

Neulasta® (pegfilgrastim)

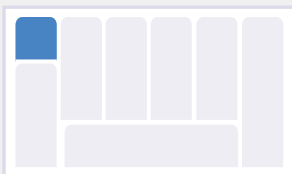
On-Body Injector

Patients Instructions for Use (IFU) v8

Approved January 2020

**On-body Injector
for Neulasta®
(pegfilgrastim)
Injection**
Patient Instructions for Use

Dosage



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:

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Important

Important Information

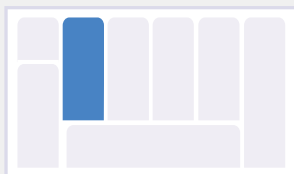
- This on-body injector delivers Neulasta with an under-the-skin (subcutaneous) injection. See Patient Information for medicine information.
- If you have concerns about your medication, call your healthcare provider immediately. Serious allergic reactions can happen with Neulasta. Ask your caregiver 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.

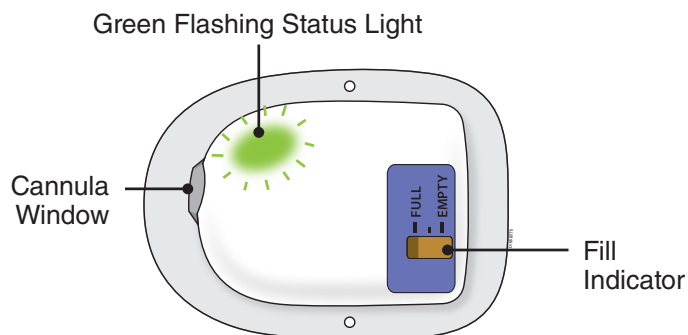
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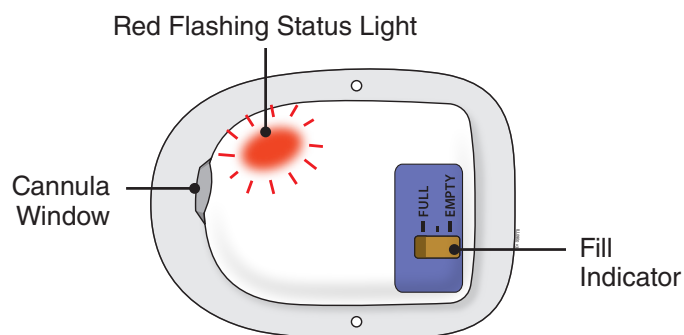
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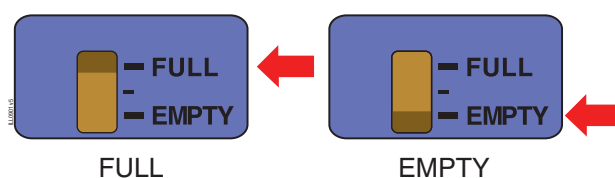
Guide to Parts for On-body Injector for Neulasta



The on-body injector is working properly.



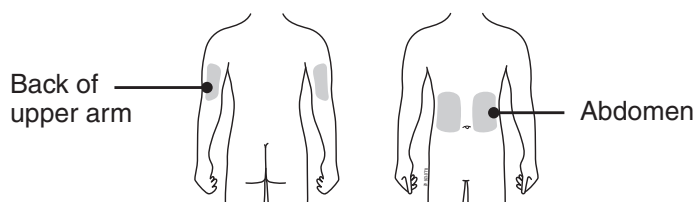
If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately, as you may need a replacement dose.



Fill indicator

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

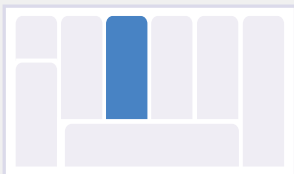
On-body Injector Placement



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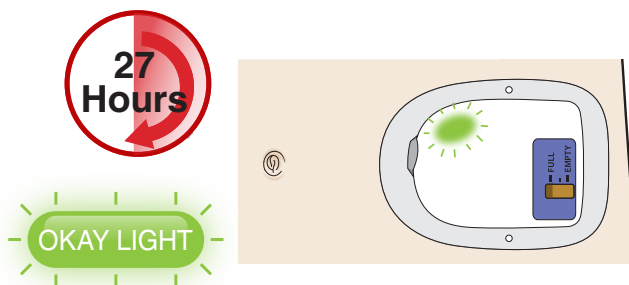
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Step 1: Monitor On-body Injector

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.

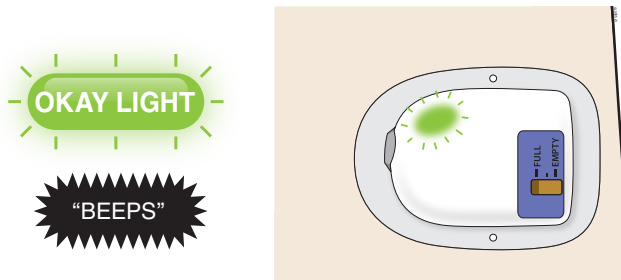


- If the on-body injector for Neulasta was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- Be careful not to bump the on-body injector, or knock the on-body injector off your body.
- If at any time you hear beeping, check the status light. 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.



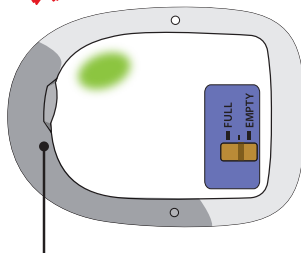
Do not remove the on-body injector before the dose delivery is complete.

Step 2: Monitor Dose Delivery



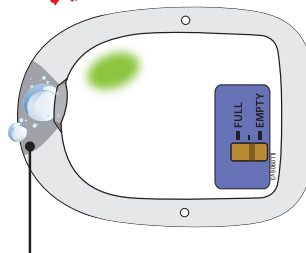
For the next 45-minutes, monitor your on-body injector frequently for leaks during dose delivery. If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor your on-body injector.

X Incorrect



Noticeably wet
(saturated) adhesive

X Incorrect



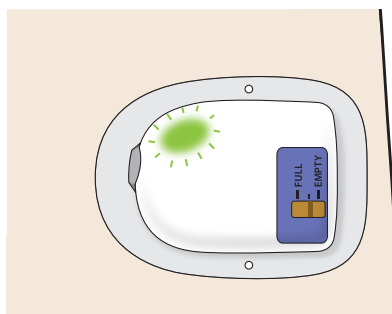
Dripping fluid
from on-body injector

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.

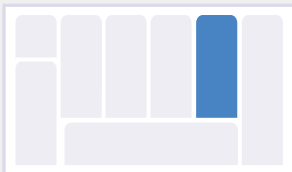
- During this time, the on-body injector will flash a fast green light.
- You may hear a series of clicks. This is okay.
- When dose delivery is complete, a long beep will sound and the status light will be solid green.



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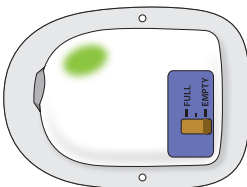
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Step 3: Remove On-body Injector When Dose Delivery Is Complete

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

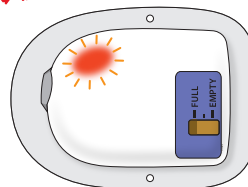
✓ Correct



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.

✗ Incorrect



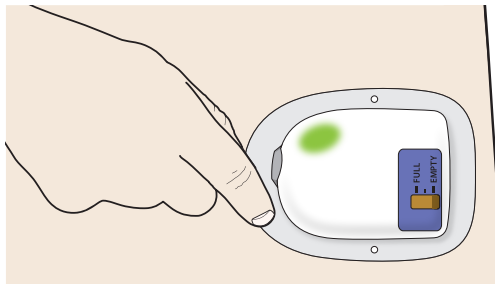
ERROR LIGHT

"BEEPS"

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.

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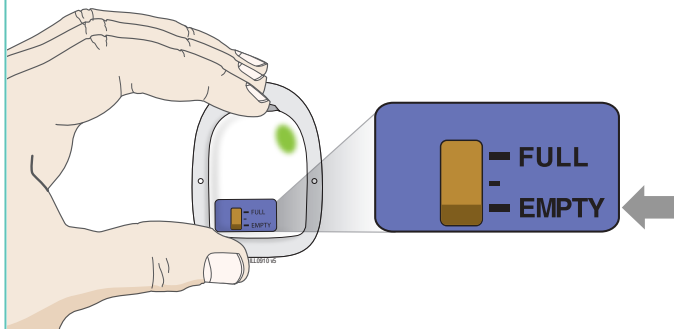
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Step 4: Finish



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

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

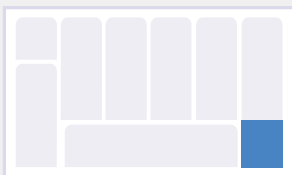
B

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.

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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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