Neulasta®

Pegfilgrastim

Information for Patients and Caregivers

This patient package insert provides information and instructions for people who will be receiving Neulasta or their caregivers. This patient package insert does not tell you everything about Neulasta. You should discuss any questions you have about treatment with Neulasta with your doctor.

What is Neulasta?

Neulasta is a man-made form of granulocyte colony-stimulating factor (G-CSF), which is made using the bacteria *Escherichia coli*. G-CSF is a substance produced by the body. It stimulates the growth of neutrophils (nu-tro-fils), a type of white blood cell important in the body’s fight against infection.

Who should not take Neulasta?

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

What important information do I need to know about receiving Neulasta?

Occasionally, pain and redness may occur at the injection site. If there is a lump, swelling, or bruising at the injection site that does not go away, talk to the doctor.

Neulasta should only be injected on the day the doctor has determined and should not be injected until approximately 24 hours after receiving chemotherapy.

If your child weighs less than 45 kg, do not use the prefilled syringe for direct administration of Neulasta. The Neulasta prefilled syringe is not designed to allow for direct administration of doses less than 6 mg.

The needle cover on the single-use prefilled syringe contains dry natural rubber (latex), which should not be handled by persons sensitive to this substance.

What should I tell my healthcare provider before taking Neulasta?

If you have a sickle cell disorder, make sure that your doctor knows about it before you start using Neulasta. If you have a sickle cell crisis after getting Neulasta, tell your doctor right away.

If you have a problem with your kidneys, make sure that your doctor knows about it before you start using Neulasta as you may need more frequent urine tests.

If you have any questions, talk to your doctor.

Why am I given Neulasta if I was exposed to radiation?

Exposure to high levels of radiation damages bone marrow. Damage to the bone marrow can be deadly. Neulasta increases your chance of survival.

Effectiveness of Neulasta in increasing survival after radiation exposure was only studied in animals. Neulasta given after deadly radiation levels could not be studied in people.

What are possible serious side effects of Neulasta?
Spleen Rupture. Your spleen may become enlarged and can rupture while taking Neulasta. A ruptured spleen can cause death. The spleen is located in the upper left section of your stomach area. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area. This pain could mean your spleen is enlarged or ruptured.

A serious lung problem called Acute Respiratory Distress Syndrome (ARDS). Call your doctor or seek emergency care right away if you have shortness of breath, trouble breathing, or a fast rate of breathing.

Serious Allergic Reactions. Neulasta can cause serious allergic reactions. These reactions can cause shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, sweating, and hives. If you start to have any of these symptoms, call your doctor or seek emergency care right away. If you have an allergic reaction during the injection of Neulasta, stop the injection. Call your doctor right away.

Sickle Cell Crises. You may have a serious sickle cell crisis if you have a sickle cell disorder and take Neulasta. Serious and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim, a medicine similar to Neulasta (pegfilgrastim). Call your doctor right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.

Kidney injury (glomerulonephritis). Kidney injury has been seen in patients who received Neulasta. Call your doctor right away if you experience puffiness in your face or ankles, blood in your urine or brown colored urine or you notice you urinate less than usual.

Increased white blood cell count (leukocytosis). Your doctor will check your blood during treatment with Neulasta.

Capillary Leak Syndrome. Neulasta can cause fluid to leak from blood vessels into your body’s tissues. This condition is called “Capillary Leak Syndrome” (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
- swelling or puffiness and are urinating less often
- trouble breathing
- swelling of your stomach-area (abdomen) and feeling of fullness
- dizziness or feeling faint
- a general feeling of tiredness

What are the most common side effects of Neulasta?
The most common side effect you may experience is aching in the bones and muscles. If this happens, it can usually be relieved with a non-aspirin pain reliever, such as acetaminophen.

What about pregnancy or breastfeeding?
Neulasta has not been studied in pregnant women, and its effects on unborn babies are not known. If you take Neulasta while you are pregnant, it is possible that small amounts of it may get into your baby’s blood. It is not known if Neulasta can get into human breast milk. If you are pregnant, plan to become pregnant, think you may be pregnant, or are breastfeeding, you should tell your doctor before using Neulasta. If you become pregnant during Neulasta treatment, you are encouraged to enroll in Amgen’s Pregnancy Surveillance Program. You should call 1-800-77-AMGEN (1-800-772-6436) to enroll.

HOW TO PREPARE AND GIVE A NEULASTA INJECTION
If your child weighs less than 45 kg, do not use the prefilled syringe for direct administration of Neulasta. The Neulasta prefilled syringe is not designed to allow for direct administration of doses less than 6 mg.
Neulasta is provided in a prefilled syringe. **Neulasta should be stored in its carton to protect from light until use.** If you are giving someone else Neulasta injections, it is important that you know how to inject Neulasta. Before getting your Neulasta injection, always check to see that:

- The name Neulasta appears on the carton and prefilled syringe label.
- The expiration date on the prefilled syringe has not passed. **You should not use a prefilled syringe after the date on the label.**
- The Neulasta liquid should always be clear and colorless. Do not use Neulasta if the contents of the prefilled syringe appear discolored or cloudy, or if the prefilled syringe appears to contain lumps, flakes, or particles.

**IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, YOU SHOULD FOLLOW THESE INSTRUCTIONS.**

**Setting up for an injection**

Note: The needle cover on the single-use prefilled syringe contains dry natural rubber (latex), which should not be handled by persons sensitive to this substance.

1. Find a clean, flat working surface, such as a table.

2. Remove the carton containing the prefilled syringe of Neulasta from the refrigerator. Allow Neulasta to reach room temperature (this takes about 30 minutes). Remove the syringe from the carton before injection. Each prefilled syringe should be used only once. **DO NOT SHAKE THE PREFILLED SYRINGE.** Shaking may damage Neulasta. If the prefilled syringe has been shaken vigorously, the solution may appear foamy and it should not be used.

3. Assemble the supplies you will need for an injection:
   - Neulasta prefilled syringe with transparent (clear) plastic blue needle guard attached
   - An alcohol swab and a cotton ball or gauze
   - Puncture-proof disposal container
4. Wash your hands with soap and warm water.

HOW TO PREPARE FOR INJECTION OF NEULASTA

5. Remove the prefilled syringe from the package and the tray. Check to see that the plastic blue needle guard is covering the barrel of the glass syringe. DO NOT push the blue needle guard over the needle cover before injection. This may activate or lock the needle guard. If the blue needle guard is covering the needle that means it has been activated. DO NOT use that syringe. Dispose of that syringe in the puncture-proof disposal container. Use a new prefilled syringe. **Do not activate the needle guard prior to injection.**

6. Hold the syringe barrel through the needle guard windows with the needle pointing up. Holding the syringe with the needle pointing up helps to prevent medicine from leaking out of the needle. Carefully pull the needle cover straight off.

7. Check the syringe for air bubbles. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.

8. Gently place the prefilled syringe with the window flat on your clean working surface so that the needle does not touch anything.

**Selecting and preparing the injection site**

9. Choose an injection site. Four recommended injection sites for Neulasta are:

- The outer area of the upper arms
- The abdomen, except for the two-inch area around the navel
- The front of the middle thighs
- The upper outer areas of the buttocks
10. Clean the injection site with an alcohol swab.

**Injecting the dose of Neulasta**

11. Pick up the prefilled syringe from your clean, flat working surface by grabbing the sides of the needle guard with your thumb and forefinger.

12. Hold the syringe in the hand you will use to inject Neulasta. Use the other hand to pinch a fold of skin at the cleaned injection site. **Note:** Hold the syringe barrel through the needle guard windows when giving the injection.

13. Holding the syringe like a pencil, use a quick “dart-like” motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.
14. Inject the prescribed dose subcutaneously as directed by your doctor, nurse, or pharmacist.

15. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.

16. Use a prefilled syringe with the needle guard only once.

**Activating the Needle Guard after the injection has been given**

17. After injecting Neulasta from the prefilled syringe, do not recap the needle. Keep your hands behind the needle at all times. While holding the clear plastic finger grip of the syringe with one hand, grasp the blue needle
guard with your free hand and slide the blue needle guard over the needle until the needle is completely covered and the needle guard clicks into place.  **NOTE: If an audible click is not heard, the needle guard may not be completely activated.**

18. Place the prefilled syringe with the activated needle guard into a puncture-proof container for proper disposal as described below.

**Disposal of prefilled syringes and needle guards**

You should always follow the instructions given by your doctor, nurse, or pharmacist on how to properly dispose of containers with used syringes and needle guards. There may be special state and local laws for disposal of used needles and syringes.

- Do not throw the container in the household trash. Do not recycle.
- **DO NOT** put the needle cover (the cap) back on the needle.
- Place all used needle covers and syringes in a hard plastic container with a screw-on cap or in a metal container with a plastic lid such as a coffee can labeled “used syringes.” If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. If a hard plastic container is used, always screw the cap on tightly after each use.
- Do not use glass or clear plastic containers.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.
- **Always** keep the container out of the reach of children.

**How should Neulasta be stored?**

Neulasta should be stored in the refrigerator at 2° to 8°C (36° to 46°F), but not in the freezer. Neulasta should be protected from light, so you should keep it in its carton until you are ready to use it. Avoid shaking Neulasta. If Neulasta is accidentally frozen, allow it to thaw in the refrigerator before injecting. However, if it is frozen a second time, do not use. Neulasta can be left out at room temperature for up to 48 hours. Do not leave Neulasta in direct sunlight. For all questions about storage, contact your doctor, nurse, or pharmacist.

**What are the ingredients in Neulasta?**

Each syringe contains pegfilgrastim in a sterile, clear, colorless, preservative-free solution containing acetate, sorbitol, polysorbate 20, and sodium.
Neulasta® (pegfilgrastim)
Manufactured by:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799


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www.neulasta.com
1-800-77-AMGEN (1-800-772-6436)
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Read this Patient Information before you receive Neulasta and each time you receive Neulasta with the On-body Injector for Neulasta. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I need to know about receiving Neulasta with the On-body Injector for Neulasta?

- **See the Instructions for Use for the On-body Injector for Neulasta for detailed information about the On-body Injector for Neulasta and important information about your dose delivery that has been written by your healthcare provider.**
  - Know the time that delivery of your dose of Neulasta is expected to start.
  - Avoid traveling, driving, or operating heavy machinery during hour 26 through hour 29 after the On-body Injector for Neulasta is applied. Avoid activities and places that may interfere with monitoring during the 45-minute period that Neulasta is expected to be delivered by the On-body Injector for Neulasta, and for 1 hour after delivery.

- A caregiver should be with you the first time that you receive Neulasta with the On-body Injector for Neulasta.

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

- 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 for Neulasta on your skin.

- **Do not** expose the On-body Injector for Neulasta to the following because the On-body Injector for Neulasta may be damaged and you could be injured:
  - MRI
  - X-ray
  - CT-Scan
  - Ultrasound
  - Oxygen rich environments, such as hyperbaric chambers
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 for Neulasta from being accidentally removed.

Keep the On-body Injector for Neulasta at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances. If the On-body Injector for Neulasta is too close to electrical equipment, it may not work correctly and can lead to a missed or incomplete dose of Neulasta.

The On-body Injector is for adult patients only.

Call your healthcare provider right away if the:
- On-body Injector for Neulasta comes off before or during a dose delivery. Do not re-apply it.
- On-body Injector for Neulasta is leaking.
- adhesive on your On-body Injector for Neulasta becomes noticeably wet (saturated) with fluid, or there is dripping. This may mean that Neulasta is leaking out of your On-body Injector for Neulasta. If this happens you may only receive some of your dose of Neulasta, or you may not receive a dose at all.
- On-body Injector for Neulasta status light is flashing red.

What is Neulasta?
Neulasta is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid), who receive anti-cancer medicines (chemotherapy) that can cause fever and low blood cell count.

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

What should I tell my healthcare provider before receiving Neulasta?
Before you receive Neulasta, tell your healthcare provider if you:
- have sickle cell trait or sickle cell disease
- have had severe skin reactions to acrylic adhesives
- are allergic to latex
- 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.

Pregnancy Registry: There is a pregnancy registry for women who become pregnant during treatment with Neulasta. The purpose of this registry is to collect information
about the health of you and your baby. You are encouraged to enroll in this registry. Your healthcare provider may enroll you, or you may enroll by calling 1-800-AMGEN (1-800-772-6436).

- are breastfeeding or plan to breastfeed. It is not known if Neulasta passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive Neulasta?

See the Instructions for Use for detailed information about how you will receive a dose of Neulasta with the On-body Injector for Neulasta, and how to remove and dispose of the On-body Injector for Neulasta.

- See the section “What is the most important information I need to know about receiving Neulasta with the On-body Injector for Neulasta?”

- Neulasta is given as an injection under the skin (subcutaneous). 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 for Neulasta will be applied to the stomach area (abdomen) or back of your arm by your healthcare provider. If the On-body Injector for Neulasta was placed on the back of your arm, a caregiver must be available to monitor the On-body Injector for Neulasta.

- Your healthcare provider should place the On-body Injector for Neulasta on an area of your skin that does not have swelling, redness, cuts, wounds, or abrasions. Tell your healthcare provider about any skin reactions that happen in the On-body Injector for Neulasta application area after it has been applied.

- The On-body Injector for Neulasta is programmed to deliver your dose about 27 hours after your healthcare provider places the On-body Injector for Neulasta on your skin.

- The dose of Neulasta will be delivered over about 45 minutes. During dose delivery and for 1 hour after delivery, it is best to stay in a place where you or a caregiver can monitor the On-body Injector for Neulasta to make sure you receive your full dose of Neulasta and watch for symptoms of an allergic reaction.

- Keep the On-body Injector for Neulasta dry for about the last 3 hours before the dose delivery is expected to start. This will help you to better detect possible leaking from the On-body Injector for Neulasta.

- Only expose the On-body Injector for Neulasta to temperatures between 41°F to 104°F (5°C to 40°C).

What should I avoid while the On-body Injector for Neulasta is in place?

While the On-body Injector for Neulasta is in place you should avoid:

- traveling, driving or operating heavy machinery during hour 26 through hour 29 after the On-body Injector for Neulasta is applied.
• sleeping on the On-body Injector for Neulasta or applying pressure on the On-body Injector for Neulasta. The On-body Injector for Neulasta may not work properly.
• bumping the On-body Injector for Neulasta or knocking it off your body.
• getting body lotion, creams, oils, and skin cleansing products near the On-body Injector for Neulasta. These products may loosen the adhesive that holds the On-body Injector for Neulasta onto your body.
• using hot tubs, whirlpools, or saunas, and direct sunlight. These may affect Neulasta.
• peeling off or disturbing the On-body Injector for Neulasta adhesive before you receive your full dose of Neulasta.

What are possible side effects of Neulasta?

Neulasta can cause serious side effects, including:

• **Spleen rupture.** Your spleen may become enlarged or may rupture during treatment with Neulasta. A ruptured spleen can cause death. 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.

• **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Call your healthcare provider or get emergency medical help right away if you get any of these symptoms of ARDS: fever, shortness of breath, trouble breathing, or a fast rate of breathing.

• **Serious allergic reactions.** Get emergency medical help right away if you get any of these symptoms of a serious allergic reaction with Neulasta: shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, sweating, and hives.

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

• **Sickle cell crises.** Severe sickle cell crises, and sometimes death, can happen in people with sickle cell trait or disease who receive filgrastim, a medicine similar to Neulasta (pegfilgrastim).

• **Kidney injury (glomerulonephritis).** Kidney injury has been seen in patients who received Neulasta. You should notify your healthcare provider right away if you experience puffiness in your face or ankles, blood in your urine or brown colored urine or you notice you urinate less than usual.

• **Increased white blood cell count (leukocytosis).** Your doctor will check your blood during treatment with Neulasta.
• **Capillary Leak Syndrome.** Neulasta can cause fluid to leak from blood vessels into your body’s tissues. This condition is called “Capillary Leak Syndrome” (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  o swelling or puffiness and are urinating less often
  o trouble breathing
  o swelling of your stomach-area (abdomen) and feeling of fullness
  o dizziness or feeling faint
  o a general feeling of tiredness

The most common side effect of Neulasta is pain in the bones and in your arms and legs.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Neulasta. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of Neulasta**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about Neulasta, talk with your healthcare provider or pharmacist. You can ask your pharmacist for information about Neulasta that is written for health professionals.

For more information, go to [www.neulasta.com](http://www.neulasta.com) or call 1-844-696-3852 (1-844-MYNEULASTA).

**What are the ingredients in Neulasta?**

Active ingredient: pegfilgrastim
Inactive ingredients: acetate, polysorbate 20, and sodium, sorbitol in Water for Injection.

This Patient Information has been approved by the U.S. Food and Drug Administration.