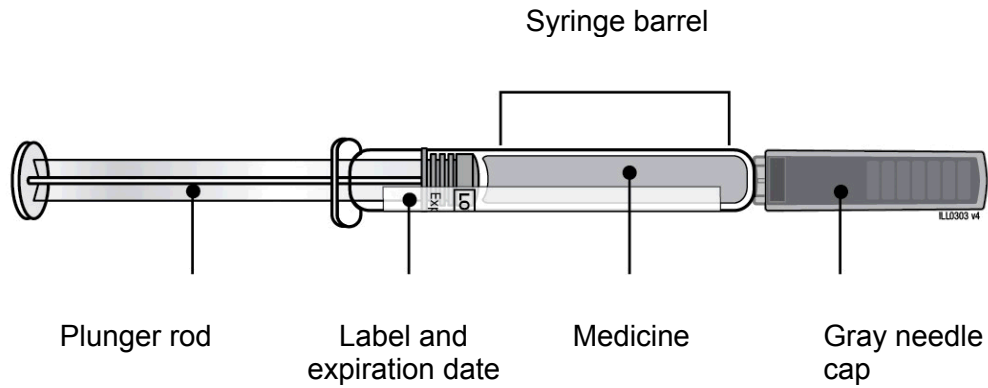


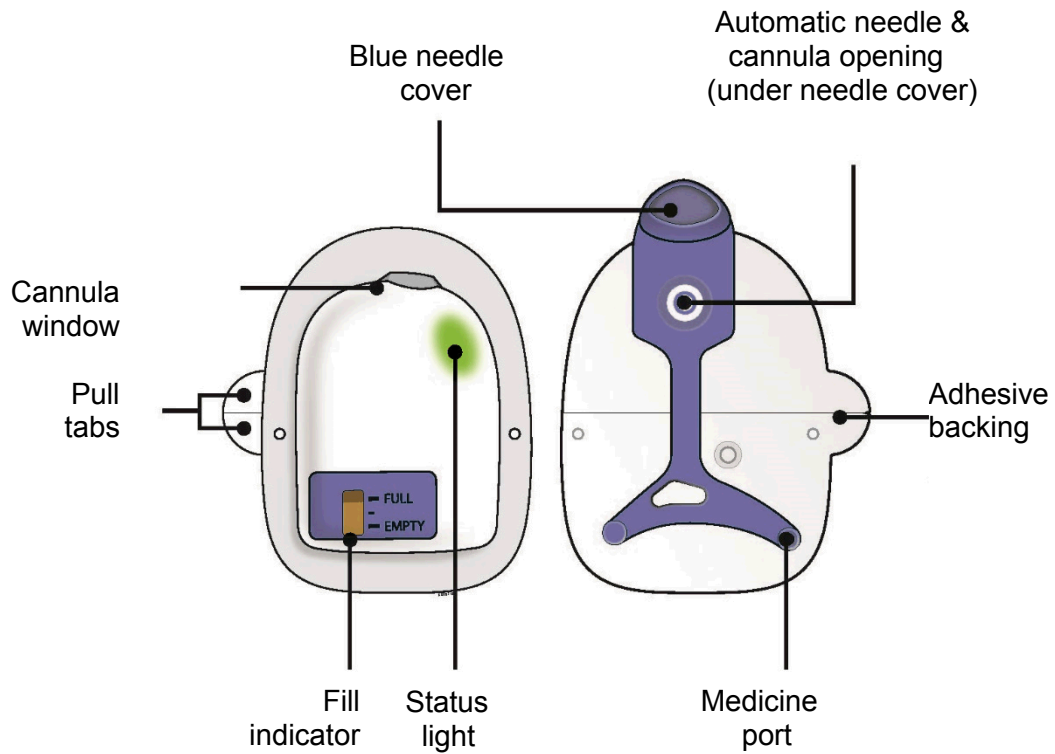
# Neulasta® (pegfilgrastim) Onpro® kit Healthcare Provider Instructions for Use

## Guide to Parts

### Neulasta Prefilled Syringe



### On-body Injector for Neulasta



## Important

### READ THE FOLLOWING INSTRUCTIONS BEFORE USING NEULASTA ONPRO KIT

**Warning:** Do not use Neulasta Onpro kit to deliver any other drug product.

- 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.
- Store Neulasta Onpro kit in the refrigerator at 36°F to 46°F (2°C to 8°C) until ready for use. If Neulasta Onpro kit is stored at room temperature for more than 12 hours, do not use. Start again with a new Neulasta Onpro kit.
- Keep the prefilled syringe in Neulasta Onpro kit carton until use to protect from light.
- 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.
- 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.
- **Do not** freeze Neulasta Onpro kit.
- **Do not** shake the prefilled syringe.
- **Do not** separate the components of Neulasta Onpro kit until ready for use.
- **Do not** modify the on-body injector.
- **Do not** warm Neulasta Onpro kit components using a heat source.
- **Do not** use Neulasta Onpro kit if expiry date on the carton or any of Neulasta Onpro kit components has passed.
- **Do not** use if the name Neulasta does not appear on Neulasta Onpro kit carton.
- **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 Neulasta Onpro kit.

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

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## Step 1: Prepare

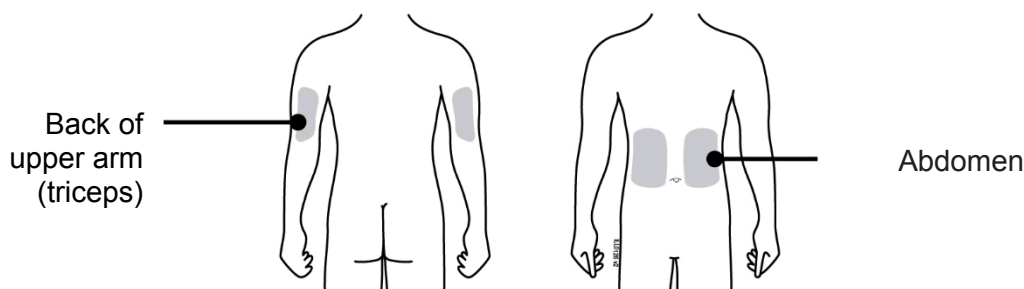
### A Remove Neulasta Onpro kit from the refrigerator.

Place the syringe tray and on-body injector tray on a clean, well lit work surface. Allow to come to room temperature for 30 minutes prior to activating. Check to make sure it contains:

- One Neulasta prefilled syringe
- One on-body injector for Neulasta
- Neulasta Patient Information
- Neulasta Prescribing Information
- Instructions for Use for healthcare provider
- Instructions for Use for patient
- Reference Guide

**Do not** use the on-body injector if its packaging has been previously opened.

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



**Choose the flattest site for the on-body injector application.**

**Consult with the patient regarding their ability to remove and monitor the entire on-body injector.**

- You can use the left or right side of the abdomen, except for a two-inch area right around navel.
  - You can use the back of upper arm only if there is a caregiver available to monitor the status of the on-body injector.
  - **Do not** apply the on-body injector on 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 surgical sites.
  - **Do not** apply the on-body injector on areas where the on-body injector will be affected by folds in the skin.
-



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

Before you apply the on-body injector to the patient, locate the medicine port on the blue needle cover to fill the on-body injector with Neulasta.

**Please note:** During filling, beeping will sound and the on-body injector will be activated.

**After activation, you will have three minutes to:**

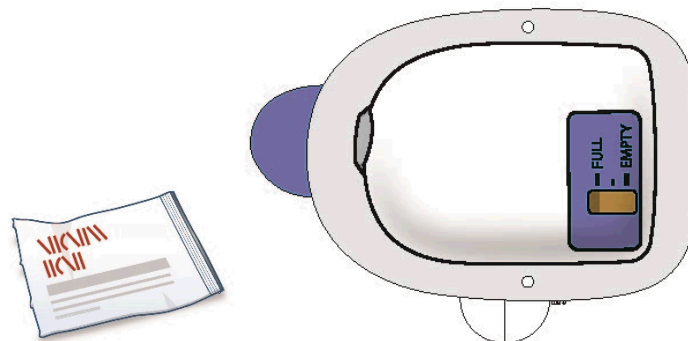
1. Completely empty syringe contents into the medicine port.
2. Remove the syringe from the port and dispose.
3. Remove the blue needle cover from back of the on-body injector.
4. Peel away the two pieces of white adhesive backing from the back of the on-body injector.
5. Attach the on-body injector to the back of patient's upper arm or abdomen.

The on-body injector will deploy the cannula in three minutes, even if not applied to the patient. If not on patient's body in three minutes, do not use the on-body Injector. Start again with a new Neulasta Onpro kit.

**When you feel you are ready, please continue...**

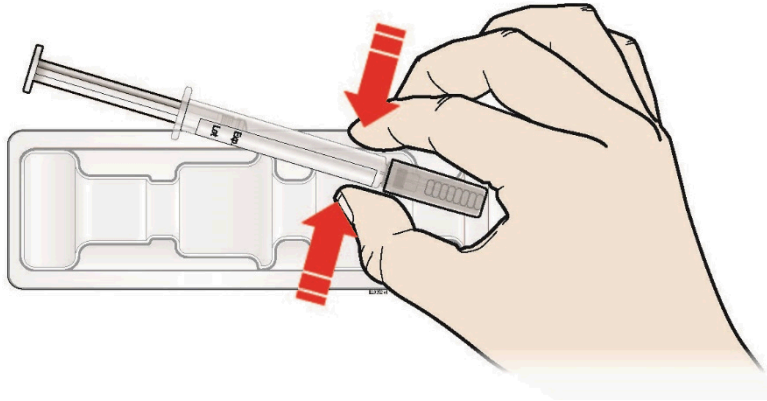
**C Clean an area on the injection site larger than the on-body injector adhesive backing.**

- Thoroughly cleaning the site will help the on-body injector adhere to the skin. **Do not** use any cleaner other than alcohol, especially those containing oils, lotions, or aloe.
- Make sure the skin is oil-free prior to applying the on-body injector. Allow the skin to completely dry.
- **Do not** touch this area again before attaching the on-body injector.



## Step 2: Get Ready

### A Remove Neulasta prefilled syringe from tray.

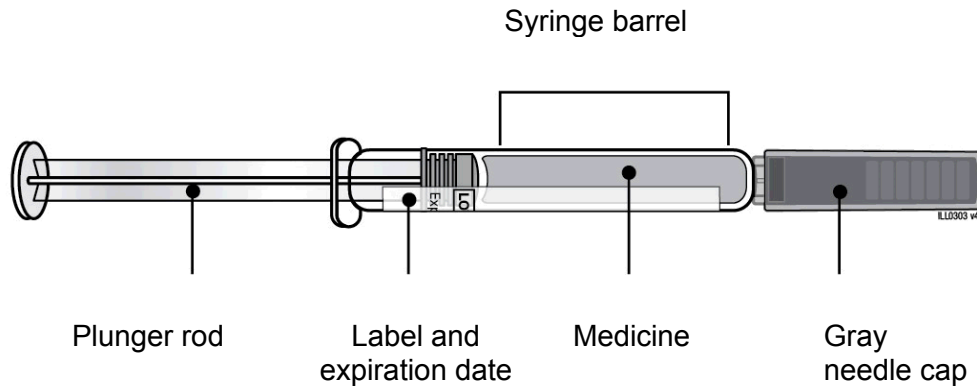


**Grab Here**

#### For safety reasons:

- **Do not** grasp the gray needle cap.
- **Do not** remove the gray needle cap until ready to fill the on-body injector.
- **Do not** grasp the plunger rod.

### B Inspect medicine and 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 if any part appears cracked or broken.
- **Do not** use if the gray needle cap is missing or not securely attached.
- **Do not** use if the expiration date printed on the label has passed.
- **Do not** remove the gray needle cap until ready to fill the on-body injector.

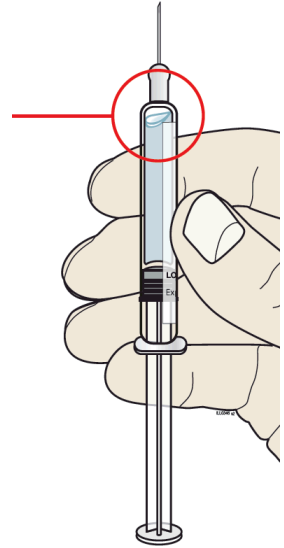
In all the above cases, start again with a new kit. Call Amgen at 1-800-772-6436.

Neulasta prefilled syringe gray needle cap contains dry natural rubber, which is derived from latex.

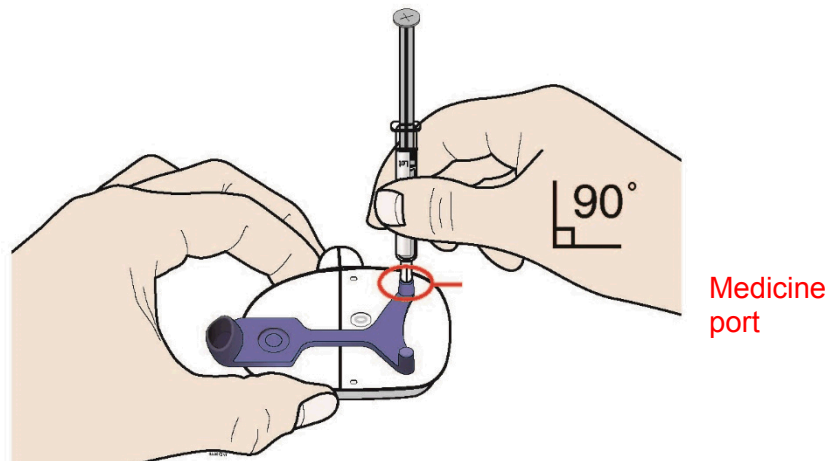
**C Remove air bubbles in prefilled syringe.**

Injecting air bubbles into the on-body injector could interfere with the full-dose delivery.

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



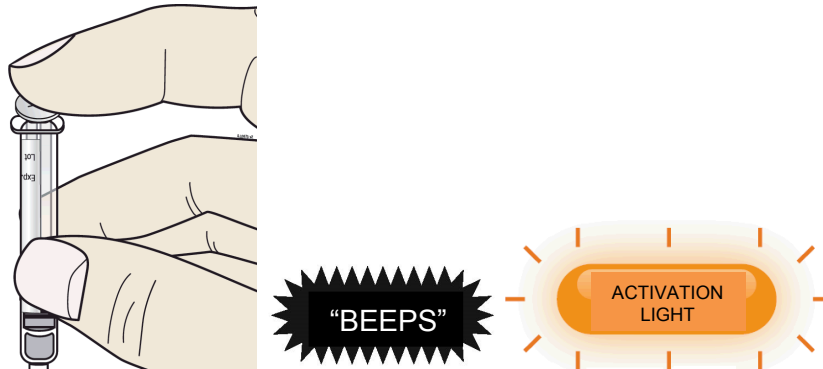
**D Center the needle directly over the medicine port at a 90 degree angle. Insert all the way into the port, avoiding sides.**



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

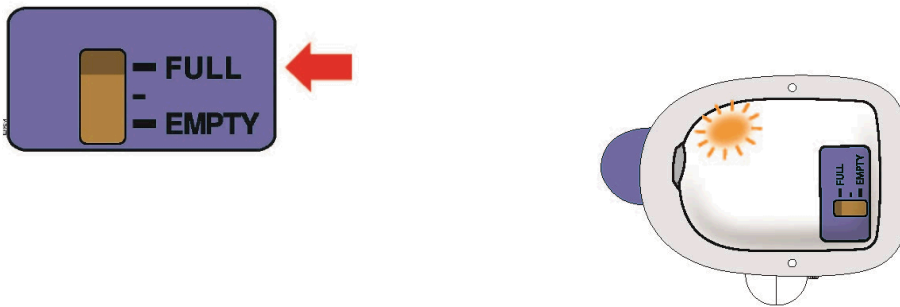
- **Do not** insert the needle more than once.
- **Do not** bend the needle. Avoid spilling the medicine.
- **Do not** remove the blue needle cover before filling the on-body injector.

- E Push the plunger rod to empty entire syringe contents. During filling, you will hear beeping. The status light will flash amber, indicating you now have three minutes to apply the on-body injector to the patient.**



Discard used syringe in sharps container.

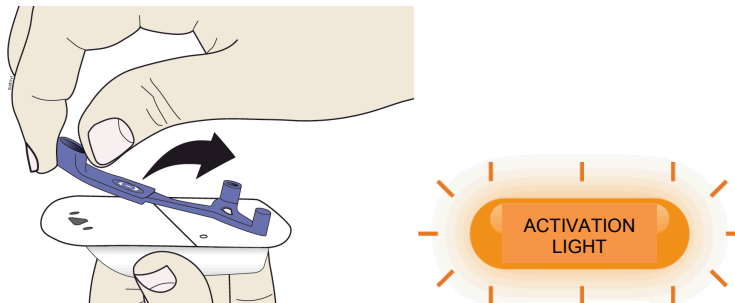
- F Check to see if the on-body injector is full and the amber light is flashing.**



You should see the amber status light flashing and 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, and call Amgen at 1-800-772-6436.

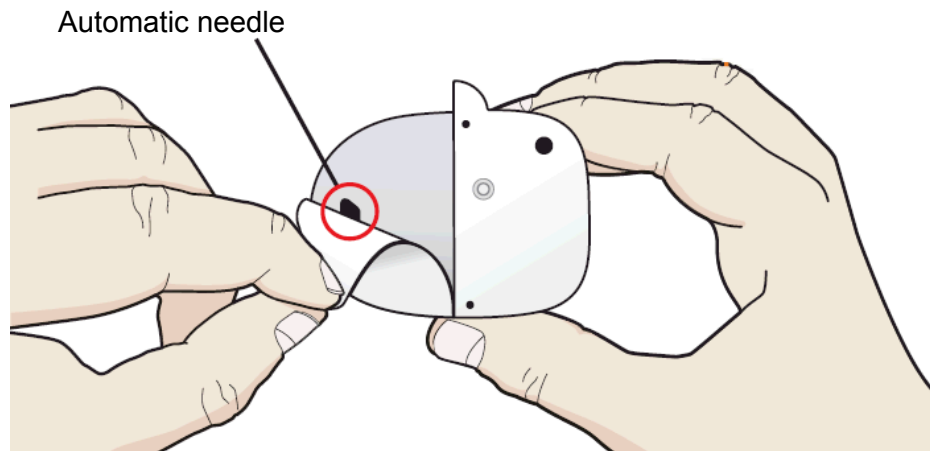
- G Firmly lift and remove the blue needle cover away from the on-body injector.**



A drop of medicine may be visible on the needle tip when the blue needle cover is removed.

### Step 3: Apply

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



- **Do not** touch or contaminate the automatic needle area.
- **Do not** pull off the adhesive pad or fold it.
- **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.**

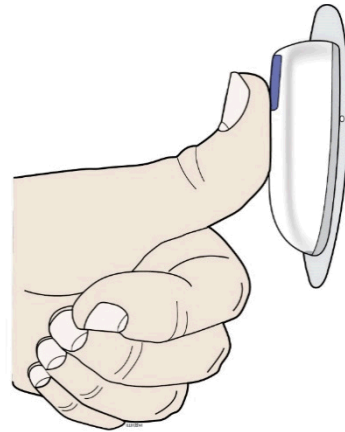
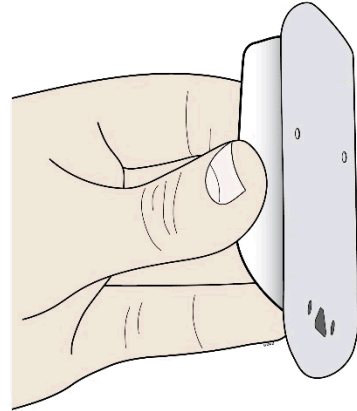
In all cases, start again with a new kit. Call Amgen at 1-800-772-6436.



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

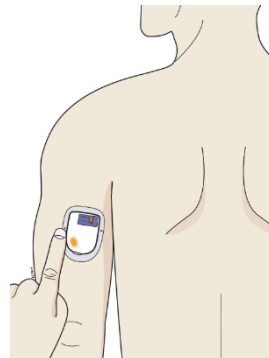
**You now have time to carefully apply the on-body injector without folding or wrinkling the adhesive.**

- **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.
- **Do not** use any additional materials to secure the on-body injector to the patient.

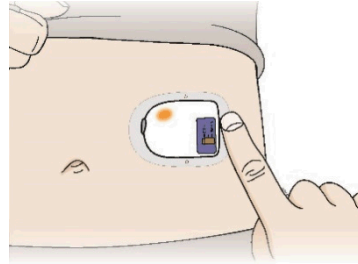


**Back of upper arm  
(triceps)**

Vertical with the  
light facing down  
toward the elbow

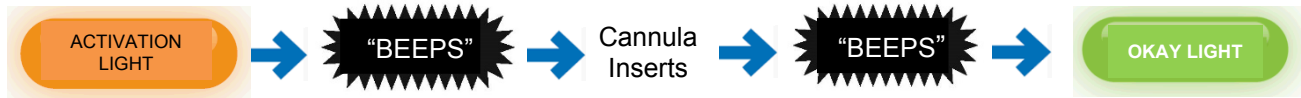


**Abdomen**  
Horizontal with the  
light facing up and  
visible to the patient



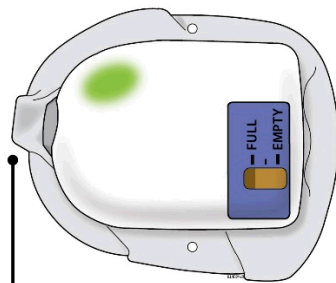
**Do not worry if the on-body injector is quiet. When three minutes are up, the on-body injector will beep telling you the cannula is about to insert.**

- C 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.

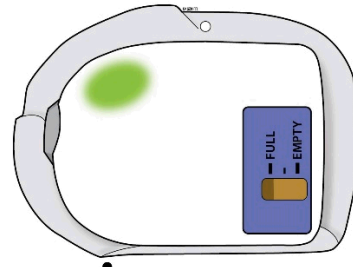


**Check the quality of adhesion before sending the patient home.**

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

## Step 4: Finish

- A Fill in the Dose Delivery Information section in the patient instructions. Be sure to include when the on-body injector was applied, when the dose will begin, and your contact information. Review this information with the patient.**

Review each step in the patient instructions with the patient. Give the patient the instructions for use, reference guide, patient information and prescribing information to take home.

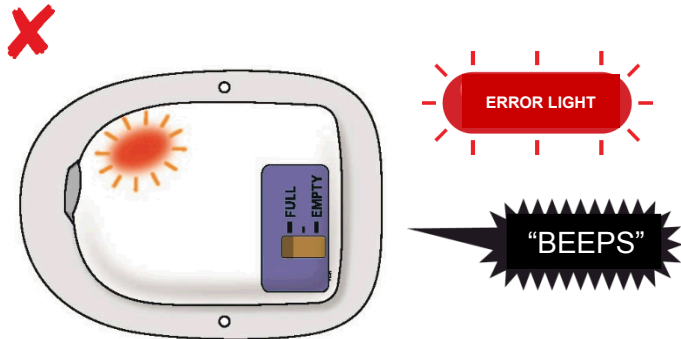
Before the patient goes home, make sure the patient understands:

The on-body injector will always flash a slow green light to let them know it is working properly.

- **After approximately 27 hours, a series of beeps will signal that the dose delivery will begin in two minutes.**
- **When the dose delivery starts it will take about 45 minutes to complete. During this time, the on-body injector will flash a fast green light.**
- The patient should remain in a place where they can monitor the on-body injector for the entire dose delivery. The patient should avoid activities and settings 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 (this includes the approximately 45 minute delivery period plus an hour post-delivery).
- If the patient has an allergic reaction during the delivery of Neulasta, the patient should remove the on-body injector and call his or her healthcare provider or seek emergency care right away.
- If placed on the back of the arm, remind the patient that a caregiver must be available to monitor 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.
- When the dose delivery is complete, the patient or caregiver will hear a long beep and see a solid green light.
- If the red error light is on, 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.
- Always dispose of the empty on-body injector in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
- Keep the on-body injector at least four 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.

## Attention!

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



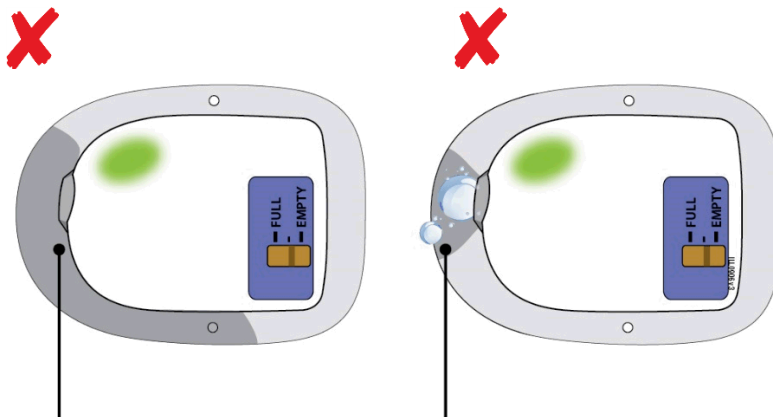
If at any time the on-body injector beeps continuously for five minutes, and the status light is flashing red, take the on-body injector off of the patient.

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

If the patient reports the red status light is on, they may not have received the full dose. Schedule a follow-up appointment and report the incident to Amgen at 1-800-772-6436.

What to do if the adhesive becomes 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, and 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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www.neulasta.com  
1-844-MYNEULASTA (1-844-696-3852)  
Issued: 06/2018  
v8

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

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)
<b>REF</b>	Reference/model number
<b>LOT</b>	Lot number
	Type BF medical device (protection from electrical shock)
<b>STERILE EO</b>	Sterilized by ethylene oxide
<b>IPX8</b>	Waterproof up to 8 feet for 1 hour
<b>Rx Only</b>	Prescription use only
	Not MRI-safe
	On-body injector for Neulasta® (pegfilgrastim)
	Neulasta® (pegfilgrastim) prefilled syringe

## 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.

<b>Electromagnetic Emissions</b>		
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	±6 kV Contact ±8 kV Air	6 kV Contact ±8 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	3 A/m	3 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 2.5 GHz	(E1)=3 V/m	<p>Portable and mobile communications equipment should be separated from the on-body injector for Neulasta by no less than the distances calculated/listed below:</p> <p><math>D = (3.5/V_1)(\sqrt{P})</math> 150 kHz to 80 MHz</p> <p><math>D = (3.5/E_1)(\sqrt{P})</math> 80 to 800 MHz</p> <p><math>D = (7/E_1)(\sqrt{P})</math> 800 MHz to 2.5 GHz</p> <p>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.</p>



## 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 $D=(3.5/V1)(\sqrt{P})$	80 MHz to 800 MHz $D=(3.5/E1)(\sqrt{P})$	800 MHz to 2.5 GHz $D=(7/E1)(\sqrt{P})$
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