see Dosage and Administration (2.1, Table 1 and 2.2)]* provides exposures comparable to those in adults receiving two 6 mg doses one week apart.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of pegfilgrastim or of other pegfilgrastim products.

Binding antibodies to pegfilgrastim were detected using a BIAcore assay. The approximate limit of detection for this assay is 500 ng/mL. Pre-existing binding antibodies were detected in approximately 6% (51/849) of patients with metastatic breast cancer. Four of 521 pegfilgrastim-treated subjects who were negative at baseline developed binding antibodies to pegfilgrastim following treatment. None of these 4 patients had evidence of neutralizing antibodies detected using a cell-based bioassay.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or mutagenesis studies have been performed with pegfilgrastim.

Pegfilgrastim did not affect reproductive performance or fertility in male or female rats at cumulative weekly doses approximately 6 to 9 times higher than the recommended human dose (based on body surface area).

14 CLINICAL STUDIES

14.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy

Neulasta was evaluated in three randomized, double-blind, controlled studies. Studies 1 and 2 were active-controlled studies that employed doxorubicin 60 mg/m^2 and docetaxel 75 mg/m^2 administered

every 21 days for up to 4 cycles for the treatment of metastatic breast cancer. Study 1 investigated the utility of a fixed dose of Neulasta. Study 2 employed a weight-adjusted dose. In the absence of growth factor support, similar chemotherapy regimens have been reported to result in a 100% incidence of severe neutropenia (ANC < 0.5×10^9/L) with a mean duration of 5 to 7 days and a 30% to 40% incidence of febrile neutropenia. Based on the correlation between the duration of severe neutropenia and the incidence of febrile neutropenia found in studies with filgrastim, duration of severe neutropenia was chosen as the primary endpoint in both studies, and the efficacy of Neulasta was demonstrated by establishing comparability to filgrastim-treated patients in the mean days of severe neutropenia.

In Study 1, 157 patients were randomized to receive a single subcutaneous injection of Neulasta (6 mg) on day 2 of each chemotherapy cycle or daily subcutaneous filgrastim (5 mcg/kg/day) beginning on day 2 of each chemotherapy cycle. In Study 2, 310 patients were randomized to receive a single subcutaneous injection of Neulasta (100 mcg/kg) on day 2 or daily subcutaneous filgrastim (5 mcg/kg/day) beginning on day 2 of each chemotherapy cycle.

Both studies met the major efficacy outcome measure of demonstrating that the mean days of severe neutropenia of Neulasta-treated patients did not exceed that of filgrastim-treated patients by more than 1 day in cycle 1 of chemotherapy. The mean days of cycle 1 severe neutropenia in Study 1 were 1.8 days in the Neulasta arm compared to 1.6 days in the filgrastim arm [difference in means 0.2 (95% CI - 0.2, 0.6)] and in Study 2 were 1.7 days in the Neulasta arm compared to 1.6 days in the filgrastim arm [difference in means 0.1 (95% CI - 0.2, 0.4)].

A secondary endpoint in both studies was days of severe neutropenia in cycles 2 through 4 with results similar to those for cycle 1.

Study 3 was a randomized, double-blind, placebo-controlled study that employed docetaxel 100 mg/m^2 administered every 21 days for up to 4 cycles for the treatment of metastatic or non-metastatic breast cancer. In this study, 928 patients were randomized to receive a single subcutaneous injection of Neulasta (6 mg) or placebo on day 2 of each chemotherapy cycle. Study 3 met the major trial outcome measure of demonstrating that the incidence of febrile neutropenia (defined as temperature ≥ 38.2°C and ANC ≤ 0.5×10^9/L) was lower for Neulasta-treated patients as compared to placebo-treated patients (1% versus 17%, respectively, $p < 0.001$). The incidence of hospitalizations (1% versus 14%) and IV anti-infective use (2% versus 10%) for the treatment of febrile neutropenia was also lower in the Neulasta-treated patients compared to the placebo-treated patients.

Study 4 was a multicenter, randomized, open-label study to evaluate the efficacy, safety, and pharmacokinetics *[see Clinical Pharmacology (12.3)]* of Neulasta in pediatric and young adult patients with sarcoma. Patients with sarcoma receiving chemotherapy age 0 to 21 years were eligible. Patients were randomized to receive subcutaneous Neulasta as a single-dose of 100 mcg/kg (n = 37) or subcutaneous filgrastim at a dose 5 mcg/kg/day (n = 6) following myelosuppressive chemotherapy. Recovery of neutrophil counts was similar in the Neulasta and filgrastim groups. The most common adverse reaction reported was bone pain.

14.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

Efficacy studies of Neulasta could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. Approval of this indication was based on efficacy studies conducted in animals

and data supporting Neulasta's effect on severe neutropenia in patients with cancer receiving myelosuppressive chemotherapy *[see Dosage and Administration (2.1)]*.

The recommended dose of Neulasta is two doses, 6 mg each, administered one week apart for humans exposed to myelosuppressive doses of radiation. For pediatric patients weighing less than 45 kg, dosing of Neulasta is weight based and is provided in Table 1 *[see Dosage and Administration (2.1, 2.2)]*. This dosing regimen is based on population modeling and simulation analyses. The exposure associated with this dosing regimen is expected to provide sufficient pharmacodynamic activity to treat humans exposed to myelosuppressive doses of radiation *[see Clinical Pharmacology (12.3)]*. The safety of Neulasta at a dose of 6 mg has been assessed on the basis of clinical experience in patients with cancer receiving myelosuppressive chemotherapy.

The efficacy of Neulasta for the acute radiation syndrome setting was studied in a randomized, placebo-controlled non-human primate model of radiation injury. Rhesus macaques were randomized to either a control (n = 23) or treated (n = 23) cohort. On study day 0, animals (n = 6 to 8 per irradiation day) were exposed to total body irradiation (TBI) of 7.50 ± 0.15 Gy delivered at 0.8 ± 0.03 Gy/min, representing a dose that would be lethal in 50% of animals by 60 days of follow-up (LD50/60). Animals were administered subcutaneous injections of a blinded treatment (control article [5% dextrose in water] or pegfilgrastim [300-319 mcg/kg/day]) on study day 1 and on study day 8. The primary endpoint was survival. Animals received medical management consisting of intravenous fluids, antibiotics, blood transfusions, and other support as required.

Pegfilgrastim significantly (at 0.0014 level of significance) increased 60-day survival in irradiated non-human primates: 91% survival (21/23) in the pegfilgrastim group compared to 48% survival (11/23) in the control group.

16 HOW SUPPLIED/STORAGE AND HANDLING

Neulasta single-dose prefilled syringe for manual use

Neulasta injection is a clear, colorless solution supplied in a prefilled single-dose syringe for manual use containing 6 mg pegfilgrastim, supplied with a 27-gauge, 1/2-inch needle with an UltraSafe® Needle Guard.

The needle cap of the prefilled syringe contains dry natural rubber (a derivative of latex).

Neulasta is provided in a carton containing one sterile 6 mg/0.6 mL prefilled syringe (NDC 55513-190-01).

Neulasta prefilled syringe does not bear graduation marks and is intended only to deliver the entire contents of the syringe (6 mg/0.6 mL) for direct administration.

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light or physical damage. Discard syringes stored at room temperature for more than 48 hours. Avoid freezing; if frozen, thaw in the refrigerator before administration. Discard syringe if frozen more than once.
Do not shake.

Neulasta Onpro® kit

Neulasta Onpro kit is provided in a carton containing one sterile prefilled syringe and one sterile on-body injector (OBI) for Neulasta (NDC 55513-192-01).

The Neulasta injection single-dose prefilled syringe contains 0.64 mL of a clear, colorless solution that delivers 6 mg/0.6 mL of pegfilgrastim when used with the OBI for Neulasta. The prefilled syringe is supplied with a 27-gauge, 1/2-inch needle. The syringe does not bear graduation marks and is only to be used with the OBI for Neulasta.

The needle cap of the prefilled syringe contains dry natural rubber (a derivative of latex).

Store Neulasta Onpro kit refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Because the OBI for Neulasta is at room temperature during the period of use, Neulasta Onpro kit should not be held at room temperature longer than 12 hours prior to use. Discard Neulasta Onpro kit if stored at room temperature for more than 12 hours. Do not freeze the kit.

Do not shake the prefilled syringe.

Do not use the OBI for Neulasta if its packaging has been previously opened.

Neulasta single-dose vial

Neulasta injection is a clear, colorless, solution, supplied in a vial containing 4 mg pegfilgrastim.

Neulasta is provided in a carton containing one 4 mg/0.4 mL vial (NDC 55513-099-01).

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. Discard vials stored at room temperature for more than 48 hours.
Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Advise patients of the following risks and potential risks with Neulasta:

- Splenic rupture and splenomegaly
- Acute Respiratory Distress Syndrome
- Serious hypersensitivity reactions
- Sickle cell crisis
- Glomerulonephritis
- Increased risk of Myelodysplastic Syndrome and/or Acute Myeloid Leukemia in patients with breast and lung cancer who receive Neulasta in conjunction with chemotherapy and/or radiation therapy
- Capillary Leak Syndrome
- Arteritis, including aortitis

Advise patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) that efficacy studies of Neulasta for this indication could not be conducted in

humans for ethical and feasibility reasons and that, therefore, approval of this use was based on efficacy studies conducted in animals *[see Clinical Studies (14.2)]*.

Instruct patients who self-administer Neulasta using the prefilled syringe of the:

- Importance of following the Instructions for Use.
- Dangers of reusing syringes.
- Importance of following local requirements for proper disposal of used syringes.

Advise patients on the use of the on-body injector (OBI) for Neulasta:

- Review the Patient Information and Patient Instructions for Use with the patient and provide the instructions to the patient.
- Refer the patient to the dose delivery information written on the Patient Instructions for Use.
- Tell the patient when their dose delivery of Neulasta will begin and when their dose delivery should be completed.
- Advise the patient that serious hypersensitivity reactions can happen with Neulasta. Patients should have a caregiver nearby for the first use. Patients should plan to be in a place where they can appropriately monitor the OBI for Neulasta during the approximately 45 minute Neulasta delivery and for an hour after the delivery. Advise the patient to avoid traveling, driving, or operating heavy machinery during hours 26 to 29 following application of the OBI for Neulasta.
- If the OBI for Neulasta is placed on the back of the arm, remind the patient that a caregiver must be available to monitor the OBI for Neulasta.
- If a patient calls the healthcare provider regarding any OBI for Neulasta problems, the healthcare provider is advised to call Amgen at 1-800-772-6436.
- Advise the patient:
    - to call their healthcare provider immediately if the status light on the OBI for Neulasta is flashing red *(see the Patient Instructions for Use)*.
    - to inform their healthcare provider if the adhesive on the OBI for Neulasta becomes saturated with fluid, or there is dripping, as this may be evidence of significant product leakage, resulting in inadequate or missed dose *(see the Patient Instructions for Use)*.
    - to keep the OBI for Neulasta dry for approximately the last 3 hours prior to the dose delivery start to better enable potential leak detection.
    - that the OBI for Neulasta should only be exposed to temperatures between 5°C to 40°C (41°F and 104°F).
    - to keep the OBI for Neulasta at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves, and other common appliances. Failure to keep the OBI for Neulasta at least this recommended distance may interfere with operation and can lead to a missed or incomplete dose of Neulasta.
    - that if the needle is exposed after OBI for Neulasta removal, place the used OBI for Neulasta in a sharps disposal container to avoid accidental needle stick and call their healthcare provider immediately.
    - to remove the OBI for Neulasta after the green light shines continuously and to place the used OBI for Neulasta in a sharps disposal container *(see the Patient Instructions for Use)*.
- Advise the patient:
    - do not reapply the OBI for Neulasta if the OBI for Neulasta comes off before full dose is delivered and instead call their healthcare provider immediately, as they may need a replacement dose.
    - avoid bumping the OBI for Neulasta or knocking the OBI for Neulasta off the body.
    - do not use other materials to hold the on-body injector in place that could cover audio/visual indicators or compress the on-body injector against the patient's skin, as this could dislodge the cannula and lead to a missed dose or incomplete dose of Neulasta.

- do not expose the OBI for Neulasta to medical imaging studies (e.g., X-ray scan, MRI, CT scan and ultrasound), radiation treatment, and oxygen rich environments such as hyperbaric chambers to avoid OBI for Neulasta damage and patient injury.

- Advise the patient to avoid:
  - airport X-ray scans and request a manual pat down instead; remind patients who elect to request a manual pat down to exercise care to avoid having the OBI for Neulasta dislodged during the pat down process.
  - sleeping on the OBI for Neulasta or applying pressure on the OBI for Neulasta as this may affect OBI for Neulasta performance.
  - getting body lotions, creams, oils, and cleaning agents near the OBI for Neulasta as these products may loosen the adhesive.
  - use of lotions, creams, or oils on their arms and abdomen prior to their next scheduled OBI for Neulasta dose (to help with device adherence to the skin).
  - using bath tubs, hot tubs, whirlpools, or saunas and avoid exposing the OBI for Neulasta to direct sunlight as these may affect the drug.
  - peeling off or disturbing the OBI for Neulasta adhesive before delivery of full dose is complete.

Neulasta® (pegfilgrastim)

Manufactured by:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
U.S. License No. 1080
Patent: http://pat.amgen.com/onpro/
© 2002-2026 Amgen Inc. All rights reserved.
www.neulasta.com
1-800-77-AMGEN (1-800-772-6436)
V30

Patient Information
Neulasta® (nu-las-tah)
(pegfilgrastim)
injection
Single-Dose Prefilled Syringe and Single-Dose Vial

What is Neulasta?

Neulasta is a prescription medicine that is used:

- in adults and children to reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid), who receive anti-cancer medicines (chemotherapy) that can cause fever and low blood cell count.
- to increase survival in adults and children with sudden exposure to high levels of radiation that damage the bone marrow so it cannot make enough blood cells (this is called hematopoietic syndrome of acute radiation syndrome [H-ARS]). The effectiveness of Neulasta for this use was only studied in animals, because it could not be studied in people.

Do not take Neulasta if you have had a serious allergic reaction to pegfilgrastim or filgrastim.

Before you receive Neulasta, tell your healthcare provider about all of your medical conditions, including if you:

- have a sickle cell disorder.
- have kidney problems.
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (derived from latex). You should not give Neulasta using the prefilled syringe if you have latex allergies.
- are pregnant or plan to become pregnant. It is not known if Neulasta will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Neulasta passes into your breast milk.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive Neulasta?

- **Neulasta is given as an injection under your skin (subcutaneous injection) by a healthcare provider. If your healthcare provider decides that the subcutaneous injections can be given at home by you or your caregiver, follow the detailed "Instructions for Use" that comes with your Neulasta for information on how to prepare and inject a dose of Neulasta using the prefilled syringe.**
- For adults of any weight and children weighing 99 pounds (45 kg) or more:
  - You and your caregiver will be shown how to prepare and inject Neulasta using the prefilled syringe before you use it.
- For children weighing less than 99 pounds (45 kg):
  - **Do not** inject a dose from a Neulasta prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the Neulasta prefilled syringes.
  - Your healthcare provider will prepare and give the dose of Neulasta using the vials.
- If you are receiving Neulasta because you are also receiving chemotherapy, the last dose of Neulasta should be injected at least 14 days before and 24 hours after your dose of chemotherapy.
- If you miss a dose of Neulasta, talk to your healthcare provider about when you should give your next dose.
- If you inject too much Neulasta, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of Neulasta?

Neulasta can cause serious side effects, including:

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Tell your healthcare provider right away if you develop pain in the left upper stomach area or your left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Tell your healthcare provider or get emergency help right away if you develop shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** Allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate, and sweating. If you develop any of these symptoms, stop using Neulasta and tell your healthcare provider or get emergency medical help right away.
- **Sickle cell crises in people with sickle cell disorder.** You may have a severe sickle cell crisis, which could lead to death. Tell your healthcare provider right away if you develop symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury**. Tell your healthcare provider right away if you develop any of the following symptoms:

- swelling of your face or ankles
- blood in your urine or dark colored urine
- you urinate less than usual

- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood count during treatment with Neulasta.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood count during treatment with Neulasta. Tell your healthcare provider if you develop unusual bleeding or bruising during treatment with Neulasta.
- **Capillary Leak Syndrome (CLS).** Neulasta can cause fluid to leak from blood vessels into your body's tissues. CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  - swelling or puffiness and are urinating less than usual
  - trouble breathing
  - swelling of your stomach area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness
- **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML).** If you have breast cancer or lung cancer, when Neulasta is used with chemotherapy and radiation therapy, or with radiation therapy alone, you may have an increased risk of developing a precancerous blood condition called MDS or a blood cancer called AML. Tell your healthcare provider if you develop any symptoms of MDS and AML, including tiredness, fever, or easy bruising or bleeding.
- **Inflammation of the arteries (arteritis).** Serious inflammation of the large and medium blood vessels that carry blood from your heart to the body, including the aorta (the largest artery), can happen in people receiving Neulasta. Tell your healthcare provider right away if you develop fever, stomach (abdominal) pain, back pain, headache, neck pain, or generally feel unwell.

The most common side effects of Neulasta are pain in the bones, arms, and legs.

These are not all the possible side effects of Neulasta.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Neulasta?

- Store Neulasta in the refrigerator between 36°F and 46°F (2°C to 8°C).
- **Avoid freezing** Neulasta prefilled syringes**.** If Neulasta prefilled syringe is frozen 1 time, thaw in the refrigerator before using it. If it is frozen more than 1 time, throw it away and use a new Neulasta prefilled syringe.
- **Do not** freeze Neulasta vials.
- Keep Neulasta in the original carton to protect from light or physical damage.
- **Do not** shake Neulasta.
- Take Neulasta out of the refrigerator 30 minutes before use and allow it to reach room temperature, 68°F to 77°F (20°C to 25°C), before preparing an injection.
- Throw away (dispose of) any Neulasta that has been left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 48 hours.

Keep Neulasta and all medicines out of the reach of children.

General information about the safe and effective use of Neulasta.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Neulasta for a condition for which it was not prescribed. Do not give Neulasta to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Neulasta that is written for health professionals.

What are the ingredients in Neulasta?

Active ingredient: pegfilgrastim
Inactive ingredients: acetate, polysorbate 20, sodium and sorbitol in water for injection.

Manufactured by:
Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799
U.S. License No. 1080

Patent: http://pat.amgen.com/onpro/

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For more information go to www.neulasta.com, or call 1-800-77-AMGEN (1-800-772-6436).

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Patient Information
Neulasta® (nu-las-tah)
(pegfilgrastim)
injection
On-body injector for Neulasta

What is the most important information I need to know about receiving Neulasta with the on-body injector for Neulasta?

- **See the Instructions for Use for the on-body injector for Neulasta for detailed information about the on-body injector for Neulasta and important information about your dose delivery that has been written by your healthcare provider.**
  - Know the time that delivery of your dose of Neulasta is expected to start.
  - Avoid traveling, driving, or operating heavy machinery during hour 26 through hour 29 after the on-body injector for Neulasta is applied. Avoid activities and places that may interfere with monitoring during the **45-minute** period that Neulasta is expected to be delivered by the on-body injector for Neulasta, and for 1 hour after delivery.
- A caregiver should be with you the first time that you receive Neulasta with the on-body injector for Neulasta.
- Before your next scheduled Neulasta dose, avoid use of lotions, creams, or oils on your arms and stomach area (abdomen) to help keep the device on your skin.
- If placed on the back of the arm, a caregiver must be available to monitor the status of the on-body injector.
- **If you have an allergic reaction during the delivery of Neulasta, remove the on-body injector for Neulasta by grabbing the edge of the adhesive pad and peeling off the on-body injector for Neulasta. Get emergency medical help right away.**
- **You should only receive a dose of Neulasta on the day your healthcare provider tells you.**
- **You should not receive your dose of Neulasta any sooner than 24 hours after you finish receiving your chemotherapy.** The on-body injector for Neulasta is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector for Neulasta on your skin.
- **Do not** expose the on-body injector for Neulasta to the following because the on-body injector for Neulasta may be damaged and you could be injured:
  - Diagnostic imaging (e.g., CT Scan, MRI, Ultrasound, X-ray)
  - Radiation treatment
  - Oxygen rich environments, such as hyperbaric chambers
- Avoid airport X-ray scans. Request a manual pat down instead. Use care during a manual pat down to help prevent the on-body injector for Neulasta from being accidentally removed.
- **Keep the on-body injector for Neulasta at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances.** If the on-body injector for Neulasta is too close to electrical equipment, it may not work correctly and can lead to a missed or incomplete dose of Neulasta.
- The on-body injector is for adults only.
- **If your on-body injector is not working properly, you may miss your dose or you may not receive your full dose of Neulasta. If you miss your dose or do not receive your full dose of Neulasta, you may have an increased risk of developing fever or infection.**
- **Call your healthcare provider right away, as you may need a replacement dose, if any of the following occur:**
  - on-body injector for Neulasta comes off before or during a dose delivery. **Do not re-apply it.**
  - on-body injector for Neulasta is leaking.
  - adhesive on your on-body injector for Neulasta becomes noticeably wet (saturated) with fluid, or there is dripping. This may mean that Neulasta is leaking out of your on-body injector for Neulasta. If this happens you may only receive some of your dose of Neulasta, or you may not receive a dose at all.
  - on-body injector for Neulasta status light is flashing red.

What is Neulasta?

Neulasta is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid), who receive anti-cancer medicines (chemotherapy) that can cause fever and low blood cell count.

Do not take Neulasta if you have had a serious allergic reaction to pegfilgrastim or filgrastim.

Before you receive Neulasta, tell your healthcare provider about all of your medical conditions, including if you:

- have a sickle cell disorder
- have had severe skin reactions to acrylic adhesives
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (derived from latex).
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if Neulasta may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Neulasta passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive Neulasta?

See the Instructions for Use for detailed information about how you will receive a dose of Neulasta with the on-body injector for Neulasta, and how to remove and dispose of the on-body injector for Neulasta.

- **See the section "What is the most important information I need to know about receiving Neulasta with the on-body injector for Neulasta?"**
- Neulasta is given as an injection under the skin (subcutaneous). Your healthcare provider will use a prefilled syringe with Neulasta to fill the on-body injector prior to applying it. The prefilled syringe with Neulasta and the on-body injector are provided to your healthcare provider as part of Neulasta Onpro® kit. The on-body injector for Neulasta will be applied to the stomach area (abdomen) or back of your arm by your healthcare provider. If the on-body injector for Neulasta was placed on the back of your arm, a caregiver must be available to monitor the on-body injector for Neulasta.
- Your healthcare provider should place the on-body injector for Neulasta on an area of your skin that does not have swelling, redness, cuts, wounds, or abrasions. Tell your healthcare provider about any skin reactions that happen in the on-body injector for Neulasta application area after it has been applied.
- The on-body injector for Neulasta is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector for Neulasta on your skin.
- The dose of Neulasta will be delivered over about 45 minutes. During dose delivery and for 1 hour after delivery, it is best to stay in a place where you or a caregiver can monitor the on-body injector for Neulasta to make sure you receive your full dose of Neulasta and watch for symptoms of an allergic reaction.
- Your healthcare provider will show you how to monitor the on-body injector for Neulasta to make sure delivery has been completed.
- Keep the on-body injector for Neulasta dry for about the last 3 hours before the dose delivery is expected to start. This will help you to better detect possible leaking from the on-body injector for Neulasta.
- Only expose the on-body injector for Neulasta to temperatures between 41°F to 104°F (5°C to 40°C).

While the on-body injector for Neulasta is in place you should avoid:

- traveling, driving or operating heavy machinery during hour 26 through hour 29 after the on-body injector for Neulasta is applied.
- sleeping on the on-body injector for Neulasta or applying pressure on the on-body injector for Neulasta. The on-body injector for Neulasta may not work properly.
- bumping the on-body injector for Neulasta or knocking it off your body.
- using other materials to hold the on-body injector in place. Using other materials could cover audio or visual indicators or press the on-body injector against your skin, and lead to a missed dose or incomplete dose of Neulasta.
- getting body lotion, creams, oils, and skin cleansing products near the on-body injector for Neulasta. These products may loosen the adhesive that holds the on-body injector for Neulasta onto your body.
- using bath tubs, hot tubs, whirlpools, or saunas, and direct sunlight. These may affect Neulasta.
- peeling off or disturbing the on-body injector for Neulasta adhesive before you receive your full dose of Neulasta.

What are the possible side effects of Neulasta?

Neulasta can cause serious side effects, including:

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Tell your healthcare provider right away if you develop pain in your left upper stomach area or left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Tell your healthcare provider or get emergency medical help right away if you develop shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.

- **Serious allergic reactions.** Allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate and sweating.

  If you have an allergic reaction during the delivery of Neulasta, remove the on-body injector for Neulasta by grabbing the edge of the adhesive pad and peeling off the on-body injector for Neulasta. Get emergency medical help right away.
- **Sickle cell crises in people with sickle cell disorder.** You may have a severe sickle cell crisis, which could lead to death. Tell your healthcare provider right away if you develop symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury.** Tell your healthcare provider right away if you develop any of the following symptoms:
  - swelling of your face or ankles
  - blood in your urine or dark colored urine
  - you urinate less than usual
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood count during treatment with Neulasta.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood count during treatment with Neulasta. Tell your healthcare provider if you develop unusual bleeding or bruising during treatment with Neulasta.
- **Capillary Leak Syndrome (CLS).** Neulasta can cause fluid to leak from blood vessels into your body's tissues. CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  - swelling or puffiness and are urinating less than usual
  - trouble breathing
  - swelling of your stomach-area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness
- **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML).** If you have breast cancer or lung cancer, when Neulasta is used with chemotherapy and radiation therapy, or with radiation therapy alone, you may have an increased risk of developing a precancerous blood condition called MDS or a blood cancer called AML. Tell your healthcare provider if you develop any symptoms of MDS and AML, including tiredness, fever, or easy bruising or bleeding.
- **Inflammation of the arteries (arteritis).** Serious inflammation of the large and medium blood vessels that carry blood from your heart to the body, including the aorta (the largest artery), can happen in people receiving Neulasta. Tell your healthcare provider right away if you develop fever, stomach (abdominal) pain, back pain, headache, neck pain, or generally feel unwell.

The most common side effect of Neulasta is pain in your bones, and in your arms, and legs.

These are not all the possible side effects of Neulasta.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Neulasta.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about Neulasta, talk with your healthcare provider or pharmacist. You can ask your pharmacist for information about Neulasta that is written for health professionals.

What are the ingredients in Neulasta?

Active ingredient: pegfilgrastim

Inactive ingredients: acetate, polysorbate 20, sodium and sorbitol in water for injection

Manufactured by:
Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799
U.S. License No. 1080

Patent: http://pat.amgen.com/onpro/

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For more information, go to www.neulasta.com or call 1-844-696-3852 (1-844-MYNEULASTA).

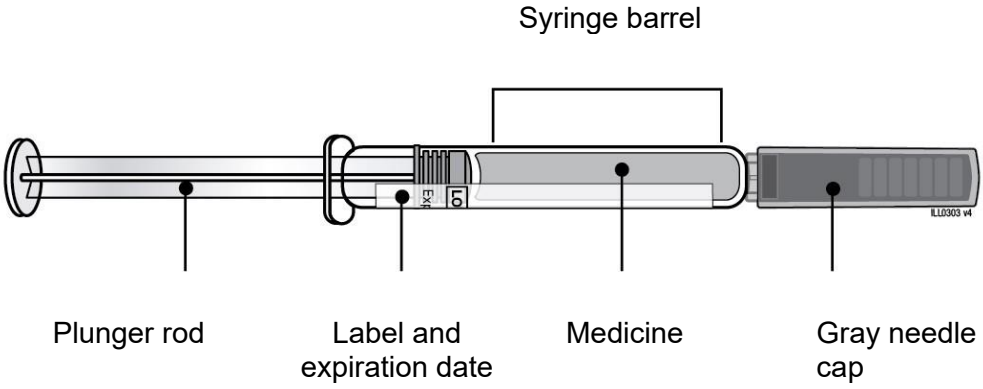
V10

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 08/2026

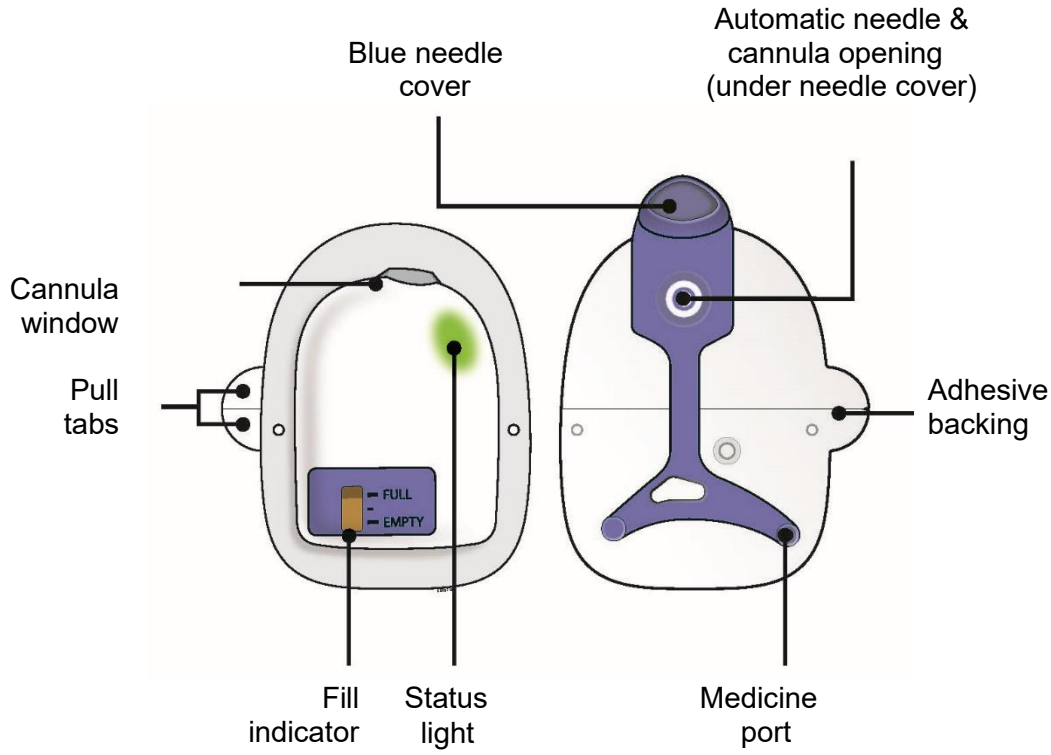
Neulasta® (pegfilgrastim) Onpro® kit
Healthcare Provider INSTRUCTIONS FOR USE

Guide to Parts

Neulasta Prefilled Syringe



On-body Injector for Neulasta



Important

READ THE FOLLOWING INSTRUCTIONS BEFORE USING NEULASTA ONPRO KIT

Prescribing Information

- See Prescribing Information for information on Neulasta.
- The on-body injector is for adult patients only.
- The on-body injector is not recommended for patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome.
- Neulasta prefilled syringe gray needle cap contains dry natural rubber, which is derived from latex.
- For patients who have had severe skin reactions to acrylic adhesives, consider the benefit:risk profile before administering pegfilgrastim via the on-body injector for Neulasta.

Application Information

- The on-body injector should be applied to intact, non-irritated skin on the abdomen or back of the arm. The back of the arm may only be used if there is a caregiver available to monitor the status of the on-body injector.
- The on-body injector has a self-adhesive backing to attach it to the skin, **do not** use additional materials to hold it in place as this could dislodge the cannula and lead to a missed or incomplete dose of Neulasta.

Environmental Information

- **Do not** expose the on-body injector for Neulasta to the following environments as the on-body injector may be damaged and the patient could be injured:
  - Diagnostic imaging (e.g., CT Scan, MRI, Ultrasound, X-ray)
  - Radiation treatment
  - Oxygen rich environments such as hyperbaric chambers

Cautions

- **Do not** use Neulasta Onpro kit to deliver any other drug product
- **Do not** use the on-body injector if its packaging has been previously opened, or the expiration date on the carton or any components has passed.
- **Do not** use if the name Neulasta does not appear on Neulasta Onpro kit carton.
- **Do not** modify the on-body injector.
- **Do not** attempt to reapply the on-body injector.
- **Do not** use if either the on-body injector or prefilled syringe is dropped. Start again with a new kit

Storage Information

- Store the kit in the refrigerator at 36°F to 46°F (2°C to 8°C) until ready for use. If the kit is stored at room temperature (68°F to 77°F [20°C to 25°C]), for more than 12 hours, do not use. Start again with a new kit.
- Keep the prefilled syringe in the kit carton until use to protect from light.
- **Do not** freeze the kit.
- **Do not** separate the components of Neulasta Onpro kit until ready for use.

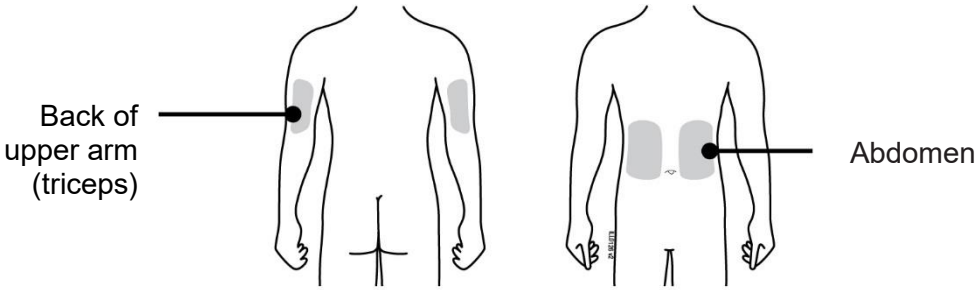
For all questions, or if a patient calls you regarding any injector problems, call Amgen at 1-800-772-6436.

Step 1: Prepare

A **Place the syringe tray and the on-body injector tray on a clean, well-lit work surface.**

Allow the syringe and on-body injector to come naturally to room temperature for 30 minutes prior to activating. **Do not** warm the kit components using a heat source.

B **Choose the patient's injection site.**



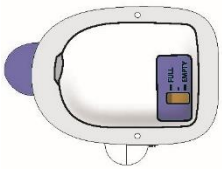
Ask the patient about their ability to monitor and remove the on-body injector.

- Use the left or right side of the abdomen, except for a two-inch area right around navel.
- Use the back of upper arm only if there is a caregiver available to monitor the status of the on-body injector.
- Apply the on-body injector to intact, non-irritated skin.
- **Do not** apply the on-body injector on surgical sites or areas with scar tissue, moles, or excessive hair. In case of excessive hair, carefully trim hair to get the on-body injector close to the skin.
- **Do not** apply the on-body injector on areas where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the on-body injector.
- **Do not** apply the on-body injector on areas where the on-body injector will be affected by folds in the skin.

C **Clean an area on the injection site larger than the on-body injector adhesive backing.**

Thoroughly clean the site with alcohol to enhance on-body adherence to the skin.

- Only use alcohol to clean the skin. Make sure the skin is oil-free prior to applying the on-body injector.
- Allow the skin to **completely dry** before attaching the on-body injector.
- **Do not** touch this area again before attaching the on-body injector.

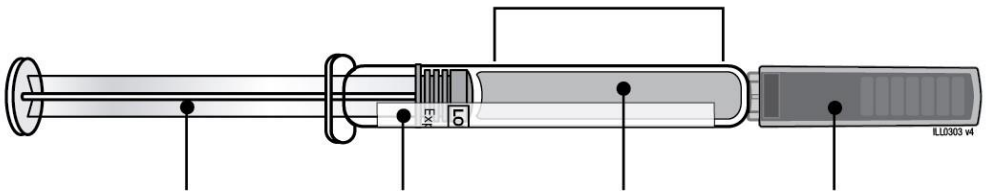


D **Remove Neulasta prefilled syringe from tray.**

For safety reasons:

- **Do not** grasp the gray needle cap.
- **Do not** grasp the plunger rod.

E Inspect Neulasta prefilled syringe. Neulasta liquid should always be clear and colorless.



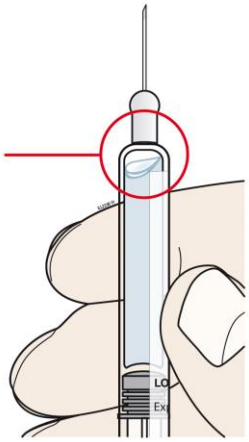
- **Do not** use if the liquid contains particulate matter or discoloration is observed prior to administration.
- **Do not** use the prefilled syringe if the expiration date has passed.
- **Do not** use if any part appears cracked or broken.
- **Do not** use if the gray needle cap is missing or not securely attached.
- **Do not** remove the gray needle cap until ready to fill the on-body injector.
- **Do not** shake the prefilled syringe.

In all the above cases, start again with a new kit.

Step 2: Fill

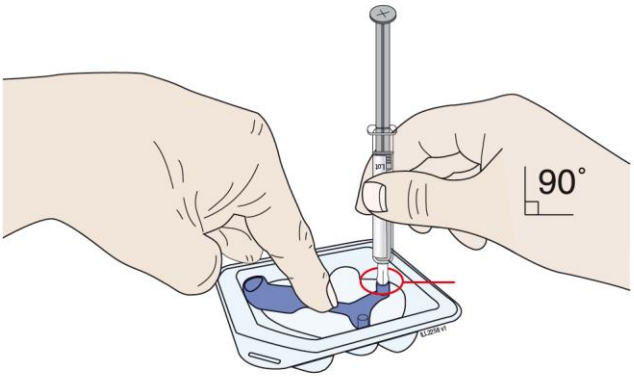
A **Remove air bubbles in prefilled syringe.**

Injecting air bubbles could interfere with proper operation of the on-body injector.



- Remove the gray needle cap.
- Gently tap the syringe with your finger until air bubbles rise to the top.
- Slowly push air out of the syringe, taking care to not expel medicine.
- A small droplet at the tip of the needle during air purging is normal.
- **Do not** recap the syringe.

B **Center the needle directly over the medicine port and insert all the way into the port, avoiding sides.**



Medicine port

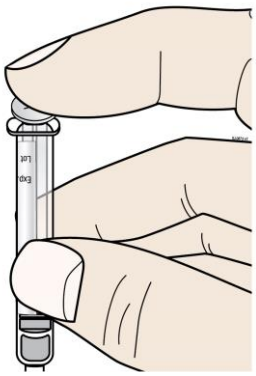
Insert needle into medicine port at a 90 degree angle only.

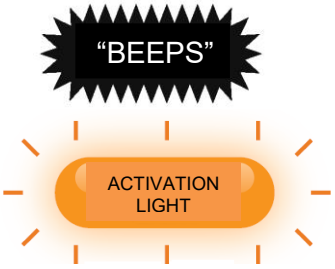
- **Do not** remove the blue needle cover before filling the on-body injector.
- **Do not** insert the needle more than once.
- **Do not** bend the needle. Avoid spilling the medicine.

C Push the plunger rod to empty entire syringe contents into the on-body injector.

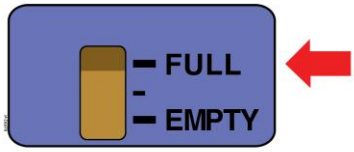
- During filling, you will hear beeping.
- The status light will flash amber.
- You now have 3 full minutes to apply the on-body injector to your patient.

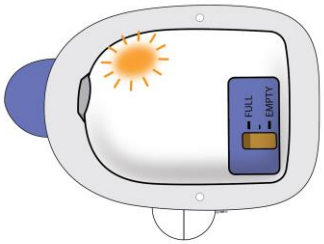
Discard used syringe in sharps container.





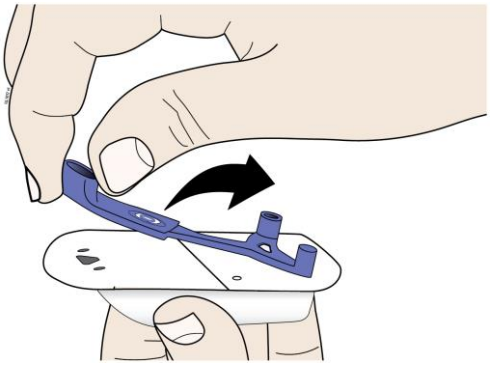
D Check to see if the on-body injector is full and the amber light is flashing. You should see a black line next to FULL on the fill indicator.

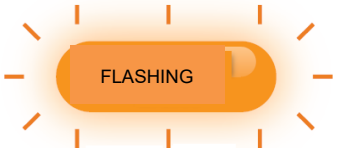




If this is not the case, do not use. Start again with a new Neulasta Onpro kit.

E Firmly lift and remove the blue needle cover away from the on-body injector.



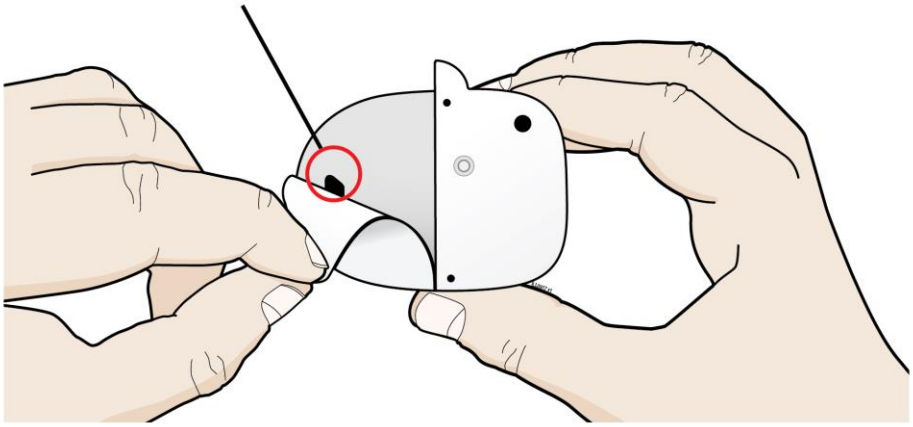


Step 3: Apply

A **Peel away both pull tabs to show the adhesive. Never touch hands or gloves to the adhesive.**

Make sure skin is dry prior to applying the on-body injector.

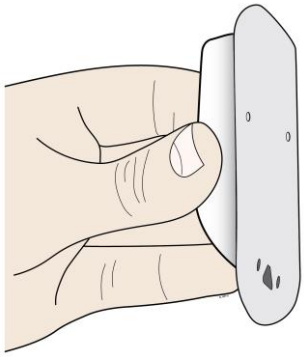
Automatic needle



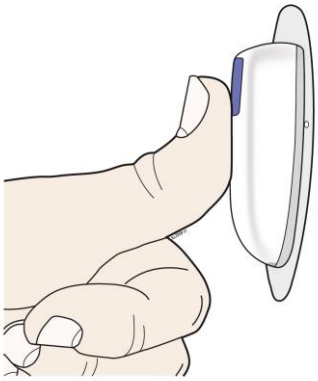
- **Do not** pull off the adhesive pad or fold it.
- **Do not** touch or contaminate the automatic needle area.
- **Do not** use if the needle or cannula is extended past the adhesive or is extended before the on-body injector is placed on the patient.
- **Do not place adhesive on skin that is damp.**

B **Before the cannula inserts, securely apply the on-body injector so it is visible and can be monitored by the patient or caregiver.**

You now have time to carefully apply the on-body injector without folding or wrinkling the adhesive.

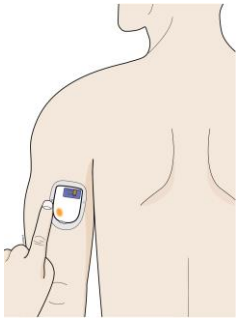


- **Do not** touch the adhesive.
- Grasp the on-body injector's plastic case with your fingertips and only by sides, keeping fingers off of the adhesive.
- **Do not** let the adhesive bend or curl while applying the on-body injector to skin.
- **Important:** Once on the skin, **press firmly on the on-body injector** to ensure proper adhesion to the patient's skin.

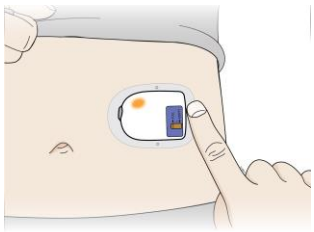


- Press around the entire adhesive so it lies down without folds or wrinkles.
- Hold the top of the on-body injector and run finger around the adhesive to create a secure attachment.
- If additional adhesion is deemed appropriate, an adhesive extender that fits around the on-body injector can be obtained by calling 1-844-MYNEULASTA (1-844-696-3852).
- **Do not** use other materials to secure the on-body injector to the patient that could cover audio/visual indicators or compress the on-body injector against the patient's skin.

Back of upper arm (triceps)
Vertical with the light facing down toward the elbow



Abdomen
Horizontal with the light facing up and visible to the patient

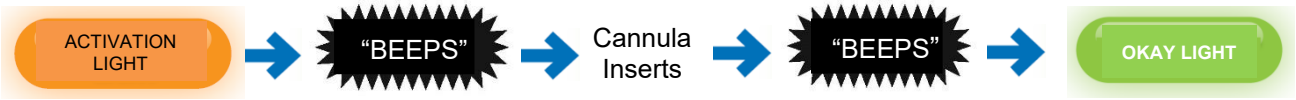


Do not worry if the on-body injector is quiet.
When 3 minutes are up, the on-body injector will beep telling you the cannula is about to insert.

Step 4: Finish

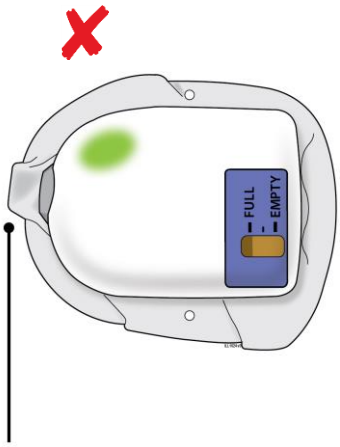
A **Wait for the status light to turn green. This means the cannula has been inserted.**

Do not remove the on-body injector during cannula insertion to avoid needle stick injury to you or to the patient.

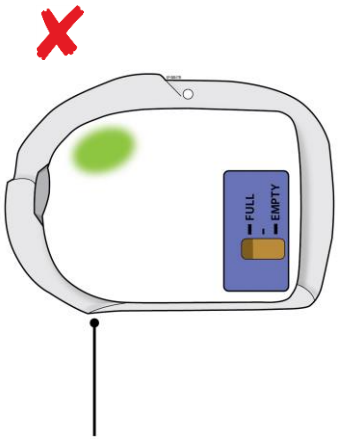


Check the quality of adhesion before sending the patient home.

If the adhesive is wrinkled in front of the cannula window or has folds anywhere that prevent the on-body injector from securely adhering, remove the on-body injector. Start again with a new kit and call Amgen at 1-800-772-6436.



Wrinkled adhesive near cannula window



Folded adhesive

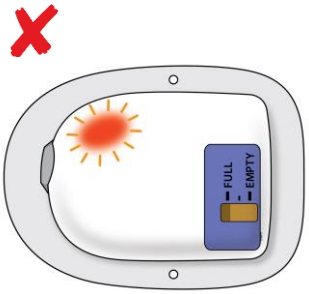
B Provide the Patient IFU Booklet for the patient to take home.

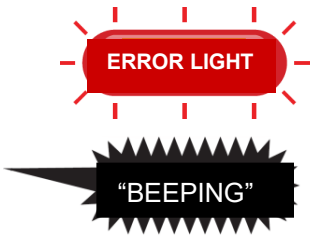
Fill in the Dose Delivery information on the booklet, and review the following instructions with your patient:

- The on-body injector will always flash a slow green light to let them know it is working properly.
- The patient should keep the on-body injector dry for at least 3 hours after it was placed on their skin.
- After approximately 27 hours, the dose delivery will begin. Dose delivery will take about 45 minutes, during this time, the on-body injector will flash a fast green light.
- **When dose delivery is complete, the on-body injector will sound a long beep, and the status light will turn SOLID GREEN.**
- **Do not remove the on-body injector until the status light is SOLID GREEN.**
- If the red error light is flashing, or the adhesive is noticeably wet (saturated), or the on-body injector is dislodged, the patient should contact their healthcare provider immediately as they may need a replacement dose.

Attention!

What to do if you hear beeping or when you look at status light and it is flashing red.





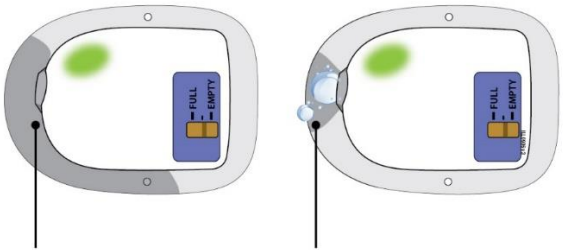
If at any time the on-body injector beeps continuously for 5 minutes, and the status light is flashing red, take the on-body injector off of the patient.

- **Do not** apply or leave the on-body injector on the patient if red error light is on.

In all cases, do not use. Start over with a new Neulasta Onpro kit, and call Amgen at 1-800-772-6436.

What to do if your patient reports the status light is flashing red.
If the patient reports the status light is flashing red, they may not have received the full dose. Schedule a follow-up appointment with your patient.

What to do if your patient reports the adhesive is saturated with fluid or the on-body injector is dripping.



Saturated adhesive

Dripping fluid from on-body injector

If the patient reports an on-body injector leak, they may not have received the full dose. Schedule a follow-up appointment with your patient.

In all cases report the incident to Amgen at 1-800-772-6436.

Neulasta® (pegfilgrastim)

Manufactured by:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
US License No. 1080

Patent: http://pat.amgen.com/onpro/
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http://www.neulasta.com/
1-844-MYNEULASTA (1-844-696-3852)
Revised: 08/2025
V14

Before You Begin

The following is an overview of on-body injector preparation steps. Read this section first

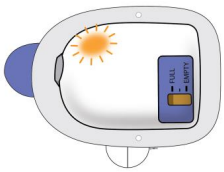
To prepare and apply the on-body injector, you will use a pre-filled syringe to fill and activate it.

As part of this process, the on-body injector uses lights and sounds as signals to help guide you through the preparation and application process.

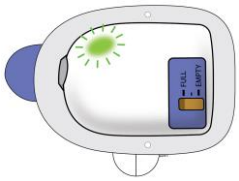
As you fill the on-body injector, the status light flashes amber and the on-body injector beeps 3 times.

When the status light flashes amber and the on-body injector beeps, this means it has been properly filled and activated.

After the on-body injector activates, you will have 3 full minutes to remove the blue needle guard and adhesive backing, and then apply the on-body injector to your patient.



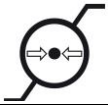
- The on-body injector will beep several times prior to inserting the cannula.
- Make sure you have the on-body injector properly secured to your patient before the cannula inserts.



When the status light flashes green, this means the on-body injector has successfully inserted the cannula.

For all questions, or if a patient calls you regarding any on-body injector problems, call Amgen at 1-800-772-6436.

Turn over to continue with the Instructions for Use

Symbol	Meaning
	Do not reuse this on-body injector. Single-use only
	Refer to Instructions for Use
	Do not use if packaging is damaged
	Temperature limitation
	Humidity limitation
	Expiration date (use by date)
	Reference/model number
	Lot number
	Type BF medical device (protection from electrical shock)
	Sterilized by ethylene oxide
	Waterproof up to 8 feet for 1 hour
	Prescription use only
	MR Unsafe
	On-body injector for Neulasta® (pegfilgrastim)
	Neulasta® (pegfilgrastim) prefilled syringe
	Pressure Limitation

Do not expose the on-body injector for Neulasta to the following environments as the on-body injector may be damaged and the patient could be injured:

- Diagnostic imaging (e.g., CT Scan, MRI, Ultrasound, X-ray)
- Radiation treatment
- Oxygen rich environments such as hyperbaric chambers

Electromagnetic Compatibility
The information contained in this section (such as separation distances) is, in general, specifically written in regard to the on-body injector for Neulasta. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes:

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC), and needs to be installed and put into service according to the EMC information provided in this document.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using cables and/or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the on-body injector for Neulasta is used adjacent to other electrical equipment; if adjacent use is inevitable, the on-body injector for Neulasta should be observed to verify normal operation in this setting.

Electromagnetic Emissions		
The on-body injector for Neulasta is intended for use in the electromagnetic environment specified below. The user of the on-body injector for Neulasta should ensure that it is used in such an environment.		
Emissions	Compliance according to	Electromagnetic environment
RF Emissions (CISPR 11)	Group 1	The on-body injector for Neulasta uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
CISPR B Emissions Classification	Class B	

Electromagnetic Immunity			
The on-body injector for Neulasta is intended for use in the electromagnetic environment specified below. The user of this equipment should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
ESD IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of typical commercial or hospital environment.
Radiated RF Fields 61000-4-3	3 V/m 80 MHz to 2.7 GHz	(E1)=3 V/m	Portable and mobile communications equipment should be separated from the on-body injector for Neulasta by no less than the distances calculated/listed below: D=(3.5/V1)(√P)150 kHz to 80 MHz D=(3.5/E1)(√P)80 to 800 MHz D=(7/E1)(√P)800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The on-body injector for Neulasta is intended for use in the radio frequency environment specified below. The user of this equipment should ensure that it is used in such an environment.

Test Frequency (MHz)	Band[a] (MHz)	Service [a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT OF ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the on-body injector for Neulasta

You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the on-body injector for Neulasta, as recommended below, according to the maximum power of the communication equipment.

Rated maximum output power of transmitter, in watts	Separation distance according to frequency of transmitter, in meters		
	150 kHz to 80 MHz D=(3.5/V1)(√P)	80 MHz to 800 MHz D=(3.5/E1)(√P)	800 MHz to 2.5 GHz D=(7/E1)(√P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Patient INSTRUCTIONS FOR USE
Neulasta® Onpro® (nu-las-tah)
(pegfilgrastim) injection
Single-Use On-body Injector

Your On-body injector was applied:

Day Time AM PM

Injection of your dose (delivery) will start around:

Day Time AM PM

Healthcare Provider name:

Healthcare Provider contact number:

On-body Injector lot number:

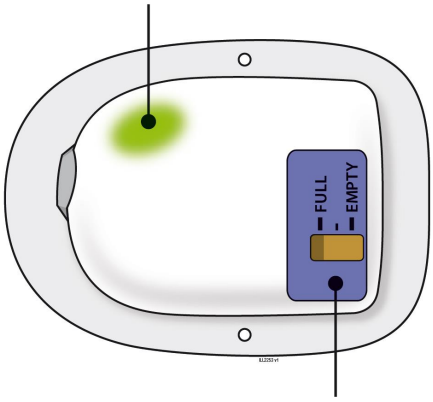
AMGEN

Neulasta® (pegfilgrastim) Onpro® kit

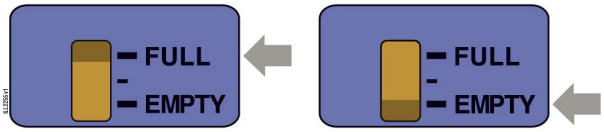
Get to Know Your On-body Injector

Parts and Signals

Status Light



Fill Indicator



Status Light

Flashing Green:
The on-body injector is working properly.
Do not remove the on-body injector if the status light is flashing green.

Solid Green (or off):
Signals dose delivery is complete.
Check to see if fill indicator reads empty.

Flashing Red:
On-body injector error.
If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away as you may need a replacement dose.

Fill Indicator:
Black line shows how much Neulasta is in the on-body injector.

Contents

IMPORTANT INFORMATION INFO

Learn about your Neulasta On-body Injector.

STEP 1: MONITOR

What to expect from your device for most of the day.

STEP 2: OBSERVE

What to watch for during dose delivery and what to do if there is an issue.

STEP 3: VERIFY

Understand when delivery is complete and when you may remove the device.

STEP 4: FINISH

Confirm the dose was delivered and dispose of the device.

FAQ

When it is safe to remove your on-body injector and answers to frequently asked questions.

Important Information

On-body Injector for Neulasta Description

INFO
- The on-body injector for Neulasta is intended for delivery of Neulasta. This on-body injector delivers Neulasta with an injection under-the-skin (subcutaneous). See the Patient Information that comes with your on-body injector for important information.
- Your healthcare provider will use a prefilled syringe with Neulasta to fill the on-body injector prior to applying it. The prefilled syringe with Neulasta and the on-body injector are provided to your healthcare provider as part of Neulasta Onpro kit. The on-body injector is applied directly to your skin using a self-adhesive backing. The on-body injector lets you know its status with sounds and lights.

Warnings

- You should only receive a dose of Neulasta on the day your healthcare provider tells you.
- You should not receive your dose of Neulasta any sooner than 24 hours after you finish receiving your chemotherapy. The on-body injector for Neulasta is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector on your skin.
- If you have concerns about your medicine, call your healthcare provider right away. Serious allergic reactions can happen with Neulasta. Ask your caregiver to be nearby for the first use. Plan to be in a place where you or your caregiver can closely monitor the on-body injector for Neulasta for about 45-minutes during Neulasta delivery and for an hour after the delivery.
- **Do not** take Neulasta if you have had a serious allergic reaction to pegfilgrastim (Neulasta) or to filgrastim (Neupogen).

Warnings (continued)

- Tell your healthcare provider if you are allergic to latex. A prefilled syringe is used to fill the on-body injector by your healthcare provider prior to applying the on-body injector. The prefilled syringe gray needle cap contains dry natural rubber, which is derived from latex. Latex may be transferred to your skin.
- Tell your healthcare provider if you have had severe skin reactions to acrylic adhesives.
- If you have an allergic reaction during the delivery of Neulasta, remove the on-body injector by grabbing the edge of the adhesive pad and peeling off the on-body injector. Get emergency medical help right away.
- Call your healthcare provider right away if you have severe pain or skin discomfort around your on-body injector.
- Call your healthcare provider right away if you have pain in your left upper stomach area or left shoulder area. This pain could mean your spleen is enlarged or ruptured.
- Call your healthcare provider or get emergency medical help right away if you get any of these symptoms of acute respiratory distress syndrome (ARDS): fever, shortness of breath, trouble breathing, or a fast rate of breathing.
- Call your healthcare provider right away if you experience any of these symptoms of kidney injury: swelling of your face or ankles, blood in your urine or dark colored urine or you urinate less than usual.
- Call your healthcare provider if you have persistent or worsening redness or tenderness at the application site (may be a sign of infection).
- The on-body injector is for adults only.

Important Information

Wearing the On-body Injector

- This on-body injector delivers Neulasta with an under-the-skin (subcutaneous) injection.
- The on-body injector is small, for one-time use, lightweight, battery-powered, and waterproof up to 8 feet for 1 hour.
- The on-body injector can be worn in a shower. After showering, check the on-body injector to ensure it has not become loose (dislodged).
- Avoid getting body lotions, creams, oils or cleaning agents near the on-body injector as these products may loosen the adhesive. Before your next scheduled Neulasta dose, avoid use of lotions, creams, or oils on your arms and stomach area (abdomen).
- Only expose the on-body injector to temperatures between 41°F and 104°F (5°C and 40°C).
- **Do not** use bath tubs, hot tubs, whirlpools, or saunas while wearing the on-body injector. This may affect your medicine.
- **Do not** expose the on-body injector to direct sunlight. If the on-body injector is exposed to direct sunlight for more than 1 hour, it may affect your medicine. Wear the on-body injector under clothing.
- **Do not** sleep on the on-body injector or apply pressure during wear, especially during dose delivery. This may affect on-body injector performance.
- **Do not** peel off or disturb the on-body injector adhesive before your full dose is complete. This may result in a missed or incomplete dose of Neulasta.

Environmental Precautions

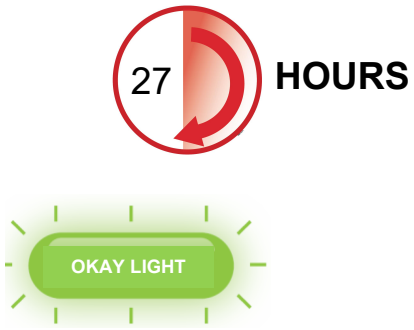
- **Do not** expose the on-body injector to the following because the on-body injector may be damaged and you could be injured:
  - Diagnostic imaging (e.g., CT Scan, MRI, Ultrasound, X-ray)
  - Radiation treatment
  - Oxygen rich environments, such as hyperbaric chambers
- Keep the on-body injector at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances. Failure to keep the on-body injector at least this recommended distance may interfere with operation and can lead to a missed or incomplete dose of Neulasta.
- Avoid activities and places that may interfere with monitoring during the dosing of Neulasta administered by the on-body injector. For example, **avoid** traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector for Neulasta (this includes the 45-minute dose delivery period plus an hour post-delivery).
- If you must travel by airplane **before** the approximately 45-minute dose delivery period with the on-body injector, avoid airport X-ray scans. Request a manual pat down instead. Use care during a manual pat down to help prevent the on-body injector from being accidentally removed. For more information go to: **http://www.tsa.gov/traveler-information/travelers-disabilities-and-medical-conditions**

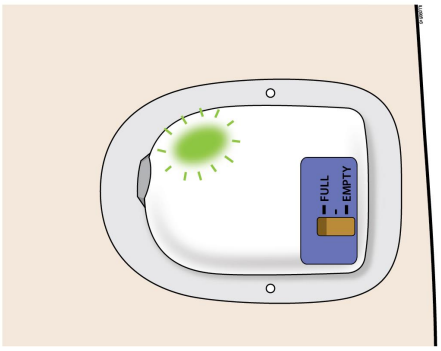
A healthcare provider who is familiar with Neulasta should answer your questions. For general questions or support call **1-844-MYNEULASTA (1-844-696-3852)** or visit **www.neulasta.com**.

Step 1: Monitor On-body Injector

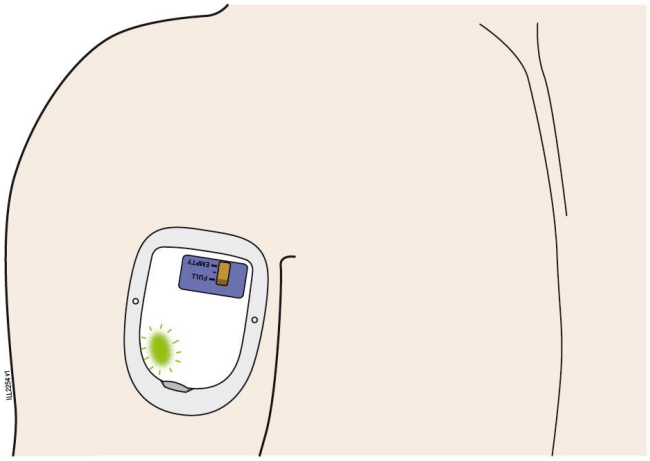
A **For the next 27 hours, occasionally check the status light for at least 10 seconds. If the status light is flashing green, it is okay.**

1





- Keep the on-body injector and adhesive backing dry for at least 3 hours after it was placed on your skin, and for 3 hours prior to dose delivery.
- Be careful not to bump the on-body injector, or knock the on-body injector off your body.
- The on-body injector has a self-adhesive backing to attach it to the skin. Do not add other materials to hold it in place as this could dislodge the cannula and lead to a missed or incomplete dose of Neulasta.



2

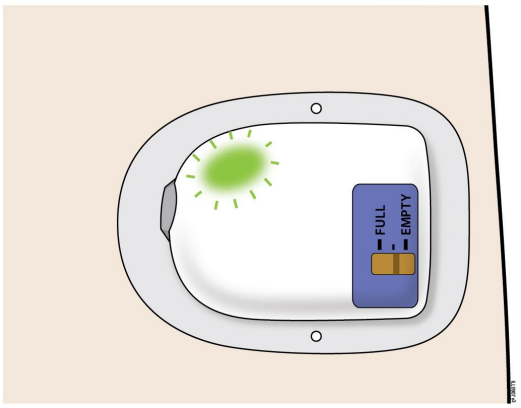
- If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- If the on-body injector comes away from your skin at any time, do not reapply it. Call your healthcare provider right away as you may need a replacement dose.
- If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away, as you may need a replacement dose.

Step 2: Observe Dose Delivery

A **After about 27 hours, your on-body injector will begin to deliver your dose of Neulasta.**

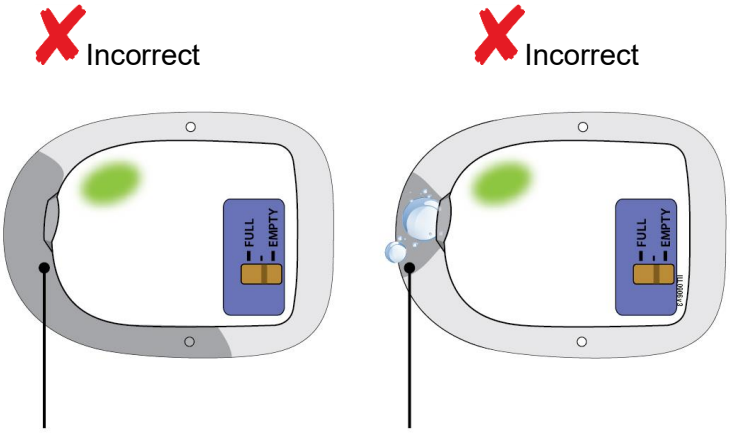
- Dose delivery will take around 45-minutes to complete. The on-body injector will flash a fast, green light.
- You may hear a series of clicks. This is okay.

2



- When dose delivery is complete, a long beep will sound and the status light will turn solid green.
- If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away, as you may need a replacement dose.
- **Do not remove the on-body injector if the status light is flashing green.**

Check your on-body injector often for leaks during the 45-minute dose delivery. If the on-body injector was placed on the back of your arm, a caregiver must be available to check your on-body injector.



Noticeably wet adhesive

Dripping fluid from on-body injector

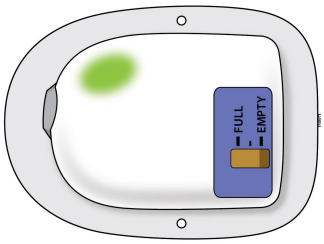
- If the adhesive is noticeably wet or dripping with medicine, call your healthcare provider right away, as you may need a replacement dose.

Step 3: Verify Dose Complete

A **After the beep, check the color of the status light.**

3

✔ Correct

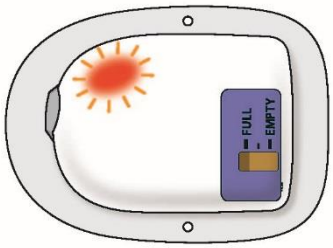


Check to see if the status light is **SOLID GREEN** or has switched off. This means the dose is complete.

If the dose is complete, go to the next step.

Do not remove the on-body injector if the status light is flashing green.

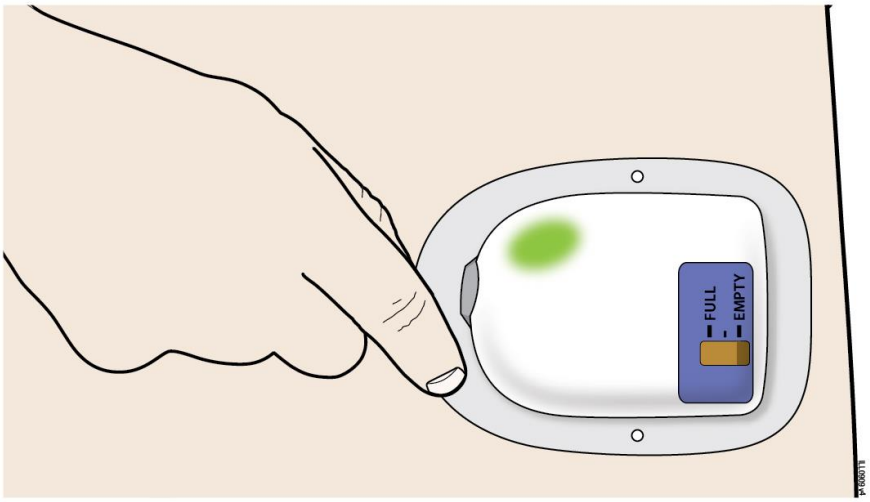
✘ Incorrect



If you see the status light is **FLASHING RED**, and your on-body injector is beeping, your on-body injector is not functioning properly.

Call your healthcare provider right away, as you may need a replacement dose.

B **Grab the edge of the adhesive pad. Slowly peel off the on-body injector.**



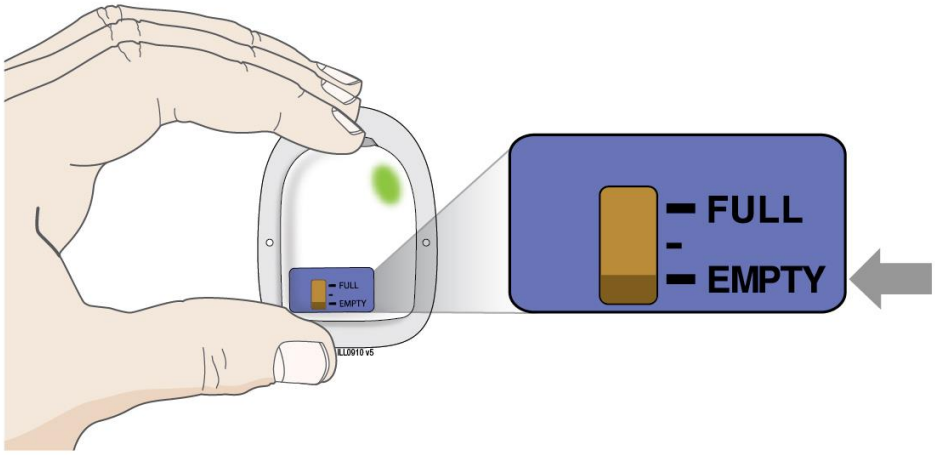
- **Do not** grasp the on-body injector itself to try to pull it off of your body.
- If medicine has leaked or the adhesive is noticeably wet or dripping, call your healthcare provider right away, as you may not have received your full dose and you may need a replacement dose.
- Remove any extra adhesive using soap and water.

Step 4: Finish

Check to see if your on-body injector is empty.

- Check your status light. Watch for at least 10 seconds. If the status light is solid green or it has switched off, it is okay.
- You should see a black line next to the EMPTY indicator. If the on-body injector is not empty, call your healthcare provider right away, as you may need a replacement dose.

4



- If you hear beeping, or when you check the status light and it is flashing red, call your healthcare provider right away.
- If the needle is exposed, call your healthcare provider right away.

A **Check off the box below to record how your on-body injector looks after use.**

☐ Status light is solid green or the status light has switched off.
This means that the delivery is complete.

☐ On-body injector leaked, call your healthcare provider right away, as you may need a replacement dose.

☐ Status light is red, call your healthcare provider right away, as you may need a replacement dose.

B **Properly dispose of the on-body injector.**

- After on-body injector removal, place the on-body injector in a sharps disposal container whether the needle is exposed or not.
- The on-body injector contains batteries, electronics, and a needle. Put the on-body injector in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) the on-body injector in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to FDA's website at: http://www.fda.gov/safesharpsdisposal.
- To participate in Amgen's voluntary disposal program, please call **1-844-MYNEULASTA (1-844-696-3852)** or visit **www.neulasta.com** to enroll.

FAQ

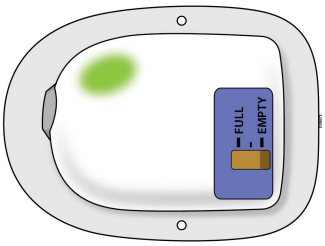
- **Keep the used on-body injector and sharps disposal container away from children.**

Frequently Asked Questions

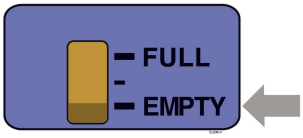
How do I know it is safe to remove the on-body injector?

It is safe to remove the on-body injector after checking the following:

✔ Correct



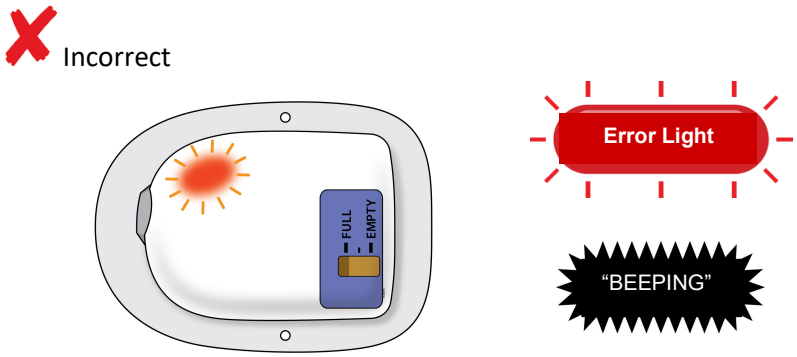
- The status light should be solid green.
- If the status light is flashing green, the dose delivery is not complete. Wait until you hear a long beep and the status light turns solid green before removing your on-body injector.
- The status light turns off 1 hour after delivery completion



- The fill indicator should have a black line next to EMPTY

What to do if you hear beeping or when you look at the status light and it is flashing red?

- If the status light is flashing red, you may not have received your full dose and may need a replacement dose. Call your healthcare provider right away.



What do I do if the on-body injector comes off before the full dose is delivered?

- Call your healthcare provider right away if the on-body injector at any time comes away from your skin before your full dose delivery, as you may need a replacement dose. **Do not** reapply it.

What if there is blood at my application site after the on-body injector has been removed?

- If there is blood, press a clean cotton ball or gauze pad on the application site. Apply an adhesive bandage if needed.

What if my application site is red or tender after on-body injector removal?

- Call your healthcare provider right away if you experience persistent or worsening redness or tenderness at the application site, as this can be a sign of infection.

Notes

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Neulasta® Onpro®

Patient INSTRUCTIONS FOR USE

Neulasta® (pegfilgrastim)

Manufactured by:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
US License No. 1080

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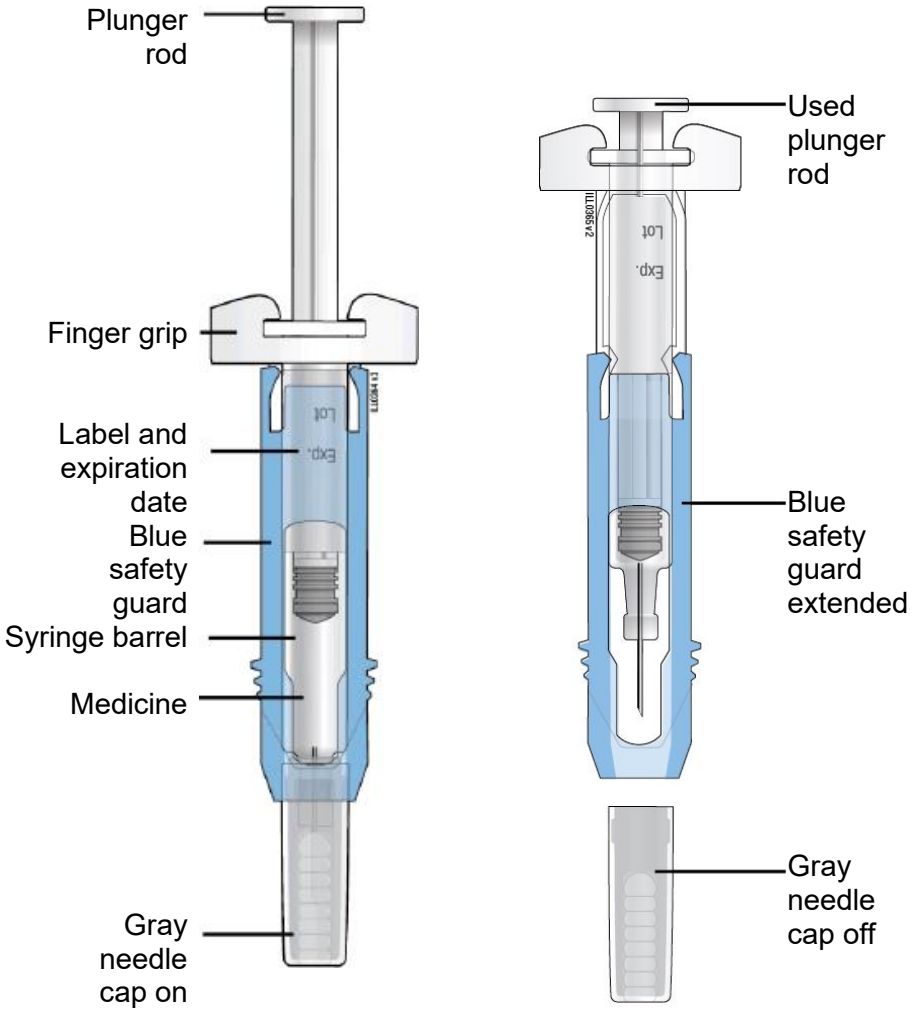
http://www.neulasta.com

1-844-MYNEULASTA (1-844-696-3852)
Revised: 08/2025
V11

Instructions for Use
Neulasta (nu-las-tah)
(pegfilgrastim)
injection, for subcutaneous use
Single-Dose Prefilled Syringe

Guide to parts

Before use **After use**



Important: The needle is covered by the gray needle cap before use.

Important

Read the Patient Information for important information you need to know about Neulasta before using these Instructions for Use.

Before you use a Neulasta prefilled syringe, read this important information.

Storing the prefilled syringe

- Store Neulasta in the refrigerator between 36°F and 46°F (2°C to 8°C).
- **Avoid freezing.** If Neulasta prefilled syringe is frozen 1 time, thaw in refrigerator before using it. If it is frozen more than 1 time, throw it away and use a new Neulasta prefilled syringe.
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- Throw away (dispose of) a syringe that has been left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 48 hours.
- **Keep the Neulasta prefilled syringe out of the reach of children.**

Using the prefilled syringe

- **It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.**
- Make sure the name Neulasta appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength is 6 mg.
- **Do not** inject a dose of Neulasta to children weighing less than 99 pounds (45 kg) from a Neulasta prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the Neulasta prefilled syringe.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe.
- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if the carton is open or damaged.
- **Do not** use a prefilled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- **Do not** slide the blue safety guard over the needle before you give the injection. This will “activate” or lock the blue safety guard. Use another prefilled syringe that has not been activated and is ready to use.
- The gray needle cap on the prefilled syringe contains dry natural rubber (made from latex). **Tell your healthcare provider if you are allergic to latex. You should not give Neulasta using the prefilled syringe if you have latex allergies.**

Call your healthcare provider if you have any questions.

Step 1: Prepare

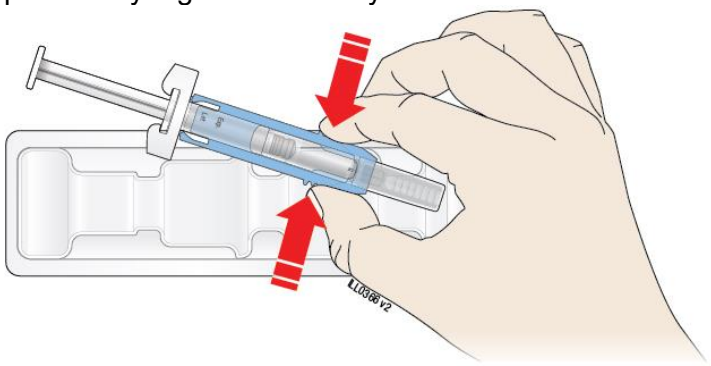
A Remove the prefilled syringe carton from the refrigerator.

Check the expiration date.
Important: **Do not** use if the expiration date has passed.

Remove the syringe tray from the carton. On a clean, well-lit surface, place the syringe tray at room temperature, 68°F to 77°F (20°C to 25°C), for **30** minutes before you give an injection.

- **Do not** use the prefilled syringe if the carton is damaged.
- **Do not** try to warm the prefilled syringe by using a heat source such as hot water or microwave.
- **Do not** leave the prefilled syringe in direct sunlight.
- **Do not** shake the prefilled syringe.

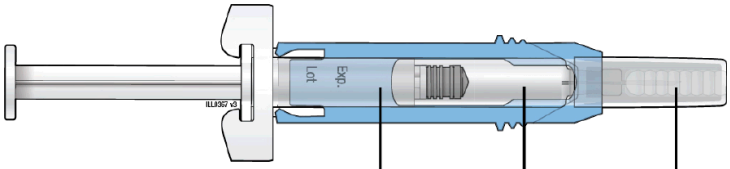
Open the tray by peeling away the cover. Grab the blue safety guard to remove the prefilled syringe from the tray.



Grab Blue Safety Guard

For safety reasons:
- **Do not** grab the plunger rod.
- **Do not** grab the gray needle cap.

B Inspect the medicine and prefilled syringe.



Label and expiration date | Medicine | Gray needle cap

Make sure the medicine in the prefilled syringe is clear and colorless. It is normal to see air bubbles in the syringe.

- **Do not** use the prefilled syringe if:
  - The medicine is cloudy or discolored or contains flakes or particles.
  - Any part appears cracked or broken.
  - The prefilled syringe has been dropped.
  - The gray needle cap is missing or not securely attached.
  - The expiration date printed on the label has passed.

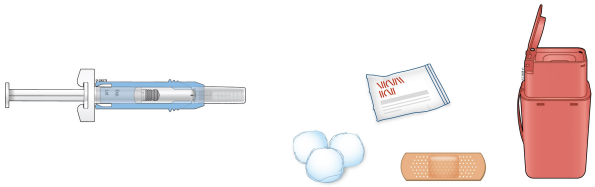
In all cases, use a new prefilled syringe and call your healthcare provider.

C Gather all materials needed for the injection.

Wash your hands thoroughly with soap and water.

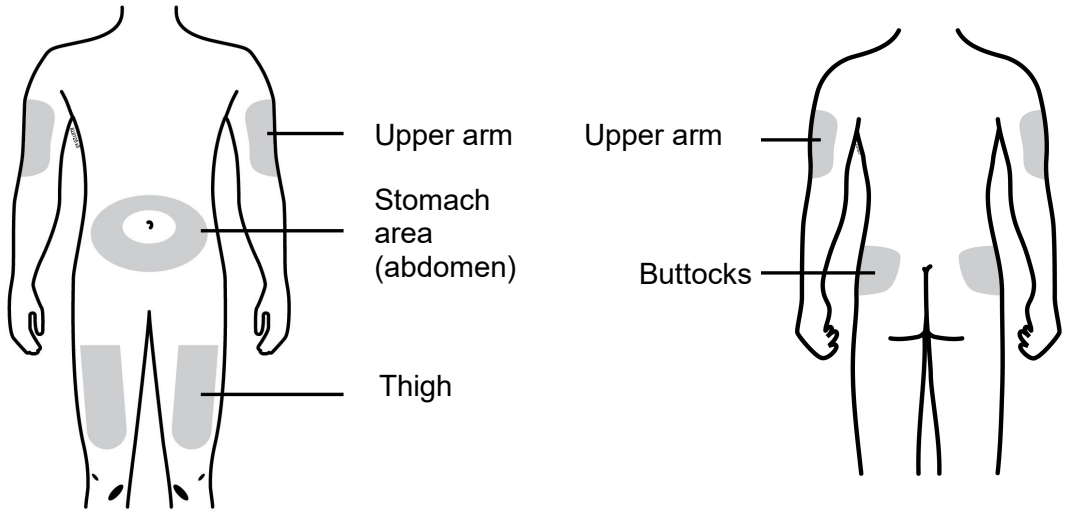
On a clean, well-lit work surface, place the:

- Prefilled syringe
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



Step 2: Get ready

D Prepare and clean the injection site.



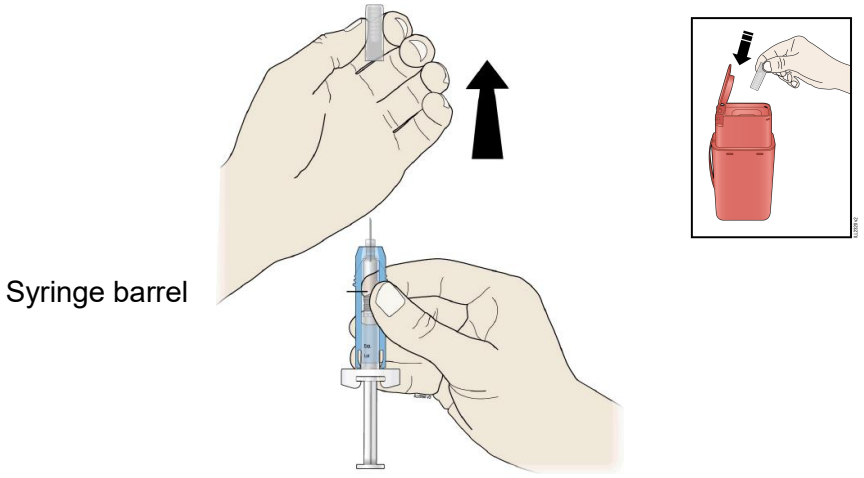
You can use:

- Thigh
- Stomach area (abdomen), except for a **2**-inch area right around the navel (belly button)
- Upper outer area of the buttocks (only if someone else is giving you the injection)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean the injection site with an alcohol wipe. Let the skin dry.

- **Do not** touch this area again before injecting.
- If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

E Hold the prefilled syringe by the syringe barrel. Carefully pull the gray needle cap straight off and away from your body.

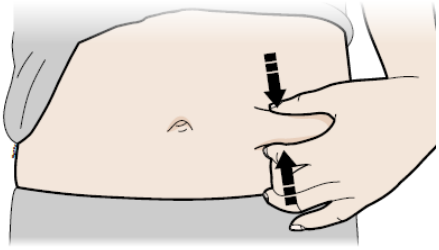


- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** twist or bend the gray needle cap.
- **Do not** hold the prefilled syringe by the plunger rod.
- **Do not** put the gray needle cap back onto the prefilled syringe.

Important: Throw the gray needle cap into the sharps disposal container.

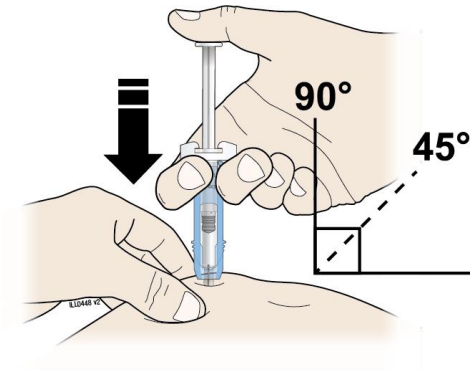
Step 3: Subcutaneous (under the skin) injection

F Pinch the injection site to create a firm surface.



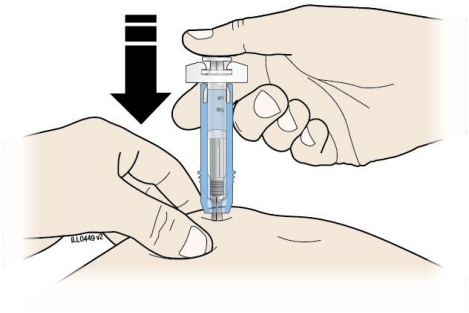
Important: Keep skin pinched while injecting.

G Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.



H Using slow and constant pressure, push the plunger rod until it reaches the bottom.

When done, gently pull the syringe off of the skin.

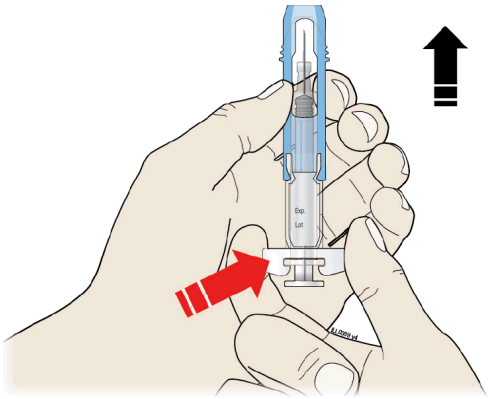


Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare provider right away.

Step 4: Finish

I STOP **Before you finish!**

For your safety, pull the blue safety guard until it clicks and covers the needle.



GRAB HERE

Once extended, the blue safety guard will lock into position and will not slide back over the needle.

Keep your hands away from the needle at all times.

J Discard (throw away) the used prefilled syringe.

- Put the used prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the syringe in the household trash.

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal

- **Do not** reuse the prefilled syringe.
- **Do not** recycle the prefilled syringe or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

K Examine the injection site.

If there is blood, press a cotton ball or gauze pad on the injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

AMGEN

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Revised: 08/2026 v5