

Patient INSTRUCTIONS FOR USE

Neulasta® Onpro® (nu-las-tah) (pegfilgrastim) injection

Single-Use On-body Injector



Your On-body injector was applied:

<input type="text"/>	<input type="text"/>
Day	Time
	AM
	PM

Injection of your dose (delivery) will start around:

<input type="text"/>	<input type="text"/>
Day	Time
	AM
	PM

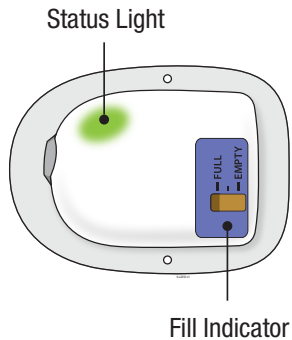
Healthcare Provider name:

Healthcare Provider contact number:

On-body Injector lot number:

Get to Know Your On-body Injector

Parts and Signals



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.

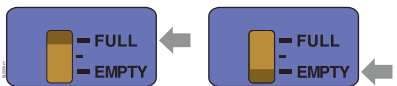


Flashing Red:

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

Learn about your Neulasta On-body Injector.

STEP 1: MONITOR

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

STEP 2: OBSERVE

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

STEP 3: VERIFY

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

STEP 4: FINISH

Confirm the dose was delivered and dispose of the device.

FAQ

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

On-body Injector for Neulasta Description

- 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.

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.

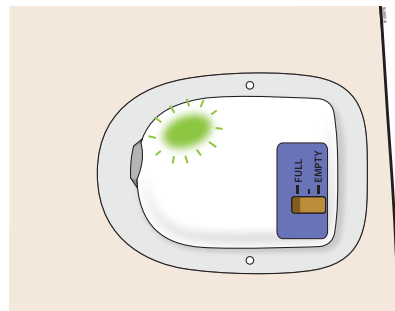
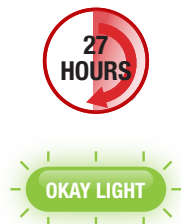
Environmental Precautions

- **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>

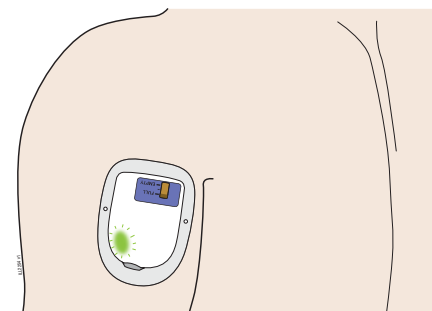
A healthcare provider who is familiar with Neulasta should answer your questions. For general questions or support call **1-844-MYNEULASTA (1-844-696-3852)** or visit **www.neulasta.com**.

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.



- 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.

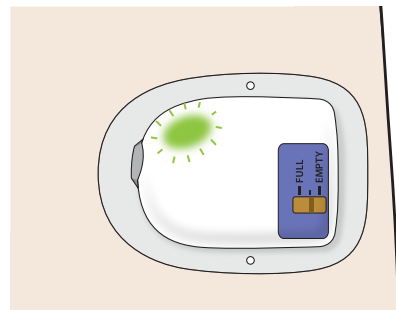


- If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- If the on-body injector comes away from your skin at any time, do not reapply it. Call your healthcare provider right away as you may need a replacement dose.
-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

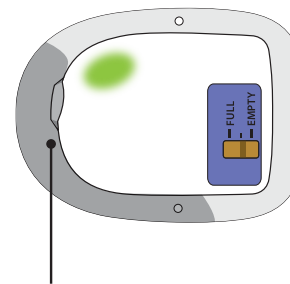


- When dose delivery is complete, a long beep will sound and the status light will turn solid green.
- If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away, as you may need a replacement dose.
- **Do not remove the on-body injector if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



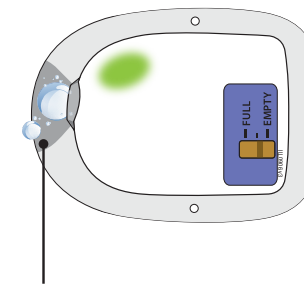
Check your on-body injector often for leaks during the 45-minute dose delivery. If the on-body injector was placed on the back of your arm, a caregiver must be available to check your on-body injector.

X Incorrect



Noticeably wet adhesive

X Incorrect

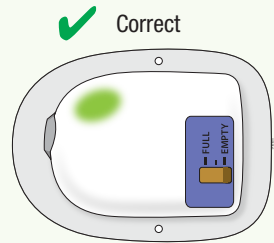


Dripping fluid from on-body injector

- 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.



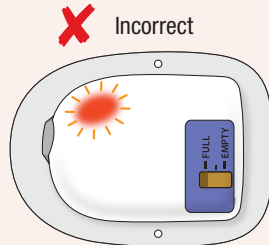
Correct

FINISH LIGHT

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

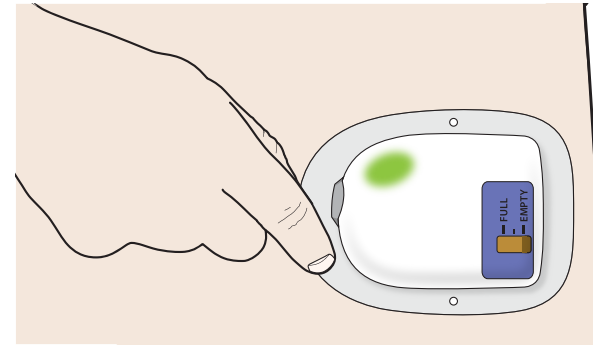
ERROR LIGHT

“BEEPING”

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.



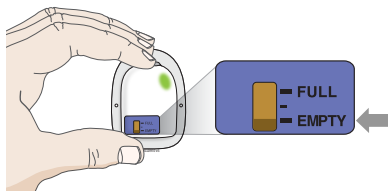
- **Do not** grasp the on-body injector itself to try to pull it off of your body.
- If medicine has leaked or the adhesive is noticeably wet or dripping, call your healthcare provider right away, as you may not have received your full dose and you may need a replacement dose.
- Remove any extra adhesive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



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

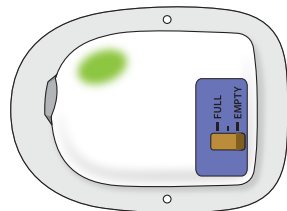


Frequently Asked Questions

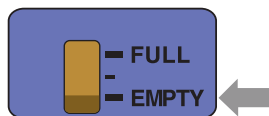
How do I know it is safe to remove the on-body injector?

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

✓ Correct



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

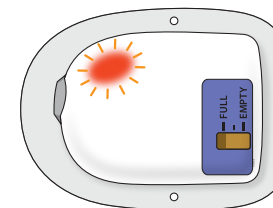


- The fill indicator should have a black line next to EMPTY

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

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

✗ Incorrect



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

AMGEN®

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)

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V9



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