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

Your On-body injector was applied:

Day Time AM PM

Injection of your dose (delivery) will start around:

Day Time AM PM

Healthcare Provider name:

Healthcare Provider contact number:

On-body Injector lot number:

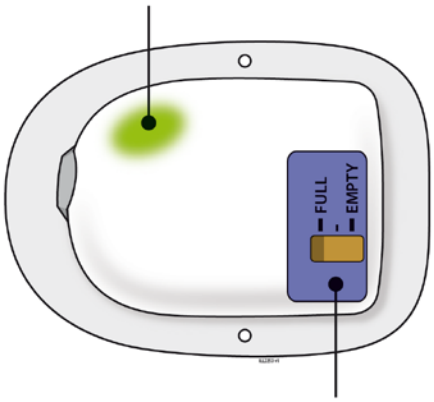
AMGEN®

Neulasta® (pegfilgrastim) Onpro® kit

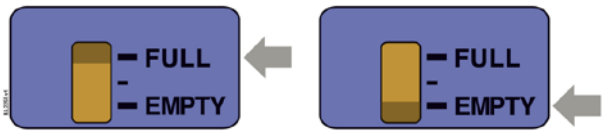
Get to Know Your On-body Injector

Parts and Signals

Status Light



Fill Indicator



Status Light

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

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

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

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

Contents

Important Information

On-body Injector for Neulasta Description

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

Warnings

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

Warnings (continued)

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

Important Information

Wearing the On-body Injector

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

Environmental Precautions

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

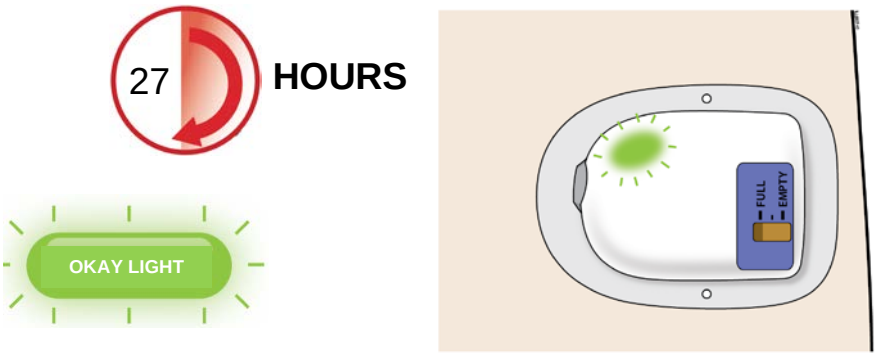
- Keep the on-body injector at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances. Failure to keep the on-body injector at least this recommended distance may interfere with operation and can lead to a missed or incomplete dose of Neulasta.
- Avoid activities and places that may interfere with monitoring during the dosing of Neulasta administered by the on-body injector. For example, **avoid** traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector for Neulasta (this includes the 45-minute dose delivery period plus an hour post-delivery).
- If you must travel by airplane **before** the approximately 45-minute dose delivery period with the on-body injector, avoid airport X-ray scans. Request a manual pat down instead. Use care during a manual pat down to help prevent the on-body injector from being accidentally removed. For more information go to: **http://www.tsa.gov/traveler-information/travelers-disabilities-and-medical-conditions**

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

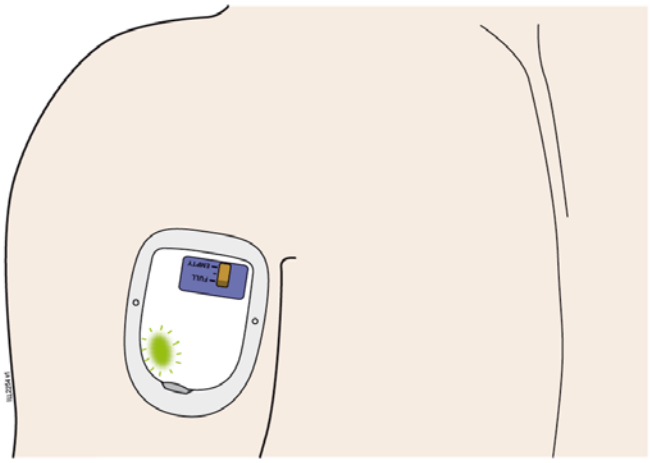
Step 1: Monitor On-body Injector

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

1



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



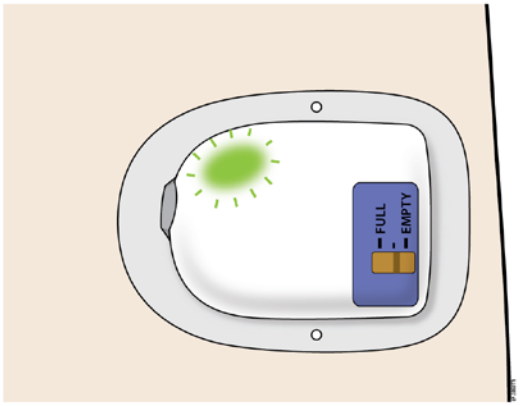
- If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- If the on-body injector comes away from your skin at any time, do not reapply it. Call your healthcare provider right away as you may need a replacement dose.
-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

Step 2: Observe Dose Delivery

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

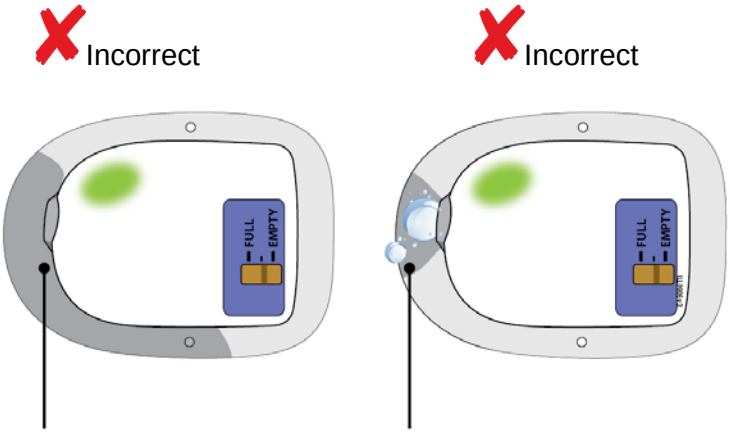
- Dose delivery will take around 45-minutes to complete. The on-body injector will flash a fast, green light.
- You may hear a series of clicks. This is okay.

2



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

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



Noticeably wet adhesive

Dripping fluid from on-body injector

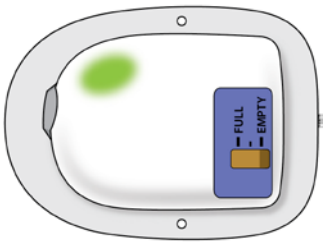
- If the adhesive is noticeably wet or dripping with medicine, call your healthcare provider right away, as you may need a replacement dose.

Step 3: Verify Dose Complete

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

3

Correct

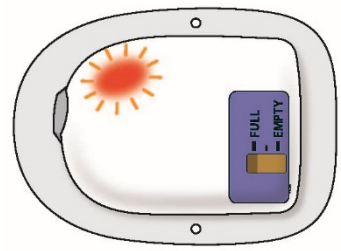


Check to see if the status light is **SOLID GREEN** or has switched off. This means the dose is complete.

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

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

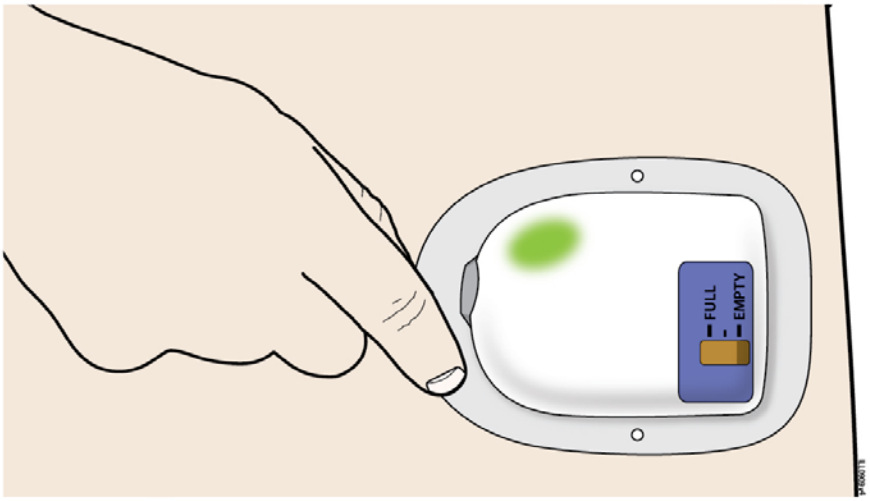
Incorrect



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

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

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



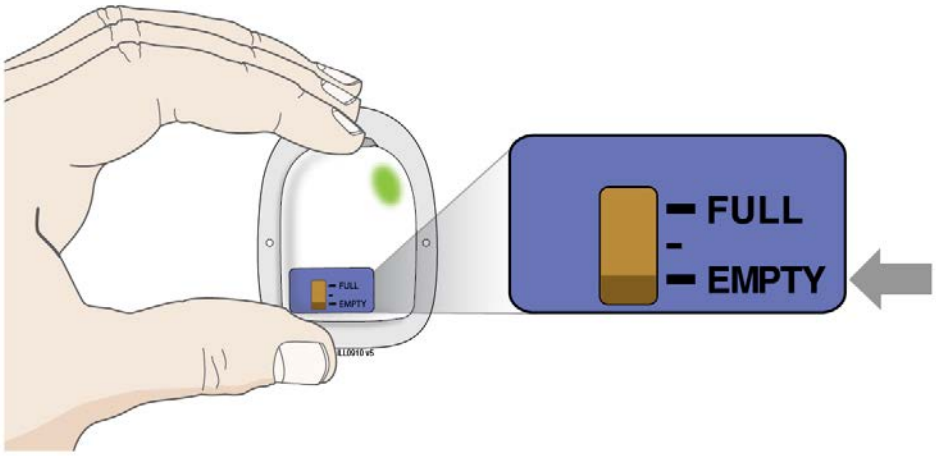
- **Do not** grasp the on-body injector itself to try to pull it off of your body.
- If medicine has leaked or the adhesive is noticeably wet or dripping, call your healthcare provider right away, as you may not have received your full dose and you may need a replacement dose.
- Remove any extra adhesive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

Step 4: Finish

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

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

4



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

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

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

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

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

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

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

FAQ

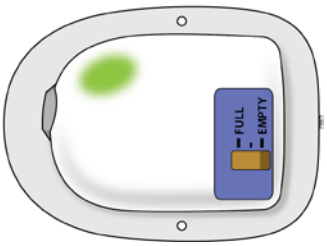
- **Keep the used on-body injector and sharps disposal container away from children.**

Frequently Asked Questions

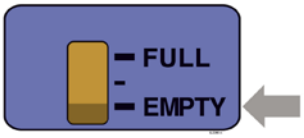
How do I know it is safe to remove the on-body injector?

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

✔ Correct



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

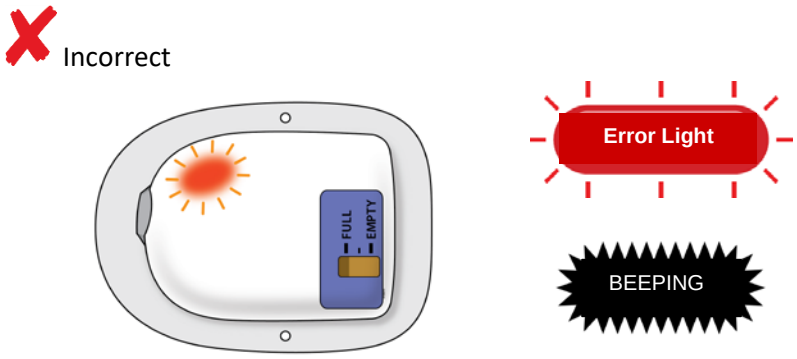


- The fill indicator should have a black line next to EMPTY

FAQ

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

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



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

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

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

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

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

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

Notes

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Neulasta® Onpro®

Patient INSTRUCTIONS FOR USE

Neulasta® (pegfilgrastim)

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

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

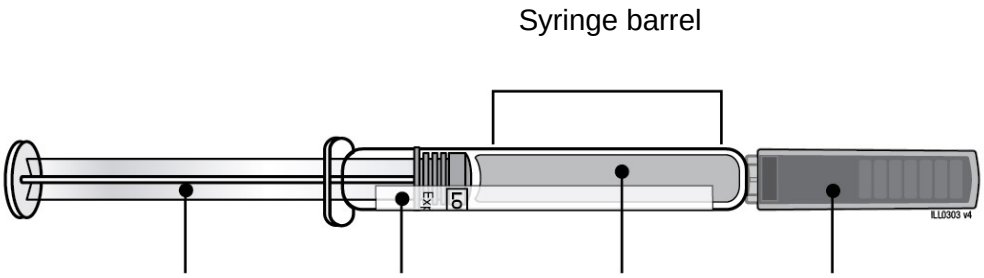
http://www.neulasta.com

1-844-MYNEULASTA (1-844-696-3852)
Revised: 11/2020
V9

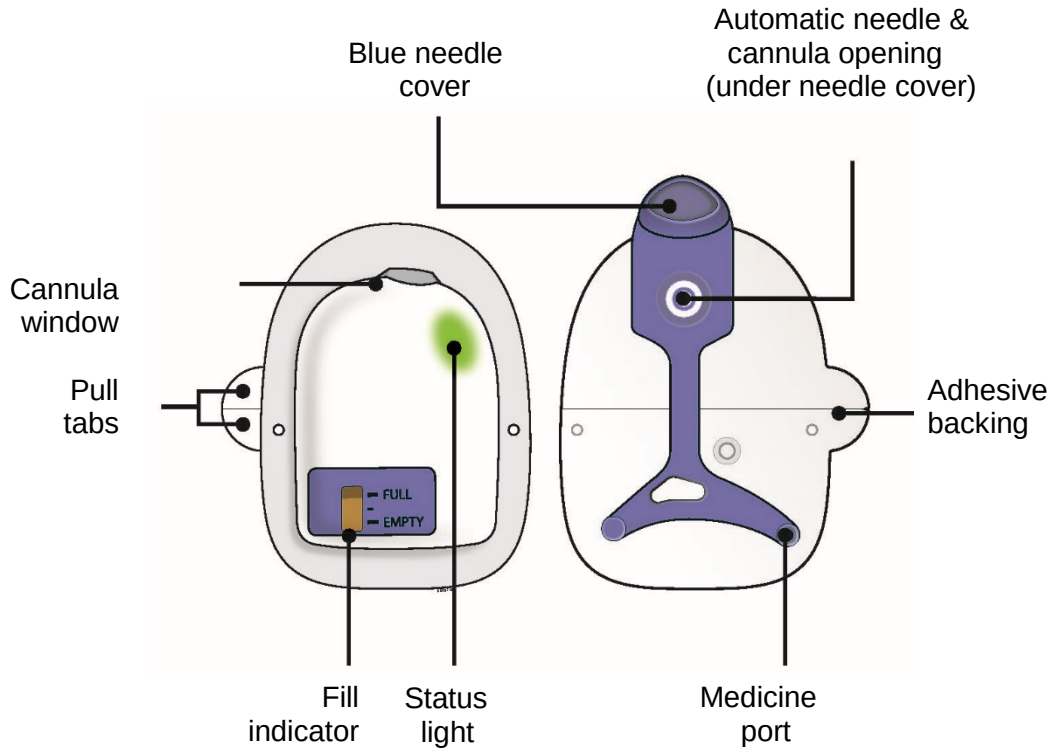
Neulasta® (pegfilgrastim) Onpro® kit
Healthcare Provider INSTRUCTIONS FOR USE

Guide to Parts

Neulasta Prefilled Syringe



On-body Injector for Neulasta



Important

READ THE FOLLOWING INSTRUCTIONS BEFORE USING NEULASTA ONPRO KIT

Prescribing Information

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

Application Information

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

Environmental Information

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

Cautions

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

Storage Information

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

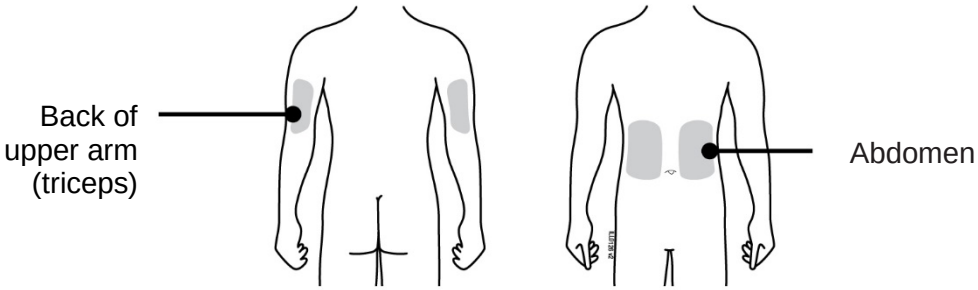
For all questions, or if a patient calls you regarding any injector problems, call Amgen at 1-800-772-6436.

Step 1: Prepare

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

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

B Choose the patient's injection site.



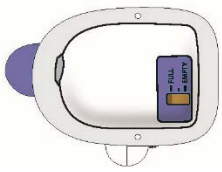
Ask the patient about their ability to monitor and remove the on-body injector.

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

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

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

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



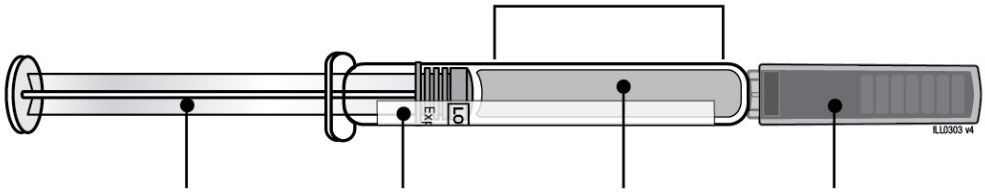
D Remove Neulasta prefilled syringe from tray.

For safety reasons:

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

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

Syringe barrel



Plunger rod | Label and expiration date | Medicine | Gray needle cap

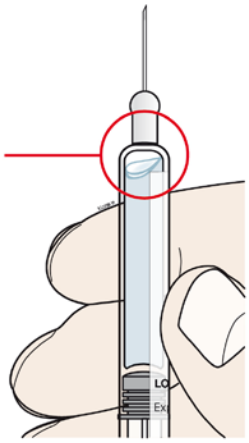
- **Do not** use if the liquid contains particulate matter or discoloration is observed prior to administration.
- **Do not** use the prefilled syringe if the expiration date has passed.
- **Do not** use if any part appears cracked or broken.
- **Do not** use if the gray needle cap is missing or not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

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

Step 2: Fill

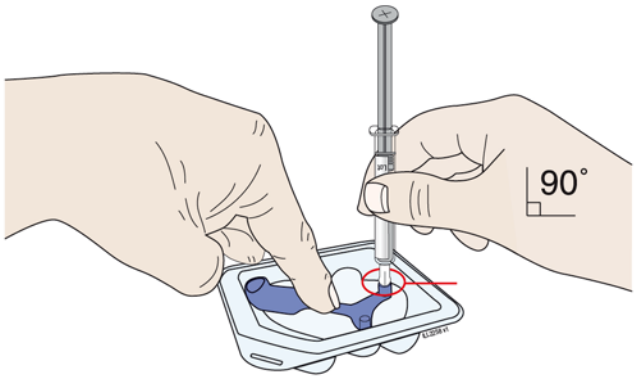
A **Remove air bubbles in prefilled syringe.**

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



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

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



Medicine port

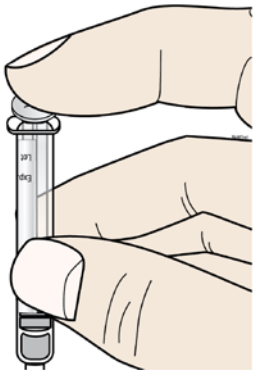
Insert needle into medicine port at a 90 degree angle only.

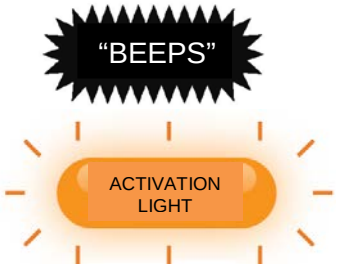
- **Do not** remove the blue needle cover before filling the on-body injector.
- **Do not** insert the needle more than once.
- **Do not** bend the needle. Avoid spilling the medicine.

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

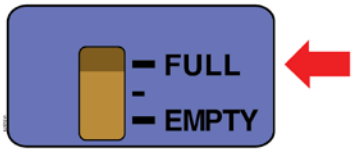
- During filling, you will hear beeping.
- The status light will flash amber.
- You now have 3 full minutes to apply the on-body injector to your patient.

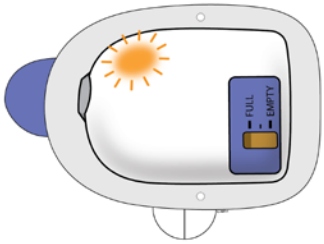
Discard used syringe in sharps container.





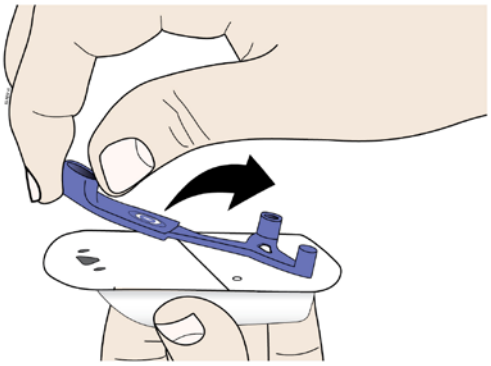
D Check to see if the on-body injector is full and the amber light is flashing. You should see a black line next to FULL on the fill indicator.

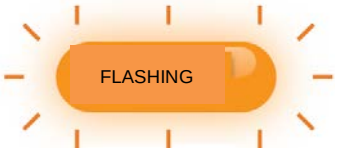




If this is not the case, do not use. Start again with a new Neulasta Onpro kit.

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



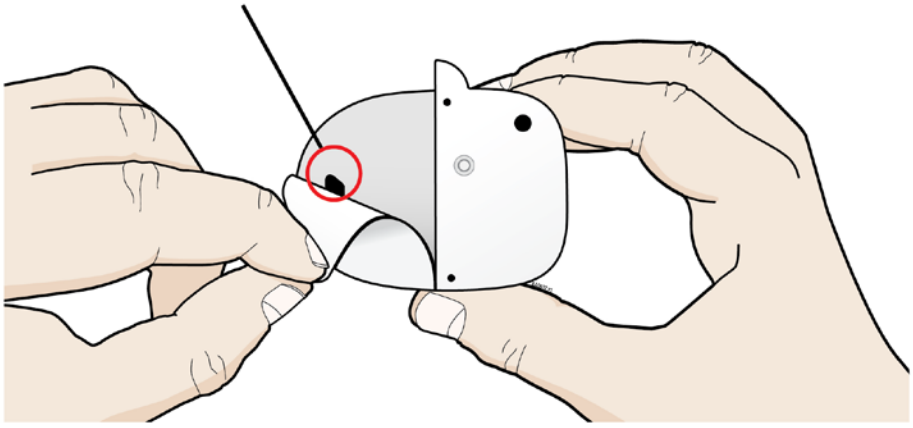


Step 3: Apply

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

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

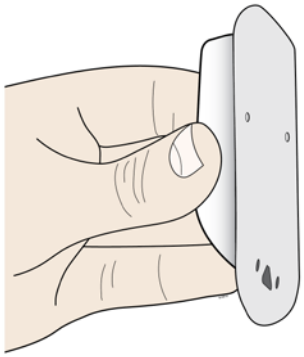
Automatic needle



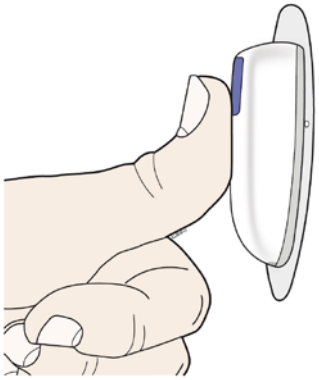
- **Do not** pull off the adhesive pad or fold it.
- **Do not** touch or contaminate the automatic needle area.
- **Do not** use if the needle or cannula is extended past the adhesive or is extended before the on-body injector is placed on the patient.
- **Do not place adhesive on skin that is damp.**

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

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

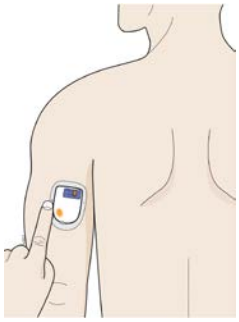


- **Do not** touch the adhesive.
- Grasp the on-body injector's plastic case with your fingertips and only by sides, keeping fingers off of the adhesive.
- **Do not** let the adhesive bend or curl while applying the on-body injector to skin.
- **Important:** Once on the skin, **press firmly on the on-body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

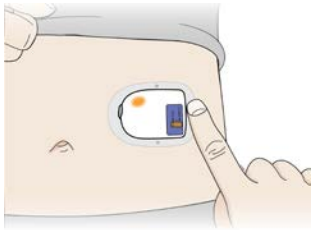


- Press around the entire adhesive so it lies down without folds or wrinkles.
- Hold the top of the on-body injector and run finger around the adhesive to create a secure attachment.
- If additional adhesion is deemed appropriate, an adhesive extender that fits around the on-body injector can be obtained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

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



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

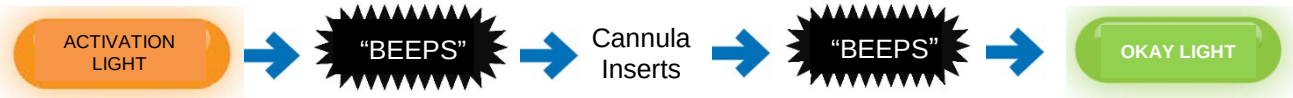


Do not worry if the on-body injector is quiet.
When 3 minutes are up, the on-body injector will beep telling you the cannula is about to insert.

Step 4: Finish

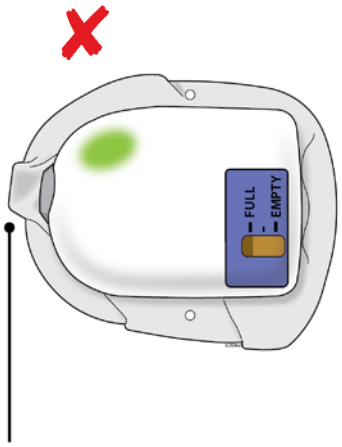
A **Wait for the status light to turn green. This means the cannula has been inserted.**

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

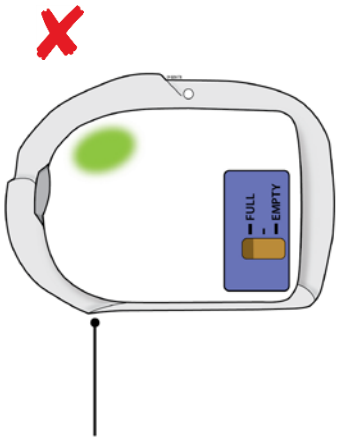


Check the quality of adhesion before sending the patient home.

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



Wrinkled adhesive near cannula window



Folded adhesive

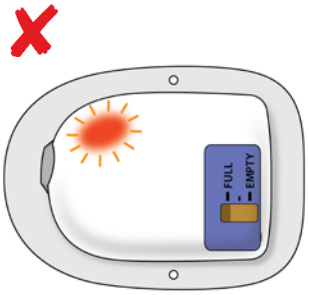
B **Provide the Patient IFU Booklet for the patient to take home.**

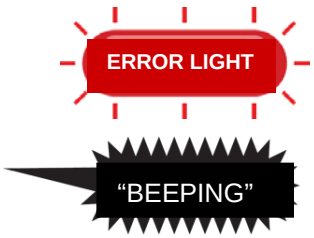
Fill in the Dose Delivery information on the booklet, and review the following instructions with your patient:

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

Attention!

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





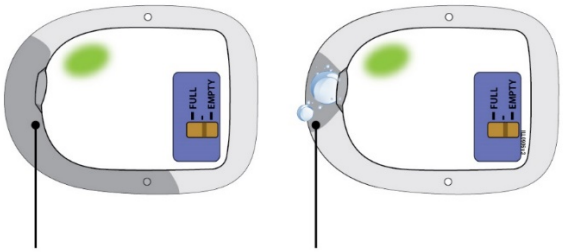
If at any time the on-body injector beeps continuously for 5 minutes, and the status light is flashing red, take the on-body injector off of the patient.

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

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

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

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



Saturated adhesive

Dripping fluid from on-body injector

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

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

Neulasta® (pegfilgrastim)

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

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

http://www.neulasta.com/
1-844-MYNEULASTA (1-844-696-3852)
Issued: 11/2020
V10

Before You Begin

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

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

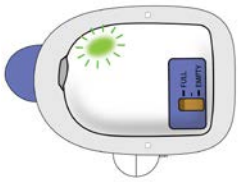
As part of this process, the on-body injector uses lights and sounds as signals to help guide you through the preparation and application process.

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

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

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

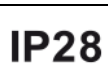
- The on-body injector will beep several times prior to inserting the cannula.
- Make sure you have the on-body injector properly secured to your patient before the cannula inserts.



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

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

Turn over to continue with the Instructions for Use

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

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

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

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

General Notes:

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

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

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

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

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

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

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

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

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

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

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

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

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

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

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

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