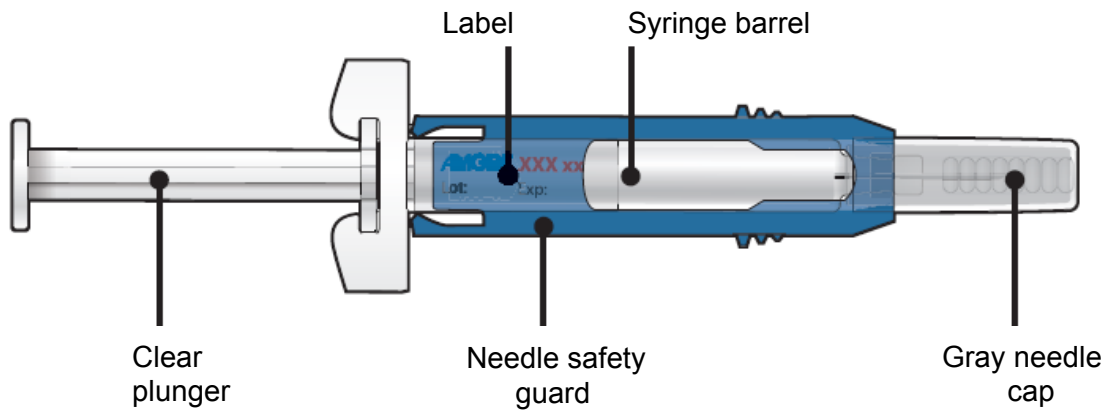


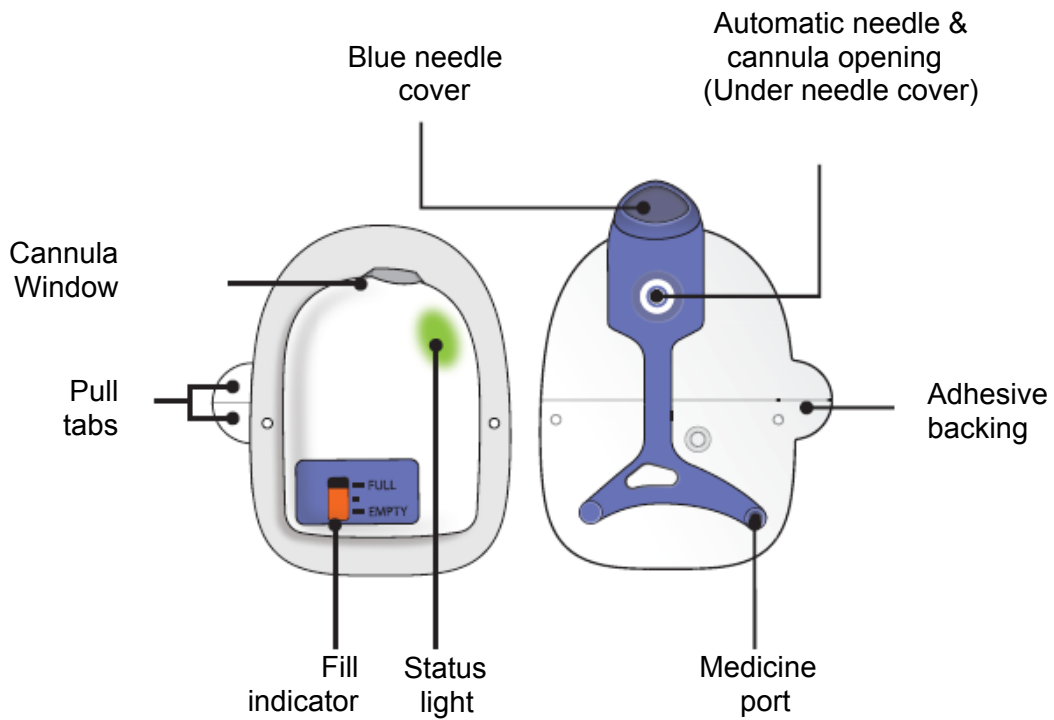
Neulasta® (pegfilgrastim) Onpro™ kit Healthcare Provider Instructions for Use

Guide to Parts

Neulasta Prefilled Syringe with Manual Needle Guard



On-body Injector for Neulasta



Important

READ THE FOLLOWING INSTRUCTIONS BEFORE USING THE ON-BODY INJECTOR

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 the 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.
- ⊘** DO NOT:
 - x** freeze Neulasta Onpro kit.
 - x** shake the prefilled syringe.
 - x** separate the components of Neulasta Onpro kit until ready for use.
 - x** modify the On-body Injector.
 - x** warm Neulasta Onpro kit components using a heat source.
 - x** use Neulasta Onpro kit if expiry date on the carton or any of the Neulasta Onpro kit components has passed.
 - x** use if the name Neulasta does not appear on the Neulasta Onpro kit carton.
 - x** attempt to reapply On-body Injector.
 - x** 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.

Step 1: Prepare

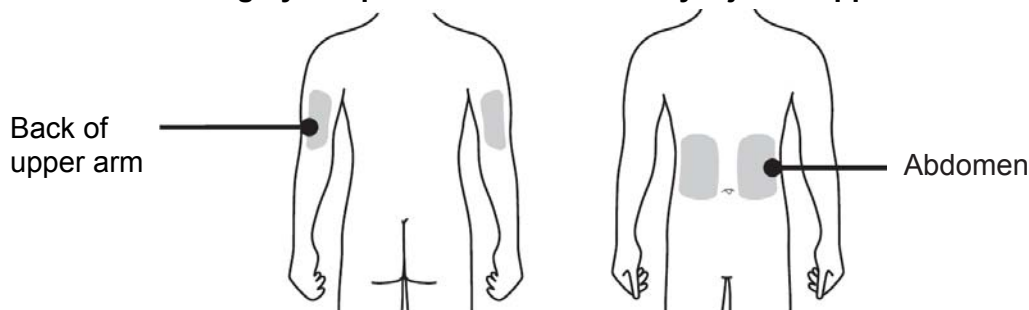
A Remove Neulasta Onpro kit from refrigerator. Check to make sure it contains:

- One Neulasta prefilled syringe
- One On-body Injector for Neulasta
- Neulasta package insert
- Instructions for use:
 - for healthcare provider
 - for patient

- Reference guide

⊘ DO NOT use On-body Injector if its packaging has been previously opened.

B Wash hands thoroughly. Prepare and clean On-body Injector application site.



Choose the flattest site for On-body Injector application. Consult with your patient regarding their ability to remove and monitor the entire On-body Injector.

You can use:

- Left or right side of abdomen, except for a 2-inch area right around navel.
- Back of upper arm, only if there is a caregiver available to monitor the status of the On-body Injector.

Choose an area larger than the adhesive pad, and clean it with an alcohol swab. Allow skin to completely dry.

⊘ DO NOT touch this area again before attaching On-body Injector.

You should avoid:

- ✗ Areas with scar tissues, moles, or excessive hair. In case of excessive hair, carefully trim hair to get On-body Injector close to skin.
- ✗ Areas where belts, waistbands, or tight clothing may rub against, disturb, or dislodge On-body Injector.
- ✗ Surgical sites.
- ✗ Areas where On-body Injector will be affected by folds in skin.



The following is an overview of On-body Injector preparation steps. Read this section first.

When ready, proceed to Step 2: Get Ready Section.

Before you apply On-body Injector to your patient, locate medicine port on 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 3 minutes to:

1. Completely empty syringe contents into medicine port.
2. Remove syringe from port and pull down needle safety guard over the exposed needle.
3. Remove blue needle cover from back of On-body Injector.
4. Peel away the two pieces of white adhesive backing from the back of the On-body Injector.

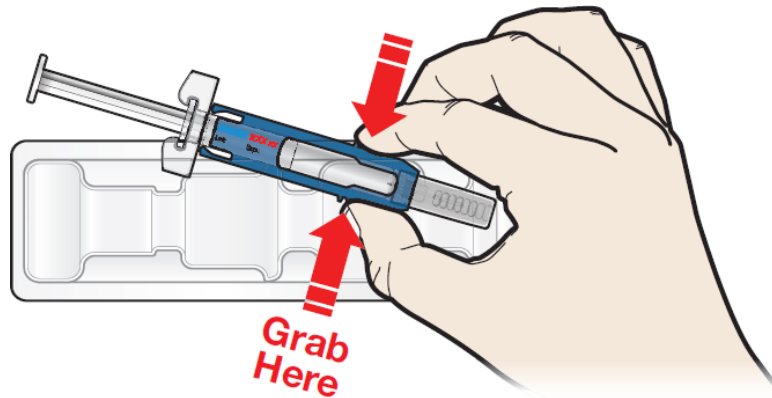
5. Attach On-body Injector to back of patient's upper arm or abdomen.

On-body Injector will deploy cannula in 3 minutes, even if not applied to patient. If not on patient's body in 3 minutes, do not use the On-body Injector. Start again with a new Neulasta Onpro kit.

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

Step 2: Get Ready

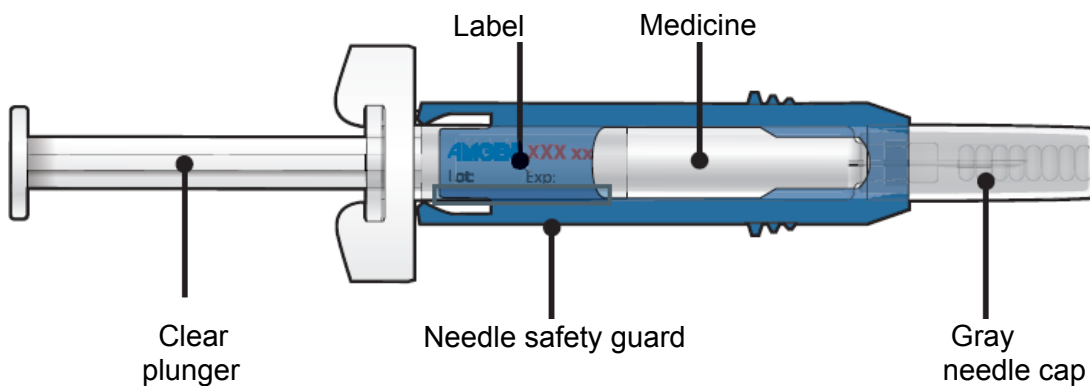
A Remove Neulasta prefilled syringe from tray.



For safety reasons:

- ⊘ DO NOT grasp gray needle cap.
- ⊘ DO NOT put the gray needle cap back onto syringe.
- ⊘ DO NOT grasp clear plunger.

B Inspect medicine and Neulasta prefilled syringe. The Neulasta liquid should always be clear and colorless.

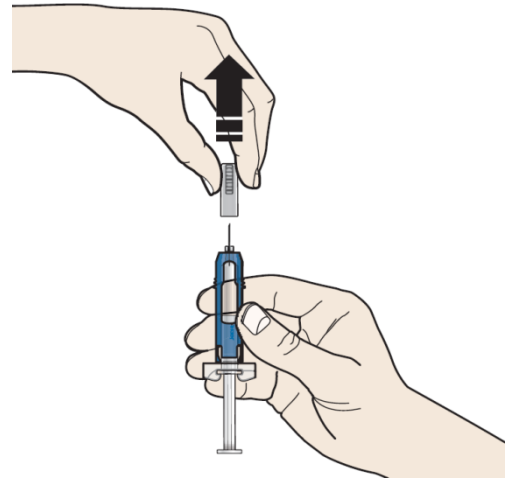


- ⊘ DO NOT use Neulasta prefilled syringe if:
 - ✗ Liquid contains particulate matter or discoloration is observed prior to administration.
 - ✗ Any part appears cracked or broken.
 - ✗ The gray needle cap is missing or not securely attached.
 - ✗ The expiration date printed on the label has passed.
- ⊘ DO NOT remove gray needle cap until ready to fill On-body Injector.
- ⊘ DO NOT pull needle safety guard down over the needle until filling is complete.

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

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

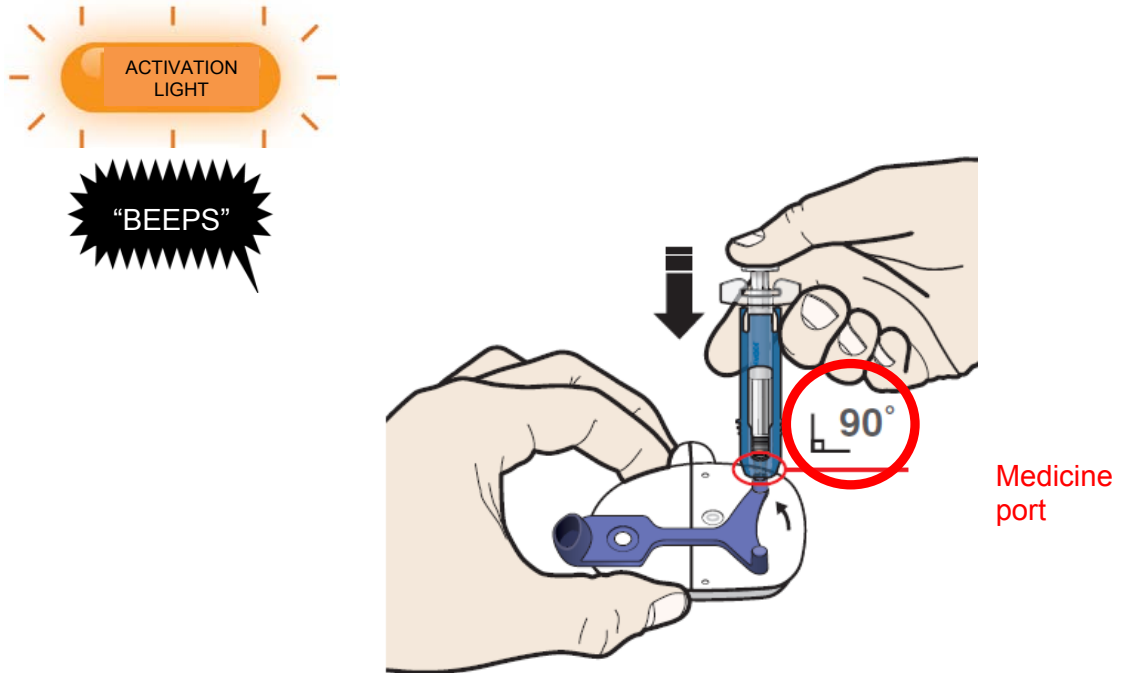
C Carefully remove gray needle cap straight out from the syringe and away from your body. Check syringe, and remove air bubbles.



! Take care to expel air only and not medicine. A small droplet at the tip of the needle during air purging is normal.

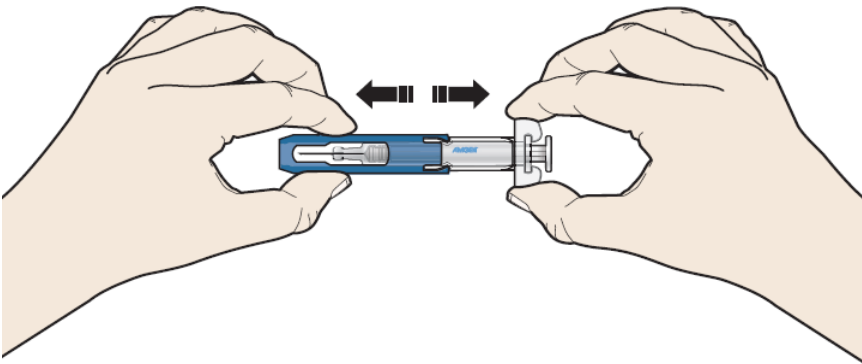
⊘ DO NOT recap syringe.

- D** Using blue needle cover, to avoid bending the needle and spilling medicine, insert syringe needle at 90 degrees all the way into medicine port. Slowly empty the entire syringe contents. Remove empty syringe from the medicine port. When beeping sounds and the status light flashes amber, the 3-minute countdown begins.

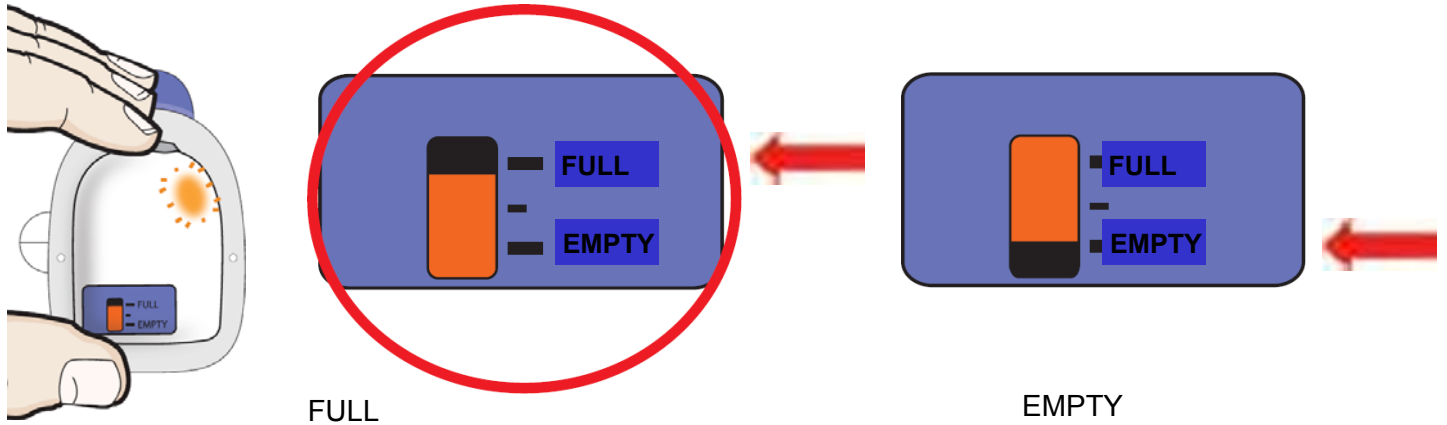


- ⊘ DO NOT insert needle into medicine port at other than a 90 degree angle
- ⊘ DO NOT insert needle more than once.
- ⊘ DO NOT remove blue needle cover before filling the On-body Injector.

- E** Pull needle safety guard down until it clicks and covers needle. Dispose of empty syringe in a sharps container.



F Check to see if the On-body Injector is full.



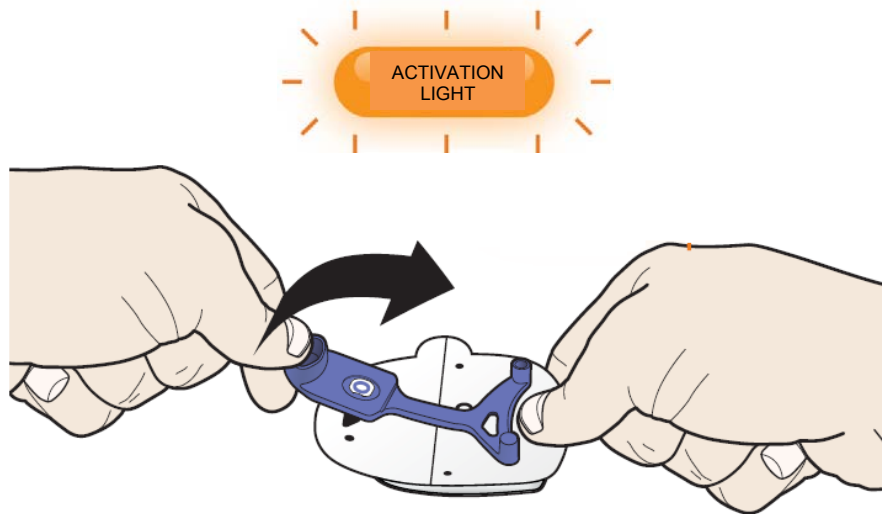
You should see:

- amber status light flashing.
- 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.

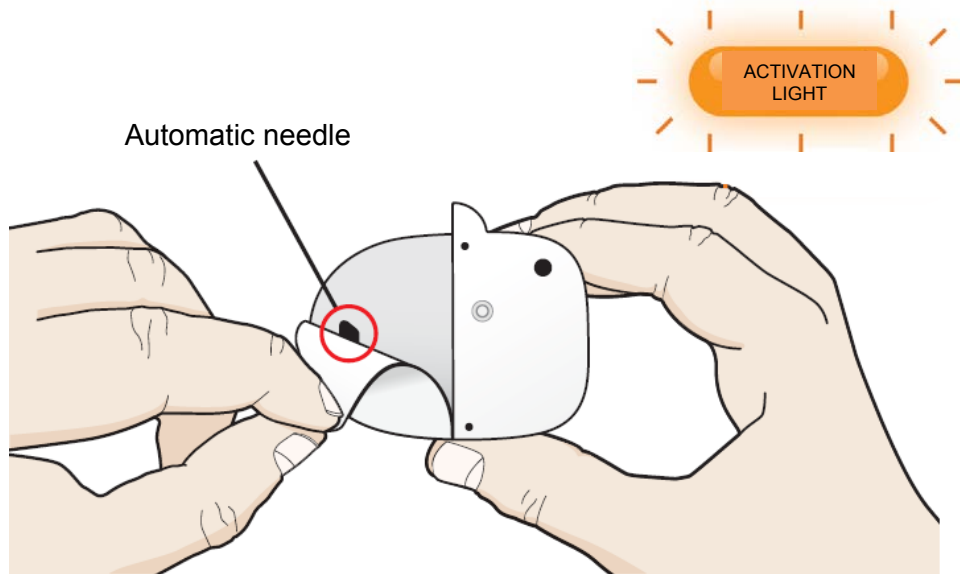
Step 3: Apply

A Firmly lift and remove blue needle cover away from On-body Injector.



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

B To expose the adhesive pad, use both pull tabs, one at a time, to peel the two pieces of white adhesive backing away from On-body Injector.

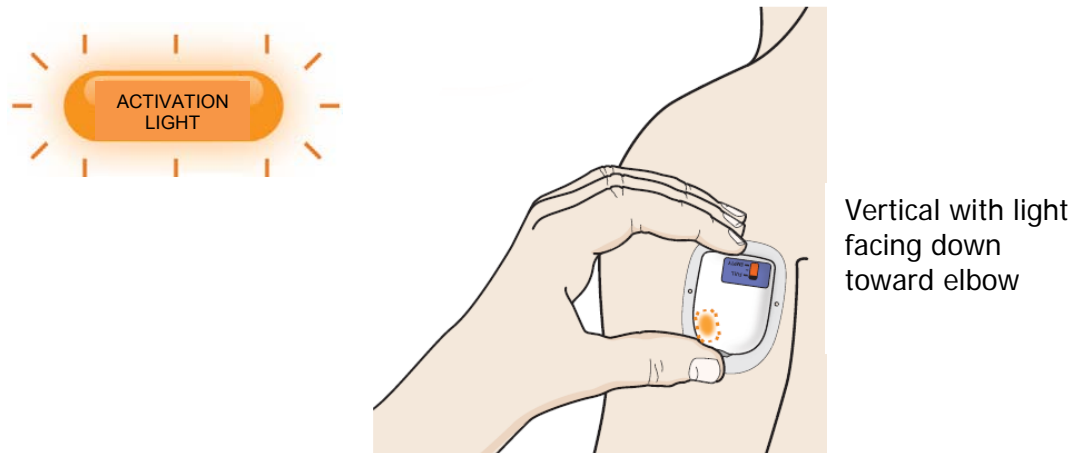


- ⊘ DO NOT touch or contaminate automatic needle area.
- ⊘ DO NOT pull off adhesive pad or fold it.
- ⊘ DO NOT use if the needle or cannula is extended past the adhesive or is extended before the On-body Injector is placed on patient.

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

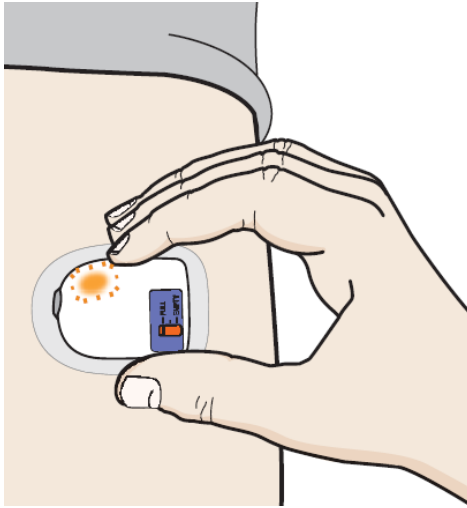
C Apply On-body Injector securely to patient with entire On-body Injector visible so it can be monitored by patient or caregiver. Before cannula deploys, place On-body Injector on your selected site, and run your finger around entire adhesive pad to make sure it is securely attached.

Back of Upper Arm



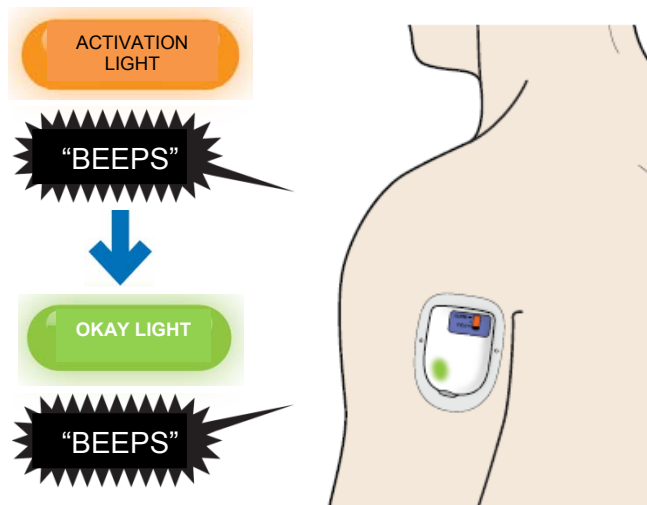
Abdomen

Horizontal
with light
facing
navel



STOP! Do not worry if On-body Injector is quiet. When 3 minutes are up, On-body Injector will beep.

- D Beeping will tell you the cannula is about to insert. You may hear a series of clicks. This is okay.
A long beep will sound, and the status light will turn to green. This means the cannula insertion is complete.**



If the adhesive folds over near the cannula window or there are folds anywhere that prevent the On-body Injector from securely adhering, remove the On-body Injector. Start again with a new Neulasta Onpro kit and call Amgen at 1-800-772-6436.

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.**

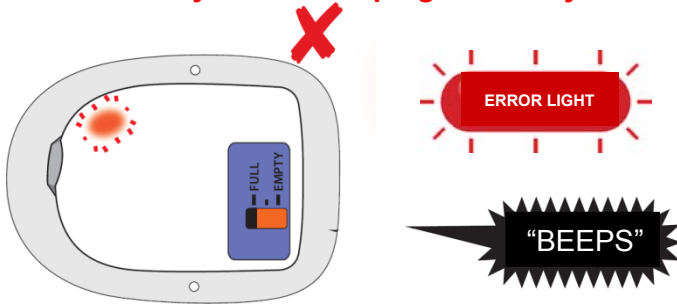
Review each step in the patient instructions with your patient. Give your patient the instructions, and reference guide to take home.

Before your patient goes home, make sure your 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, beeps will signal that the dose delivery will begin in 2 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.
- When the dose delivery is complete, the patient or caregiver will hear a beep and see a solid green light.
- 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 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.

Attention!

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

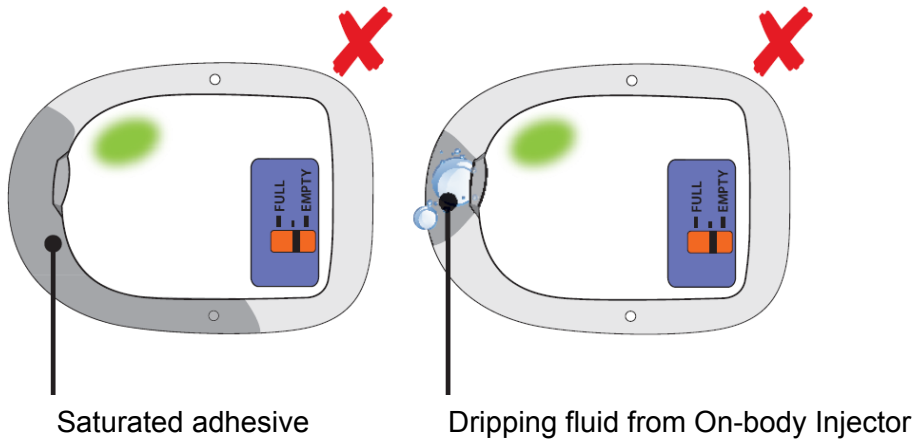


If at any time the On-body Injector beeps continuously for 5 minutes, and the status light is flashing red, take the On-body Injector off of the patient.

- ⊘ DO NOT apply On-body Injector to patient if red error light is on.
- ⊘ DO NOT leave On-body Injector on 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 the adhesive becomes saturated with fluid or the On-body Injector is dripping.



If patient reports an On-body Injector leak, they might not have received 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

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www.neulasta.com 1-800-772-6436 (1-800-77-AMGEN)

Issued: 4/2016

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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:

- MRI
- X-ray
- CT-Scan
- Ultrasound
- 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)
	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
	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.

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	±6kV Contact ±8kV Air	6kV Contact ±8kV 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	3A/m	3A/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)=3V/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>$D=(3.5/V1)(\sqrt{P})$ 150 kHz to 80 MHz</p> <p>$D=(3.5/E1)(\sqrt{P})$ 80 to 800 MHz</p> <p>$D=(7/E1)(\sqrt{P})$ 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 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

{SIDE 1 Information}

Patient Instructions for Use

On-body Injector for Neulasta Description

The On-body Injector for Neulasta is intended for delivery of Neulasta. The On-body Injector is small, for one-time use, lightweight, battery-powered, and waterproof up to 8 feet for 1 hour. 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 informs you of its status with sounds and lights.

The On-body Injector contains electronic components as well as: a plastic housing, acrylic adhesive, batteries, a cannula introducer (needle) and a cannula. The On-body Injector is approximately: 2.4 in long, 1.6 in wide, 0.7 in height (62 mm long, 41 mm wide, 17 mm height).

Warnings

- **Before** you receive Neulasta, tell your healthcare provider if you:
 - Have sickle cell trait or sickle cell disease
 - Have problems with your kidneys
 - Have any other medical 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 breastmilk.
- **DO NOT** take Neulasta if you have had a serious allergic reaction to pegfilgrastim (Neulasta®) or to filgrastim (Neupogen®).
- 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.
- The On-body Injector is for adult patients only.
- 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>
- 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 immediately 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 (glomerulonephritis): puffiness in your face or ankles, blood in your urine or brown colored urine or you notice you urinate less than usual.
- Keep children away from the used On-body Injector.
- 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.
- **DO NOT** expose the On-body Injector to the following because the On-body Injector may be damaged and you could be injured:
 - MRI
 - X-ray
 - CT-Scan
 - Ultrasound
 - Oxygen rich environments, such as hyperbaric chambers
- **DO NOT** use 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 the On-body Injector performance.
- **DO NOT** peel off or disturb the On-body Injector's adhesive before your full dose is complete. This may result in a missed or incomplete dose of Neulasta.

Precautions

Environmental:

- Keep the On-body Injector dry for the last 3 hours prior to the dose delivery start.
- Only expose the On-body Injector to temperatures between 41°F and 104°F (5°C-40°C).
- 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.

Activity Related:

- Avoid getting body lotions, creams, oils or cleaning agents near the On-body Injector as these products may loosen the adhesive.
- Be careful not to bump the On-body Injector or knock the On-body Injector off your body.

Biohazard:

Properly dispose of the On-body Injector:

- The On-body Injector contains batteries, electronics, and a needle. The On-body Injector should be placed in a sharps disposal container, with an appropriate sized opening, regardless of whether or not the needle is exposed. Follow instructions provided by your healthcare provider or by state or local laws.
- To participate in Amgen's voluntary disposal program, please call 1-844-MYNEULASTA (1-844-696-3852) or visit www.neulasta.com to enroll.
- 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>.

Risks

You can avoid most risks related to using the On-body Injector for Neulasta by following the Patient Instructions for Use. Immediately call your healthcare provider if any of the following occur:

- The adhesive becomes noticeably wet (saturated) with fluid, or you see dripping
- If the On-body Injector fill indicator is not at the empty position after On-body Injector removal (You should see a black line next to the EMPTY indicator.)
- The On-body Injector comes off from the skin before or during a dose delivery (**DO NOT re-apply it.**)
- Status light is flashing red
- Allergic reaction
- Persistent or worsening redness or tenderness at the application site (may be a sign of infection)
- Severe pain or skin discomfort around your On-body Injector
- Any concern about your medication
- If the needle is exposed after On-body Injector removal

{SIDE 2 Information}

On-body Injector for Neulasta® (nu-las-tah) (pegfilgrastim) Injection Patient Instructions for Use

Dose Delivery Information

Your On-body Injector was applied:

Day	Time	AM / PM
-----	------	---------

Your dose delivery will start around:

Day	Time	AM / PM
-----	------	---------

Name of Healthcare Provider:

Last, First

Healthcare Provider contact number:

On-body Injector lot number:

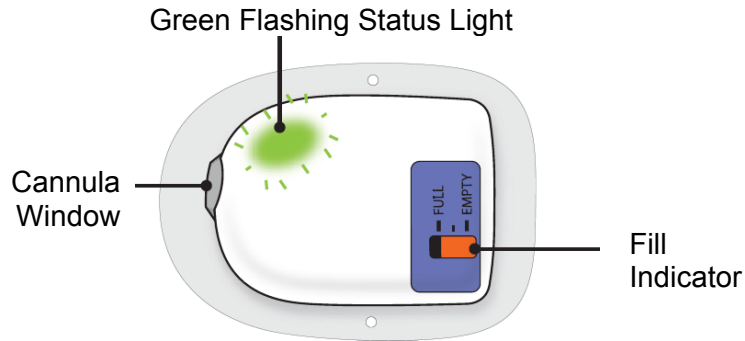
Important Information

- !** This On-body Injector delivers Neulasta with an under-the-skin (subcutaneous) injection. See Patient Information for medicine information.
- !** If you have concerns about your medication, call your healthcare provider immediately. 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 appropriately monitor the On-body Injector for Neulasta during the approximately 45 minute Neulasta delivery and for an hour after the delivery.
- !** Avoid activities and places that may interfere with monitoring during the dosing of Neulasta administered by the On-body Injector (hours 26-29).

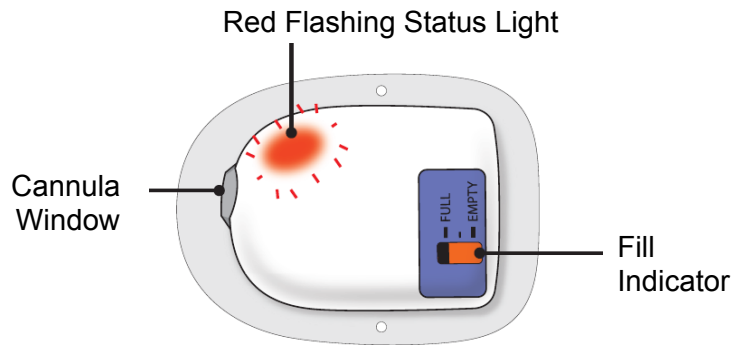
- ❗ If you have an allergic reaction during the delivery of Neulasta, remove the On-body Injector by grabbing the edge of the adhesive pad and peeling off the On-body Injector. Get emergency medical help right away.
 - ❗ The On-body Injector should be applied to intact, non-irritated skin on the stomach area (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.
 - ❗ Call your healthcare provider immediately if you have severe pain or skin discomfort around your On-body Injector.
 - ❗ Be careful not to bump the On-body Injector or knock the On-body Injector off your body.
 - ❗ Avoid getting body lotions, creams, oils or cleaning agents near the On-body Injector as these products may loosen the adhesive.
 - ❗ Keep the On-body Injector dry for the last 3 hours prior to the dose delivery start.
 - ❗ Only expose the On-body Injector to temperatures between 41°F and 104°F (5°C and 40°C).
 - ❗ After On-body Injector removal, properly dispose of it in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
 - ❗ 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.
- ⊘ **DO NOT:**
- ✗ use hot tubs, whirlpools, or saunas while wearing the On-body Injector. This may affect your medicine.
 - ✗ 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.
 - ✗ sleep on the On-body Injector or apply pressure during wear, especially during dose delivery. This may affect On-body Injector performance.
 - ✗ 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.

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.

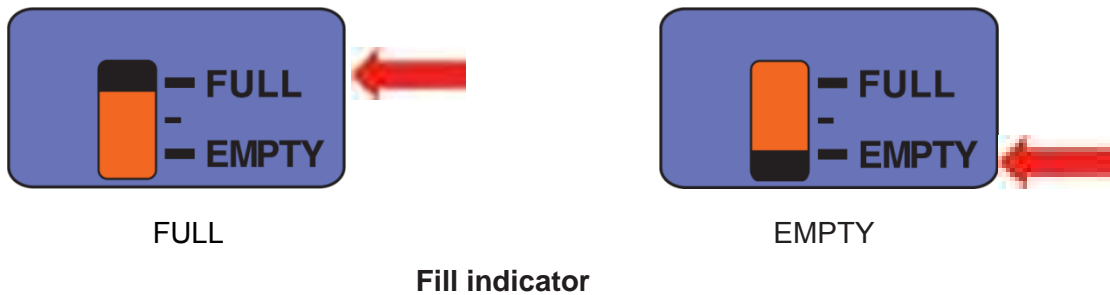
Guide to Parts for On-body Injector for Neulasta



The On-body Injector is working properly.

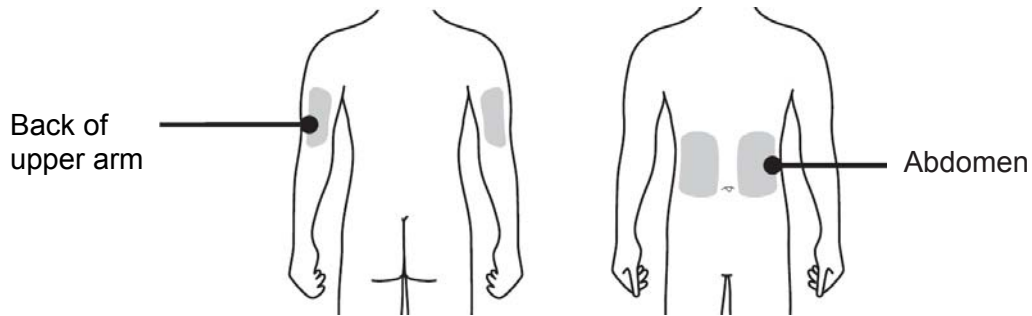


If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately.



After your dose delivery is complete, check to see if the black line on your On-body Injector fill indicator is at empty.

On-body Injector Placement

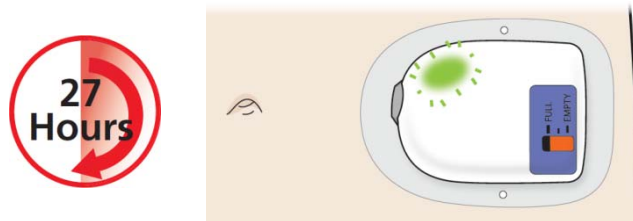


Step 1: Monitor On-body Injector

- A Check your status light occasionally for approximately 27 hours. Since it flashes slowly, watch for at least 10 seconds. If the status light is flashing green, it is okay.**
- !** If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately.

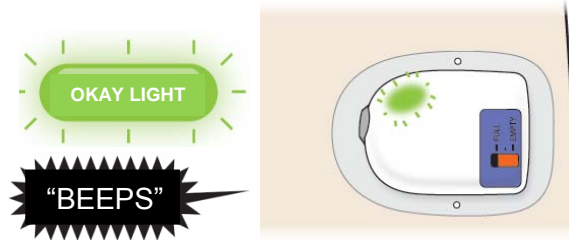


If the On-body Injector for Neulasta was placed on the back of your arm, a caregiver must be available to monitor the status of the On-body Injector.



B After approximately 27 hours, your On-body Injector will beep to let you know your dose delivery will begin in 2 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.

! If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately.

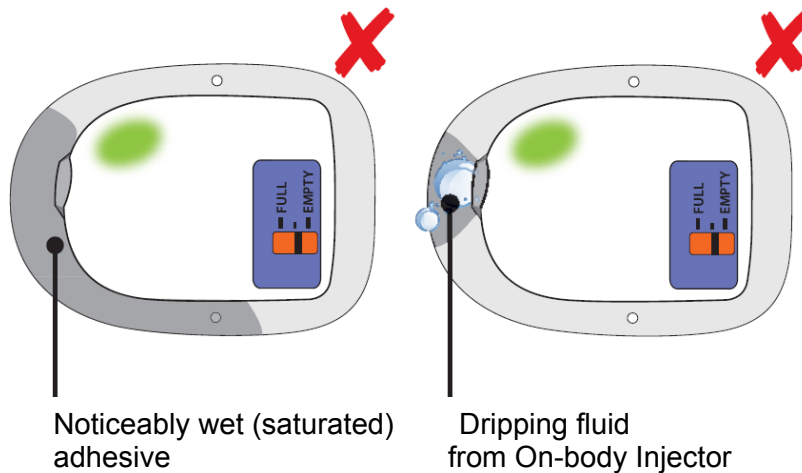


⊘ DO NOT remove the On-body Injector before the dose delivery is complete.

Step 2: Monitor Dose Delivery



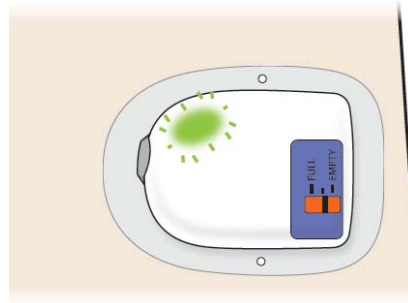
For the next 45 minutes, monitor your On-body Injector frequently for leaks during dose delivery. If the On-body Injector was placed on the back of your arm, a caregiver must be available to monitor your On-body Injector.



If the adhesive becomes noticeably wet (saturated) with fluid, or you see dripping, call your healthcare provider immediately.

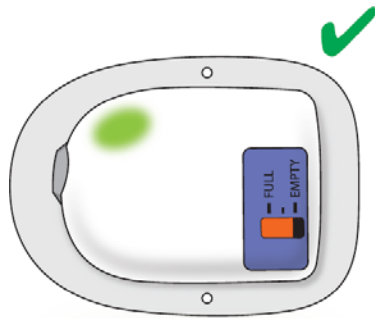
A Your dose delivery will take around 45 minutes to complete.

- You may hear a series of clicks. This is okay.
- A beep will sound when the dose delivery is complete.

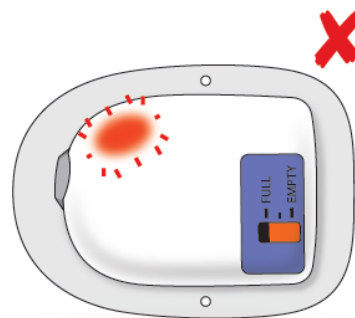


Step 3: Remove On-body Injector When Dose Delivery Is Complete

A When beeping starts, check to see the color of the status light.



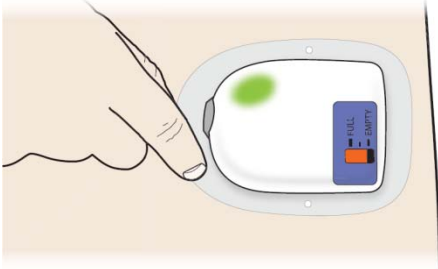
Check to see if the status light is SOLID GREEN or has switched off. This means the dose is complete. Remember, **any time you see a leak, call your healthcare provider immediately.** If the dose is complete, go to the next step.



If you see the status light is flashing red, your On-body Injector is not functioning properly. Call your healthcare provider immediately, as you may not have received a full dose.

B Grab the edge of the adhesive pad. Slowly peel off the On-body Injector.

- If medicine has leaked or the adhesive is noticeably wet (saturated), call your healthcare provider immediately as you may not have received your full dose.
- Remove any extra adhesive using soap and water.



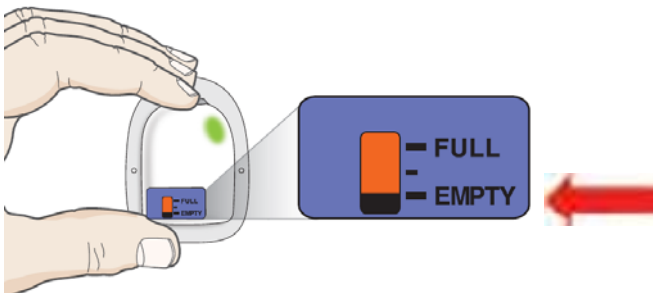
⊘ **DO NOT** grasp the On-body Injector itself to try to pull it off of your body.

Step 4: Finish



Check to see if your On-body Injector is empty.

- You should see a black line next to the EMPTY indicator. If the On-body Injector is not empty, call your healthcare provider immediately.



- Check your status light again. Watch for at least 10 seconds. If the status light is solid green or it has switched off, it is okay.
- If you hear beeping, or when you check the status light and it is flashing red, call your healthcare provider immediately.

! After On-body Injector removal, place the On-body Injector in a sharps disposal container whether the needle is exposed or not. If the needle is exposed, call your healthcare provider immediately.

A Record the end state of your On-body Injector.

- Mark the box of the description that represents your On-body Injector after it has been used.

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 immediately.

Status light is red, call your healthcare provider immediately.

B Properly dispose of the On-body Injector.

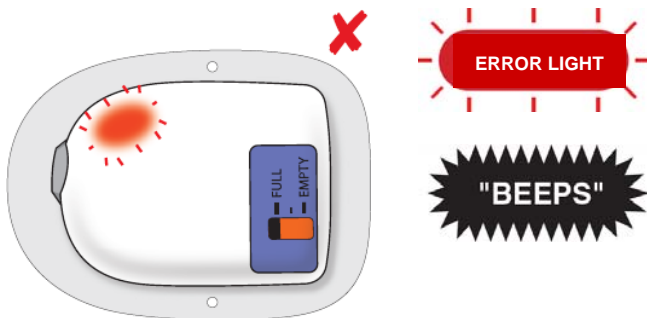
- The On-body Injector contains batteries, electronics, and a needle. Dispose of it in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
- To participate in Amgen's voluntary disposal program, please call 1-844-MYNEULASTA (1-844-696-3852) or visit www.neulasta.com to enroll. 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>.

! Keep children away from the used On-body Injector.

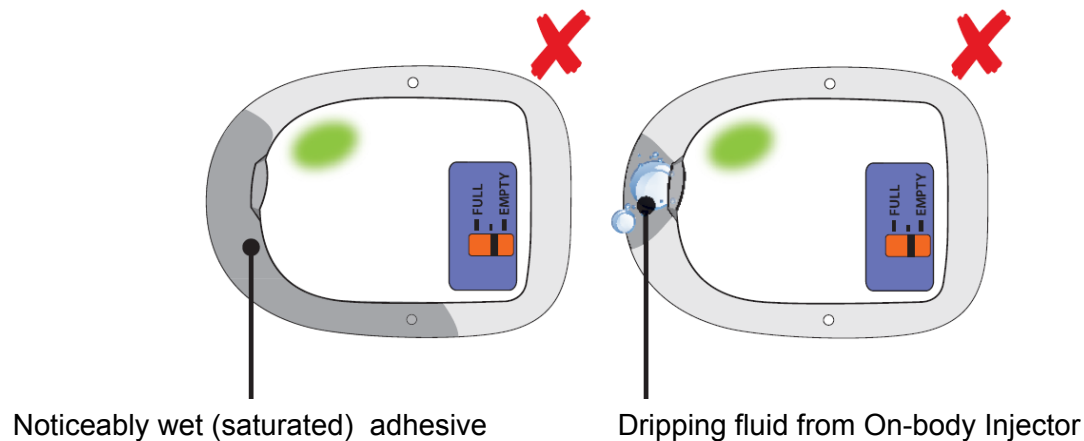
Attention!

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. Call your healthcare provider immediately.



What to do if the On-body Injector adhesive becomes noticeably wet (saturated) with fluid, or you see dripping.



- !** If the adhesive becomes saturated with fluid, or you see dripping, your medicine may have leaked out.
- !** Even with a leak, the status light may remain green and the fill indicator may be at EMPTY.
- !** Call your healthcare provider immediately as you may not have received your full dose.

Note: It is normal to see a few drops of fluid at the application site, but not normal to see a noticeably wet (saturated) adhesive.

What do I do if the On-body Injector comes off before the full dose is delivered?

Call your healthcare provider immediately if the On-body Injector at any time comes away from your skin before your full dose delivery, **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 immediately if you experience persistent or worsening redness or tenderness at the application site, as this can be a sign of infection.



Neulasta® (pegfilgrastim)

Manufactured by:

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

Patent: <http://pat.amgen.com/neulasta/>

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1-844-MYNEULASTA (1-844-696-3852) Issued: 11/2015 v4