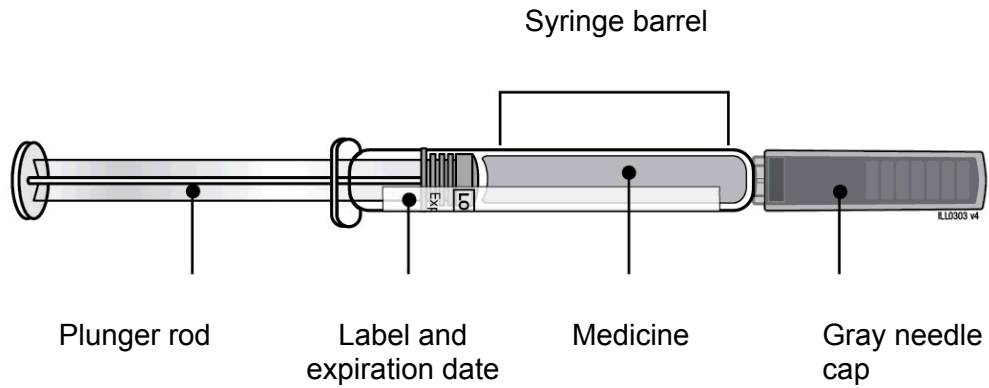


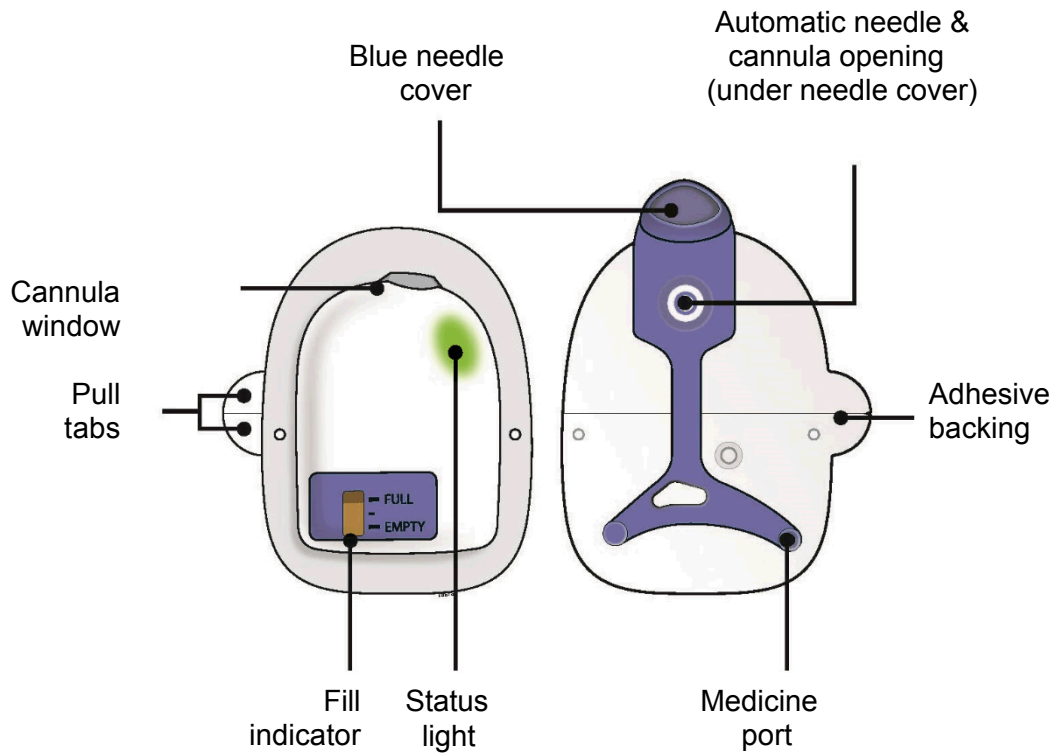
Neulasta® (pegfilgrastim) Onpro® kit Healthcare Provider Instructions for Use

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 other materials to hold it 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 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.

Step 1: Prepare

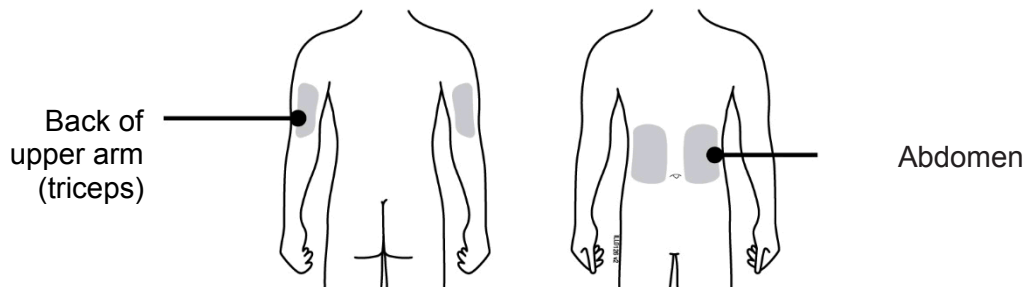
A Remove Neulasta Onpro kit from the refrigerator.

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.
-

STOP



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:

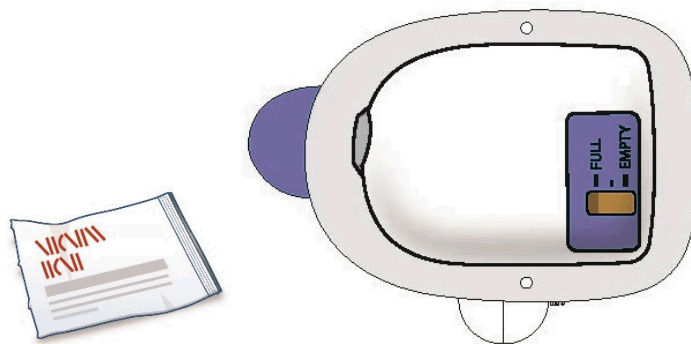
1. Completely empty syringe contents into the medicine port.
2. Remove the syringe from the port and dispose.
3. Remove the blue needle cover from back of the on-body injector.
4. Peel away the two pieces of white adhesive backing from the back of the on-body injector.
5. Attach the on-body injector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

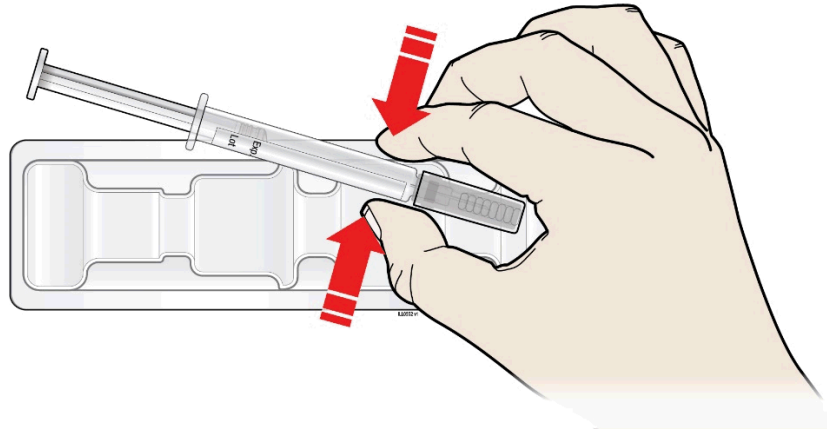
C Clean an area on the injection site larger than the on-body injector adhesive backing.

- Thoroughly clean the site with alcohol to enhance on-body injector 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**.
- **Do not** touch this area again before attaching the on-body injector.



Step 2: Get Ready

A Remove Neulasta prefilled syringe from tray.

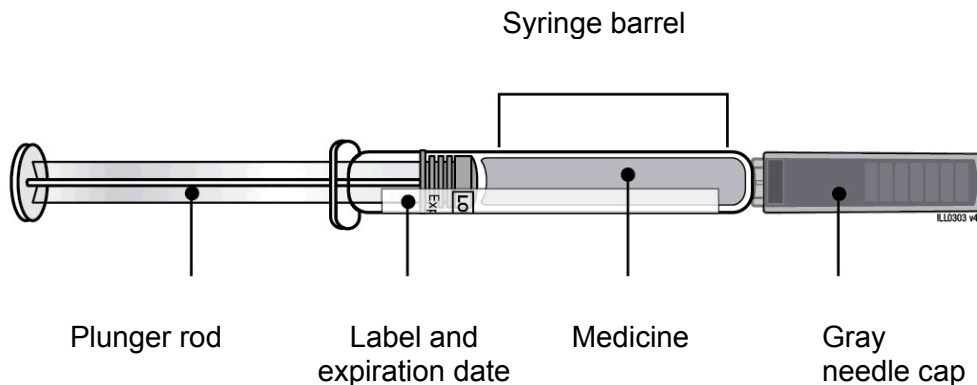


Grab Here

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.

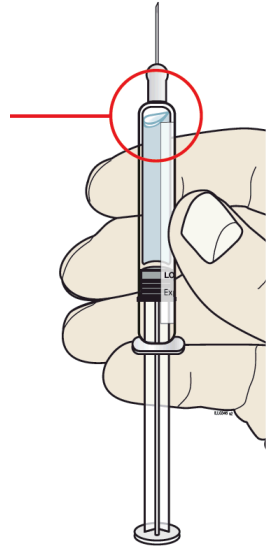
In all the above cases, start again with a new kit. Call Amgen at 1-800-772-6436.

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

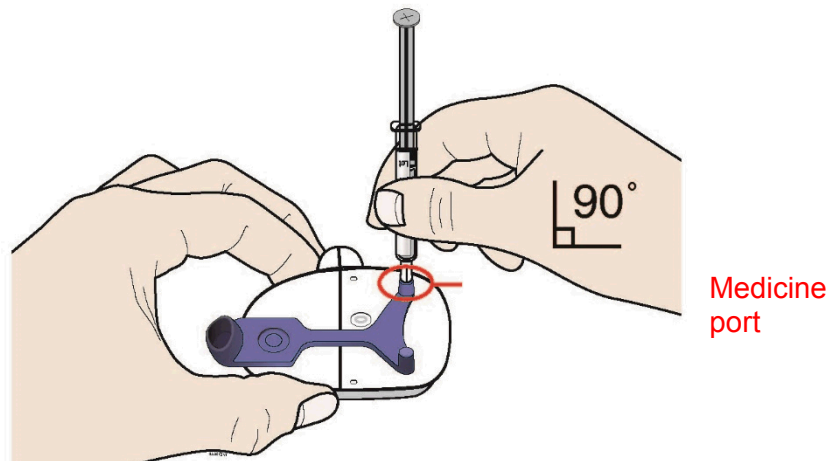
C Remove air bubbles in prefilled syringe.

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.



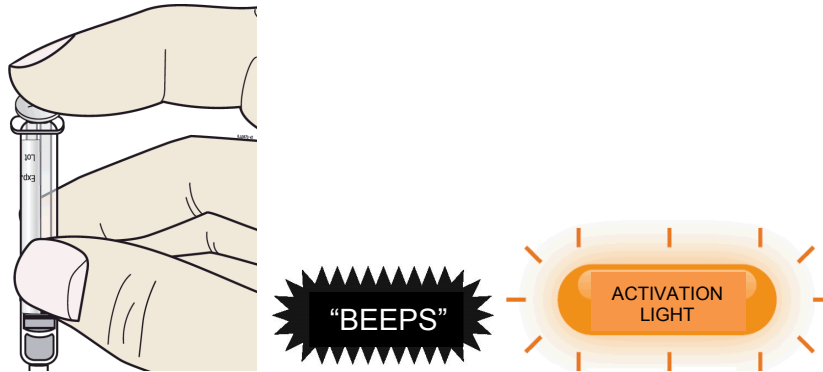
D Center the needle directly over the medicine port at a 90 degree angle. Insert all the way into the port, avoiding sides.



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

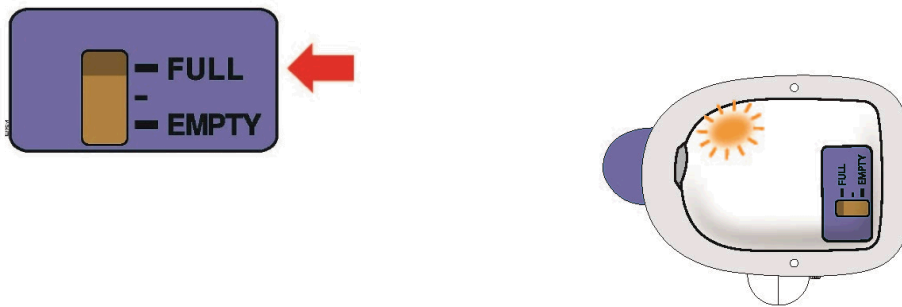
- **Do not** insert the needle more than once.
- **Do not** bend the needle. Avoid spilling the medicine.
- **Do not** remove the blue needle cover before filling the on-body injector.

- 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.

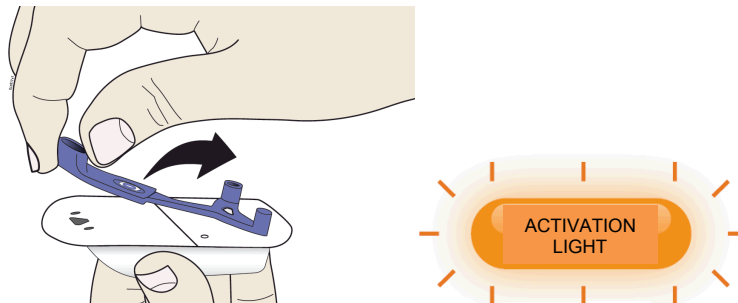
- F** Check to see if the on-body injector is full and the amber light is flashing.



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.

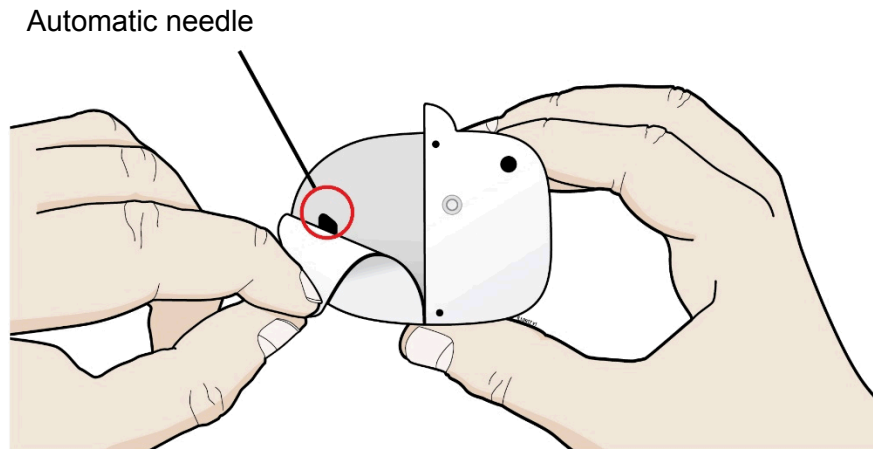
- G** Firmly lift and remove the blue needle cover away from the on-body injector.



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.



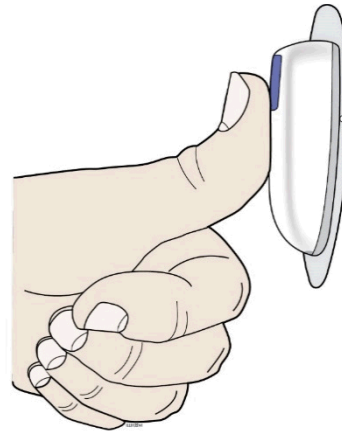
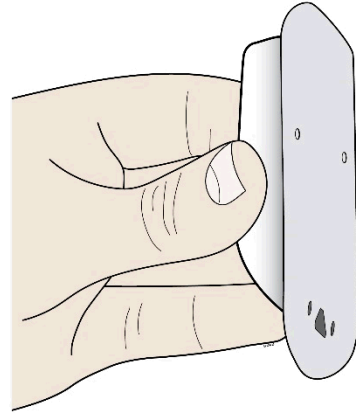
- **Do not** touch or contaminate the automatic needle area.
- **Do not** pull off the adhesive pad or fold it.
- **Do not** use if the needle or cannula is extended past the adhesive or is extended before the on-body injector is placed on the patient.
- **Do not place adhesive on skin that is damp.**

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.

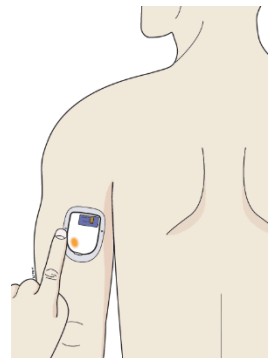
You now have time to carefully apply the on-body injector without folding or wrinkling the adhesive.

- **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.
- 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.

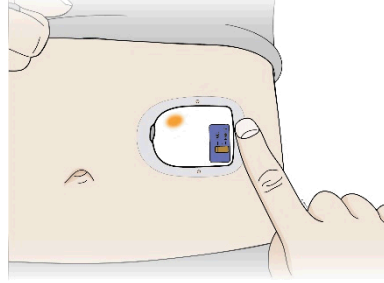


**Back of upper arm
(triceps)**

Vertical with the
light facing down
toward the elbow



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

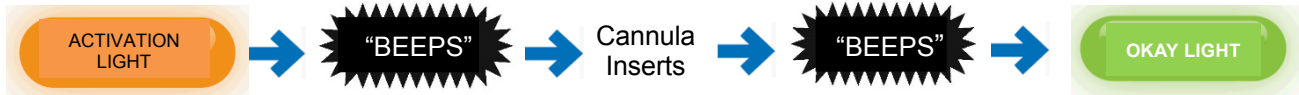


STOP



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.

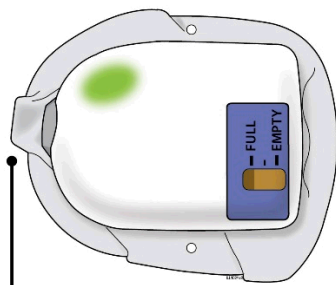


STOP

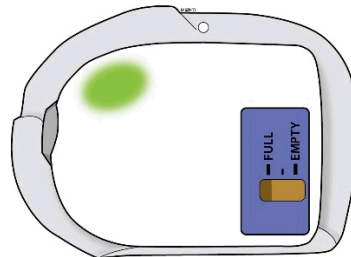


Check the quality of adhesion before sending the patient home.

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.

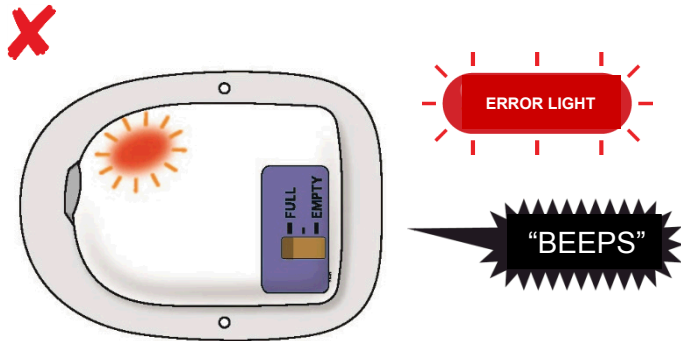
Before the patient goes home, make sure the patient understands:

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 other materials to hold it 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 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.



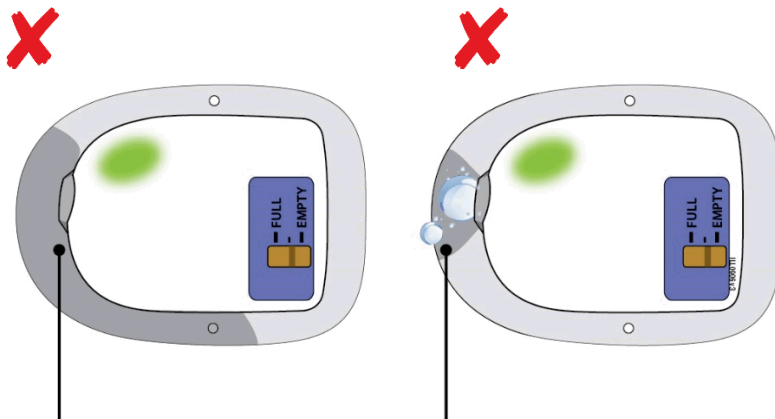
If at any time the on-body injector beeps continuously for five minutes, and the status light is flashing red, take the on-body injector off of the patient.

- **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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<http://www.neulasta.com/>
1-844-MYNEULASTA (1-844-696-3852)
Issued: 01/2020
V9

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)
	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	±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	Portable and mobile communications equipment should be separated from the on-body injector for Neulasta by no less than the distances calculated/listed below: $D = (3.5/V1)(\sqrt{P})$ 150 kHz to 80 MHz $D = (3.5/E1)(\sqrt{P})$ 80 to 800 MHz $D = (7/E1)(\sqrt{P})$ 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.

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

{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.

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.

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:

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

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 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 reapply 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:

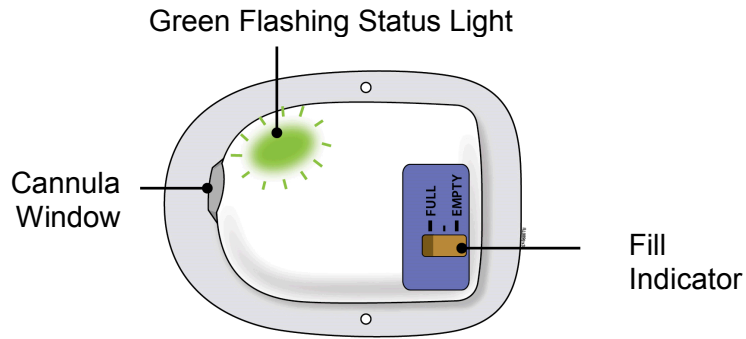
Important Information

- 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).

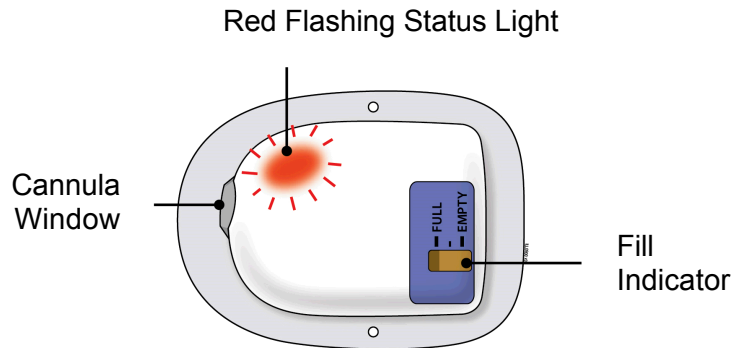
- If you have an allergic reaction during the delivery of Neulasta, remove the on-body injector by grabbing the edge of the adhesive pad and peeling off the on-body injector. Get emergency medical help right away.
- The on-body injector should be applied to intact, non-irritated skin on the stomach area (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.
- The on-body injector has a self-adhesive backing to attach it to the skin.
- **Do not** use other materials to hold it 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 or incomplete dose of Neulasta.
- If the on-body injector at any time comes away from your skin before your full dose delivery, **do not** reapply it. Call your healthcare provider immediately as you may need a replacement dose.
- 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).
- 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).
- 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 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 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.

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.

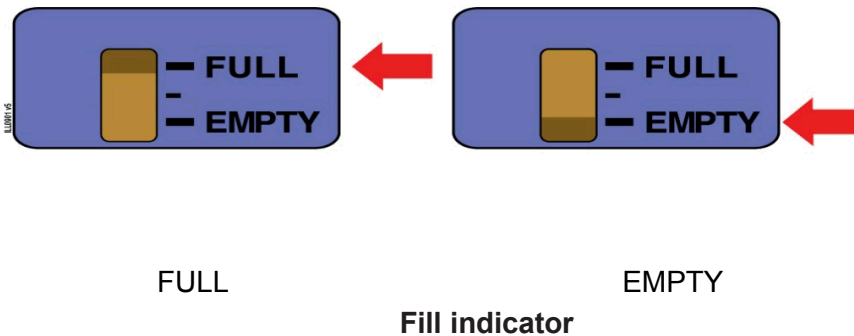
Guide to Parts for On-body Injector for Neulasta



The on-body injector is working properly.

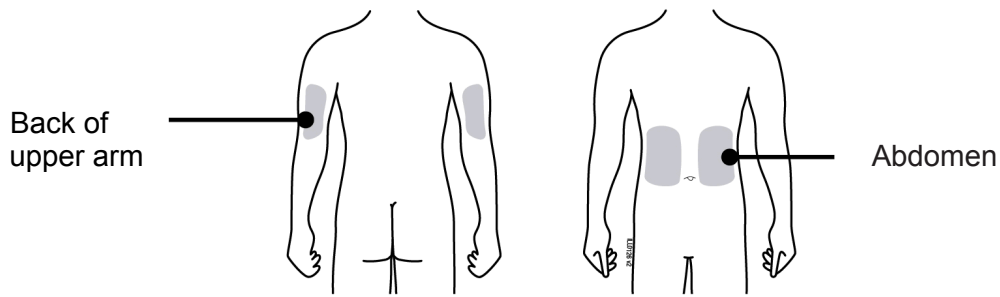


If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately, as you may need a replacement dose.



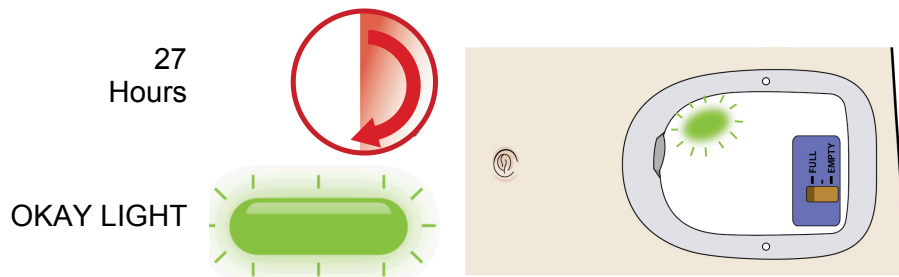
After your dose delivery is complete, check to see if the black line on your on-body injector fill indicator is at empty.

On-body Injector Placement



Step 1: Monitor On-body Injector

- A** 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.

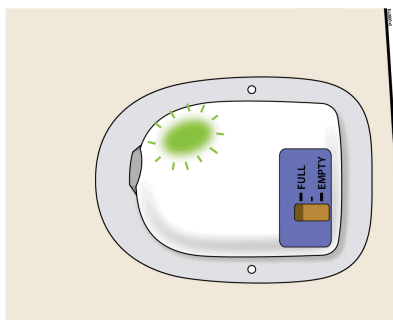


- If the on-body injector for Neulasta was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- Be careful not to bump the on-body injector, or knock the on-body injector off your body.
- If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately, as you may need a replacement dose.

B After about 27 hours, your on-body injector will produce a series of beeps to let you know your dose delivery is about to begin.

Do not remove the on-body injector at this time.

- Dose delivery will start and take about 45-minutes to complete. 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, as you may need a replacement dose.



Do not remove the on-body injector before the dose delivery is complete.

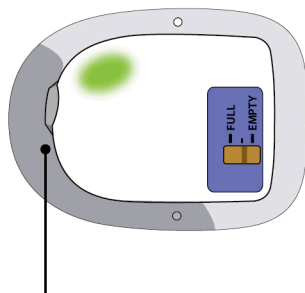
Step 2: Monitor Dose Delivery

STOP



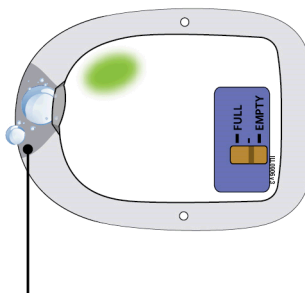
For the next 45-minutes, monitor your on-body injector frequently for leaks during dose delivery. If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor your on-body injector.

X Incorrect



Noticeably wet (saturated) adhesive

X Incorrect



Dripping fluid from on-body injector

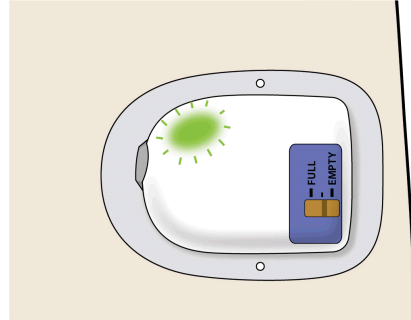
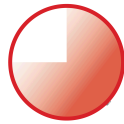
If the adhesive becomes noticeably wet (saturated) with fluid, or you see dripping, call your healthcare provider immediately, as you may need a replacement dose.

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

- During this time, the on-body injector will flash a fast green light.
- You may hear a series of clicks. This is okay.
- When dose delivery is complete, a long beep will sound and the status light will be solid green.

OKAY LIGHT

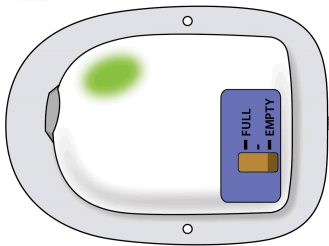
45
Minutes



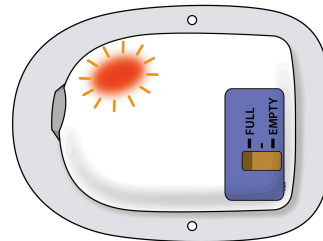
Step 3: Remove On-body Injector When Dose Delivery Is Complete

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

✓ Correct



✗ Incorrect

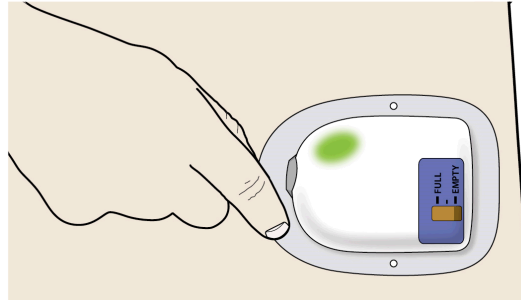


Check to see if the status light is SOLID GREEN or has switched off. This means the dose is complete. If the dose is complete, go to the next step.

If you see the status light is flashing red, your on-body injector is not functioning properly. Remember, **any time you see a status light flashing red, call your healthcare provider immediately, as you may need a replacement 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 and you may need a replacement 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.

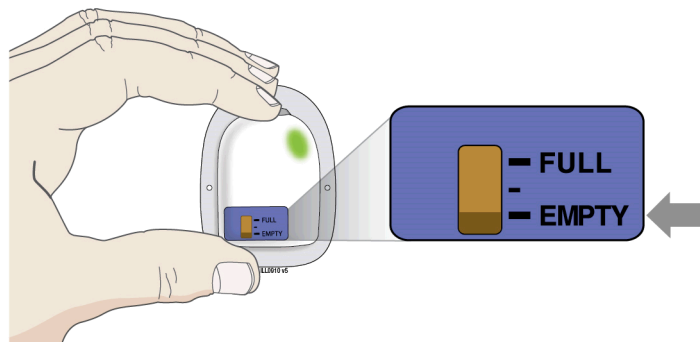
Step 4: Finish

STOP



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, as you may need a replacement dose.



- 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, as you may need a replacement dose.

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

B Properly dispose of the on-body injector.

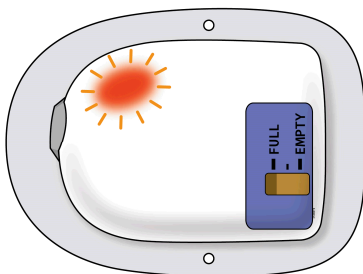
- The on-body injector contains batteries, electronics, and a needle. Dispose of it in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
- To participate in Amgen's voluntary disposal program, please call 1-844-MYNEULASTA (1-844-696-3852) or visit www.neulasta.com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

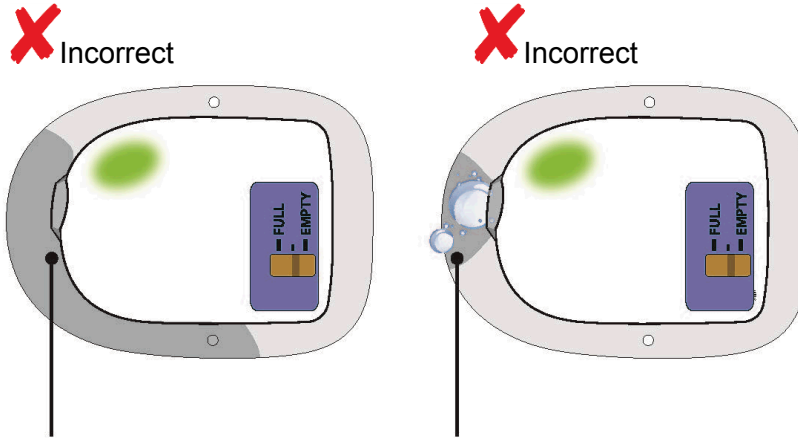
What to do if you hear beeping or when you look at the status light and it is flashing red.

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

X Incorrect



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



Noticeably wet (saturated) adhesive

Dripping fluid from on-body injector

- 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 and may need a replacement 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, 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 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/onpro/>

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<http://www.neulasta.com>

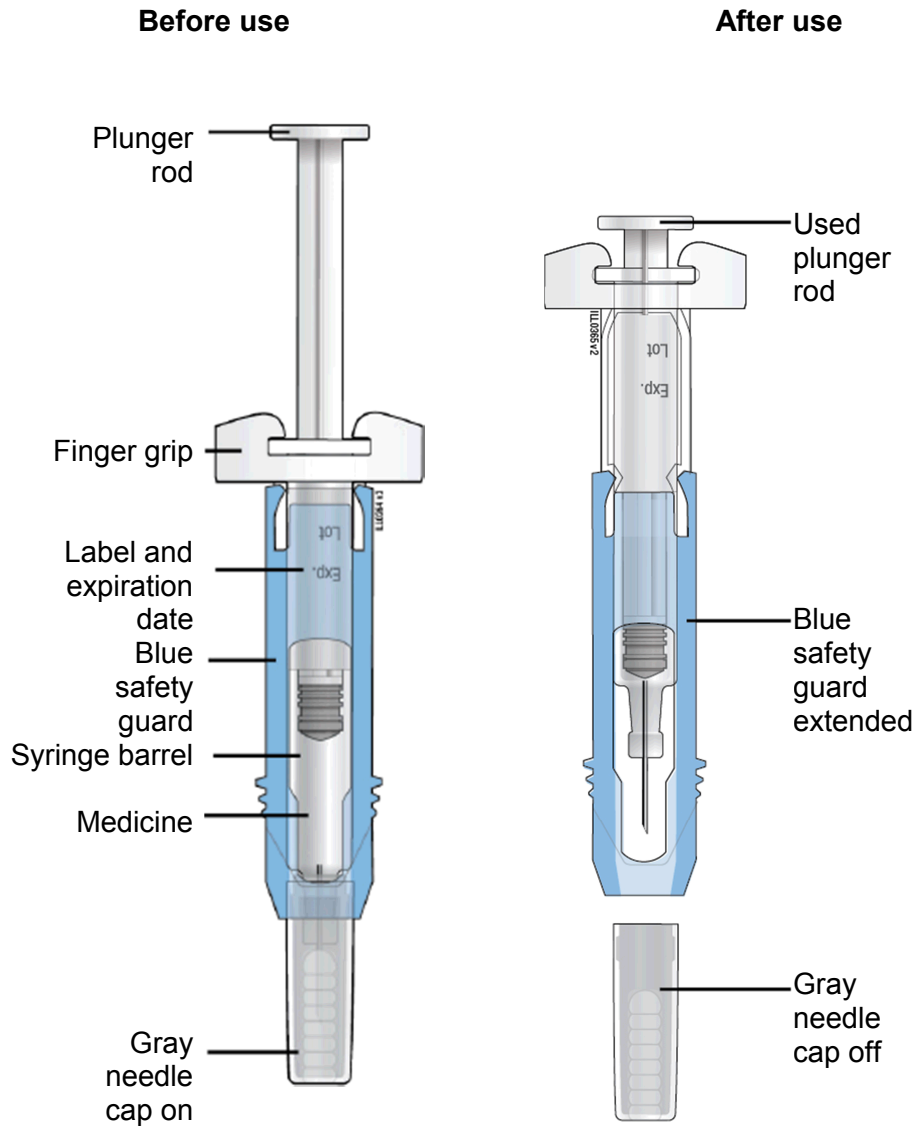
1-844-MYNEULASTA (1-844-696-3852)

Issued: 01/2020

v8

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

Guide to parts



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 to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- Take the prefilled syringe out of the refrigerator 30 minutes before use and allow it to reach room temperature 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 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.
- You should not inject a dose of Neulasta to children weighing less than 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

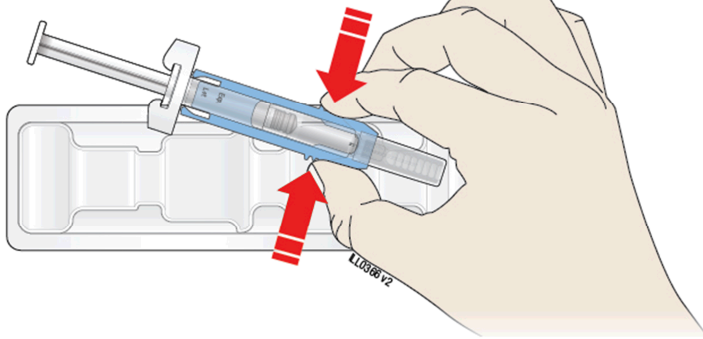
A Remove the prefilled syringe carton from the refrigerator.

Put the original carton with any unused prefilled syringes back in the refrigerator.

Remove the syringe tray from the carton. On a clean, well-lit surface, place the syringe tray at room temperature 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.

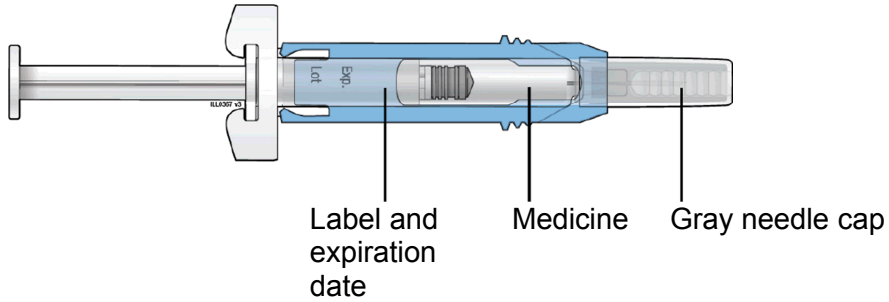


Grab Blue Safety Guard

For safety reasons:

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

B Inspect the medicine and prefilled syringe.



Make sure the medicine in the prefilled syringe is clear and colorless.

- **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.

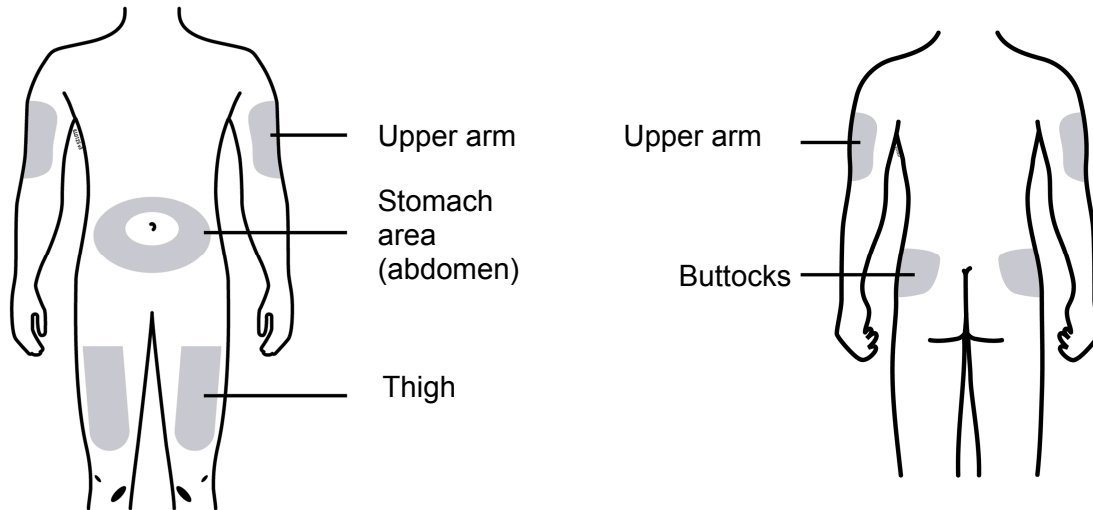
On a clean, well-lit work surface, place the:

- 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(s).



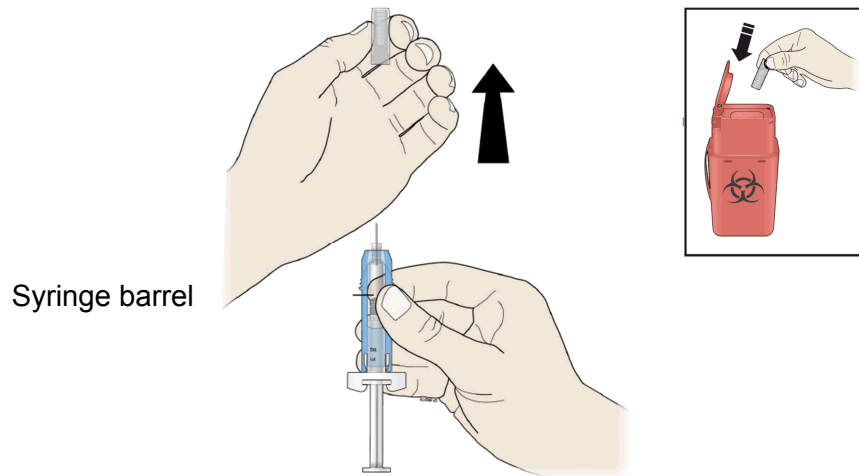
You can use:

- 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 the body.



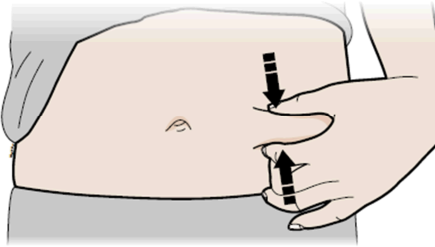
Syringe barrel

- **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.

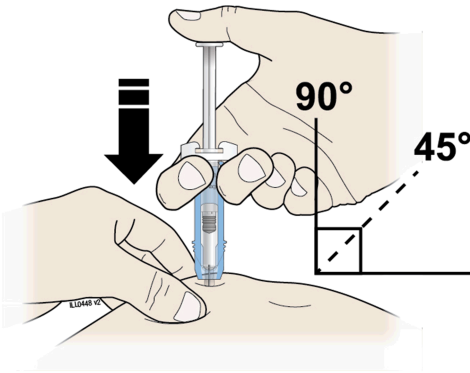
Step 3: Subcutaneous (under the skin) injection

F Pinch the injection site to create a firm surface.



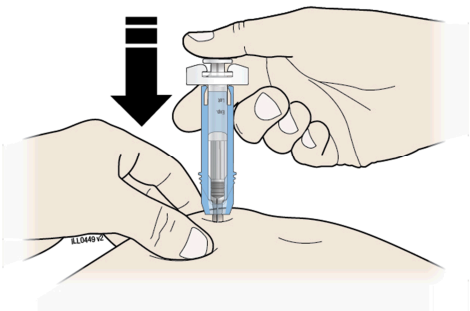
Important: Keep skin pinched while injecting.

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.

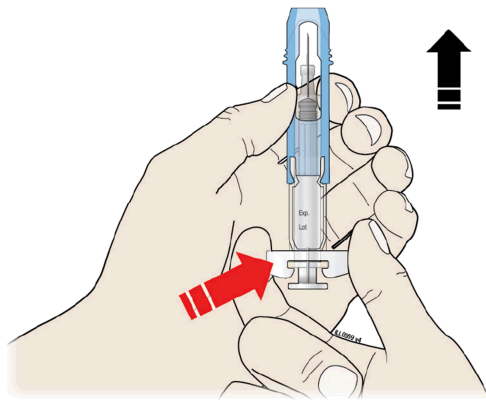


Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare provider right away.

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 a 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 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. 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.



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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