

## {SIDE 1 Information}

### Patient Instructions for Use On-body Injector for Neulasta Description

The on-body injector for Neulasta is intended for delivery of Neulasta. The on-body injector is small, for one-time use, lightweight, battery-powered, and waterproof up to 8 feet for 1 hour. Your healthcare provider will use a prefilled syringe with Neulasta to fill the on-body injector prior to applying it. The prefilled syringe with Neulasta and the on-body injector are provided to your healthcare provider as part of Neulasta Onpro® kit. The on-body injector is applied directly to your skin using a self-adhesive backing. The on-body injector informs you of its status with sounds and lights.

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

### Warnings

**Before** you receive Neulasta, tell your healthcare provider if you:

- Have sickle cell trait or sickle cell disease.
- Have problems with your kidneys.
- Have any other medical problems.
- Are pregnant or plan to become pregnant. It is not known if Neulasta may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Neulasta passes into your breastmilk.

**Do not** take Neulasta if you have had a serious allergic reaction to pegfilgrastim (Neulasta®) or to filgrastim (Neupogen®).

Tell your healthcare provider if you are allergic to latex. A prefilled syringe is used to fill the on-body injector by your healthcare provider prior to applying the on-body injector. The prefilled syringe gray needle cap contains dry natural rubber, which is derived from latex. Latex may be transferred to your skin.

Tell your healthcare provider if you have had severe skin reactions to acrylic adhesives.

The on-body injector is for adult patients only.

Avoid activities and places that may interfere with monitoring during the dosing of Neulasta administered by the on-body injector. For example, **avoid** traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector for Neulasta (this includes the 45-minute dose delivery period plus an hour post-delivery).

If you must travel by airplane **before** the approximately 45-minute dose delivery period with the on-body injector, avoid airport X-ray scans. Request a manual pat down instead. Use care during a manual pat down to help prevent the on-body injector from being accidentally removed. For more information go to:

<http://www.tsa.gov/traveler-information/travelers-disabilities-and-medical-conditions>.

If you have an allergic reaction during the delivery of Neulasta, remove the on-body injector by grabbing the edge of the adhesive pad and peeling off the on-body injector. Get emergency medical help right away.

Call your healthcare provider immediately if you have severe pain or skin discomfort around your on-body injector.

Call your healthcare provider right away if you have pain in your left upper stomach area or left shoulder area. This pain could mean your spleen is enlarged or ruptured.

Call your healthcare provider or get emergency medical help right away if you get any of these symptoms of acute respiratory distress syndrome (ARDS): fever, shortness of breath, trouble breathing, or a fast rate of breathing.

Call your healthcare provider right away if you experience any of these symptoms of kidney injury (glomerulonephritis): puffiness in your face or ankles, blood in your urine or brown colored urine or you notice you urinate less than usual.

Keep children away from the used on-body injector.

You should only receive a dose of Neulasta on the day your healthcare provider tells you.

You should not receive your dose of Neulasta any sooner than 24 hours after you finish receiving your chemotherapy. The on-body injector for Neulasta is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector on your skin.

**Do not** expose the on-body injector to the following because the on-body injector may be damaged and you could be injured:

- 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](http://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

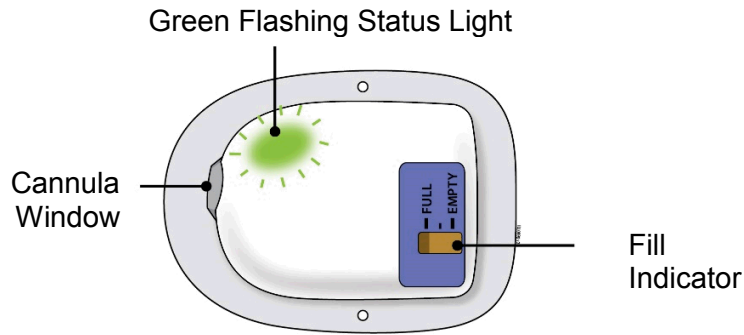
- This on-body injector delivers Neulasta with an under-the-skin (subcutaneous) injection. See Patient Information for medicine information.
- If you have concerns about your medication, call your healthcare provider immediately. Serious allergic reactions can happen with Neulasta. Ask your caregiver 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 additional 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 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.
- Keep the on-body injector dry for the last 3 hours prior to the dose delivery start.
- Only expose the on-body injector to temperatures between 41°F and 104°F (5°C and 40°C).
- After on-body injector removal, properly dispose of it in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
- Keep the on-body injector at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances. Failure to keep the on-body injector at least this recommended distance may interfere with operation and can lead to a missed or incomplete dose of Neulasta.
- **Do not** use 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.

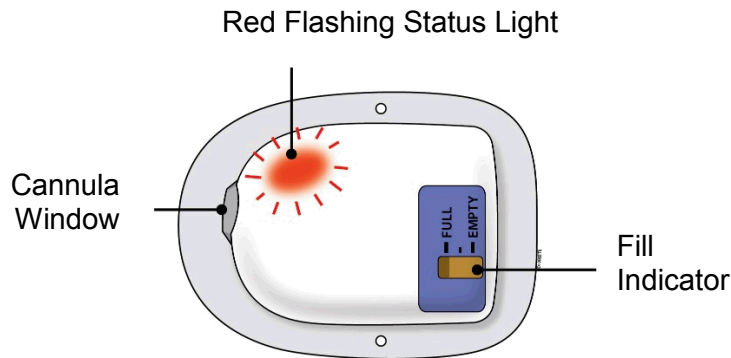
A healthcare provider who is familiar with Neulasta should answer your questions. For general questions or support call 1-844-MYNEULASTA (1-844-696-3852) or visit [www.neulasta.com](http://www.neulasta.com).

---

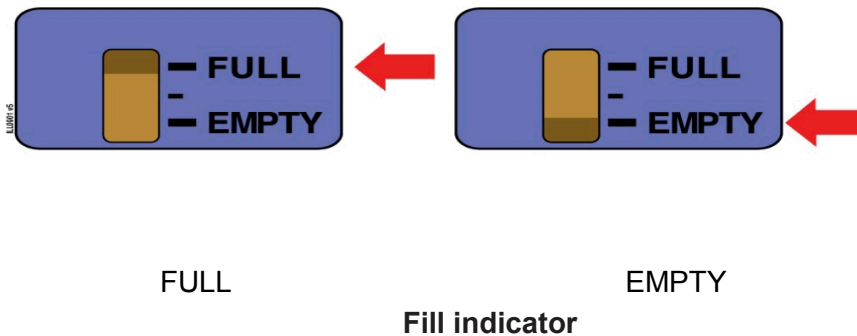
## Guide to Parts for On-body Injector for Neulasta



The on-body injector is working properly.

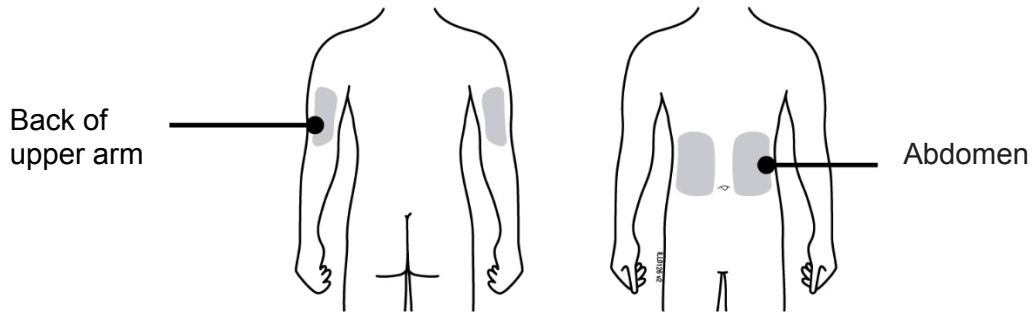


If at any time you hear beeping, check the status light. If it is flashing red, call your healthcare provider immediately, as you may need a replacement dose.



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.

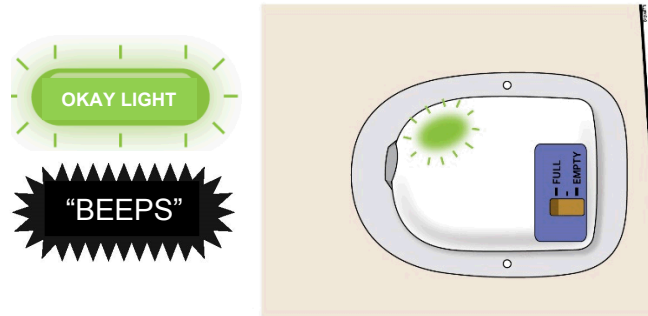


- If the on-body injector for Neulasta was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- Be careful not to bump the on-body injector, or knock the on-body injector off your body.
- If at any time you hear beeping, check the status light.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

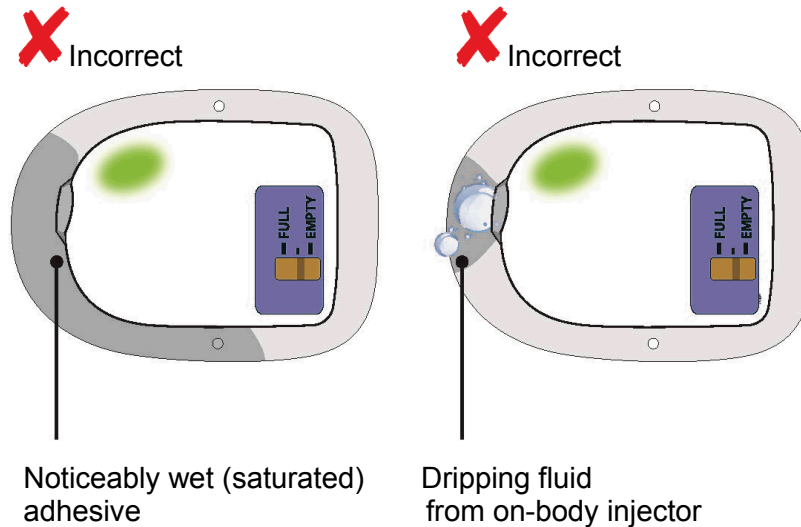


**Do not remove the on-body injector before the dose delivery is complete.**

## Step 2: Monitor Dose Delivery



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

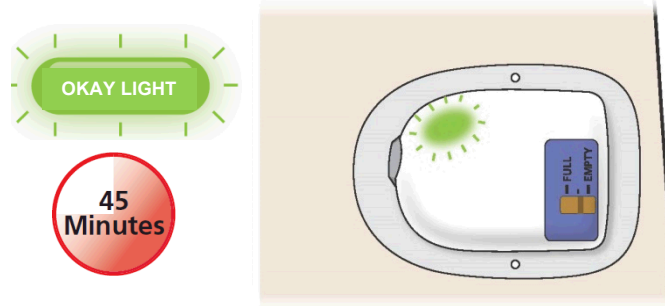


**If the adhesive becomes noticeably wet (saturated) with fluid, or you see dripping, call your healthcare provider immediately, as you may need a replacement dose.**

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



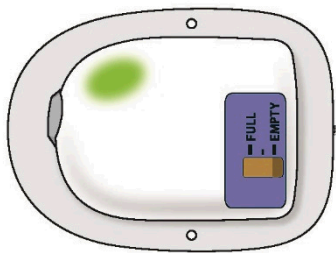
- During this time, the on-body injector will flash a fast green light.
- You may hear a series of clicks. This is okay.
- When dose delivery is complete, a long beep will sound and the status light will be solid green.



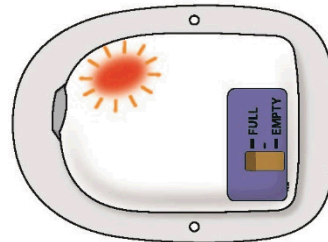
### Step 3: Remove On-body Injector When Dose Delivery Is Complete

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

✓ Correct



✗ Incorrect

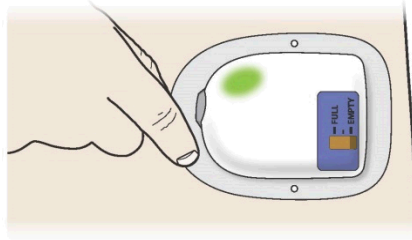


Check to see if the status light is SOLID GREEN or has switched off. This means the dose is complete. If the dose is complete, go to the next step.

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.



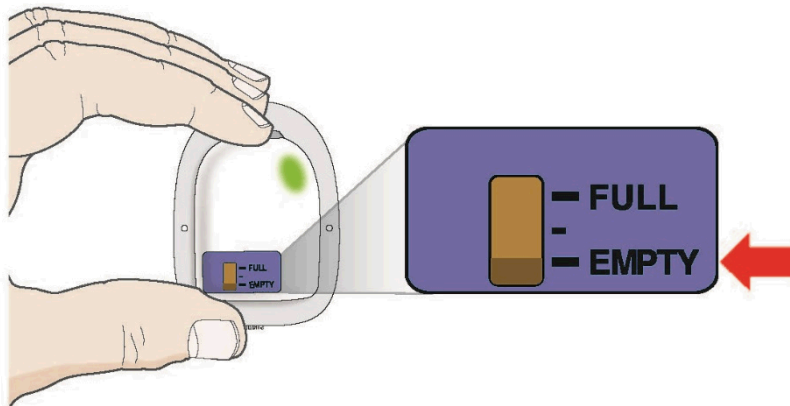
- **Do not** grasp the on-body injector itself to try to pull it off of your body.

### Step 4: Finish



**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.**

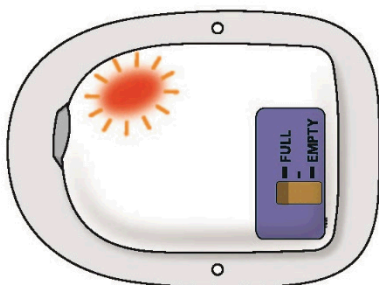
- The on-body injector contains batteries, electronics, and a needle. Dispose of it in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
- To participate in Amgen's voluntary disposal program, please call 1-844-MYNEULASTA (1-844-696-3852) or visit [www.neulasta.com](http://www.neulasta.com)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

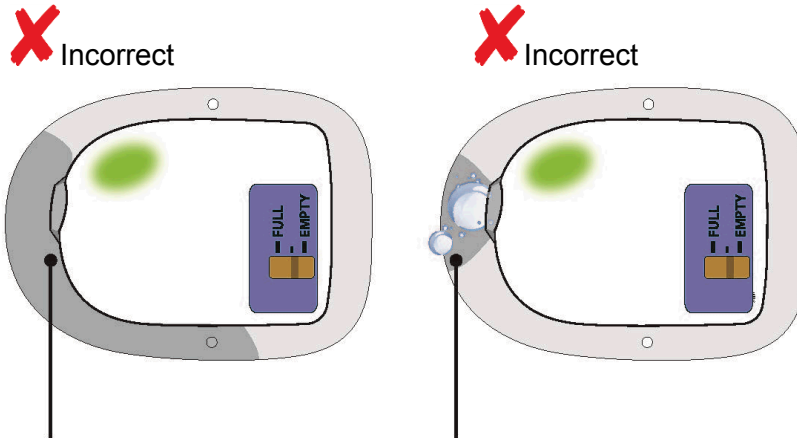
**What to do if you hear beeping or when you look at the status light and it is flashing red.**

- 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 in-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/>

© 2002 to 2018 Amgen Inc. All rights reserved.

[www.neulasta.com](http://www.neulasta.com)

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

Issued: 06/2018

v7