

FDA APPROVED PATIENT LABELING

Neulasta®

Pegfilgrastim

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 *E 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.

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 using Neulasta. If you have a sickle cell crisis after getting Neulasta, tell your doctor right away.

If you have any questions, talk to your doctor.

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.

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

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.

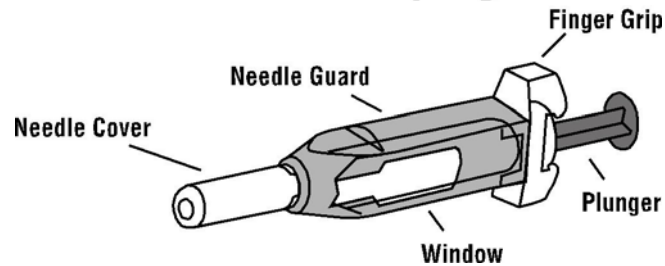
IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, YOU SHOULD FOLLOW THESE INSTRUCTIONS.

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

Prefilled Syringe



- An alcohol swab and a cotton ball or gauze

Alcohol Swab



Cotton Ball



- Puncture-proof disposal container

4. Wash your hands with soap and warm water.



HOW TO PREPARE FOR INJECTION OF NEULASTA

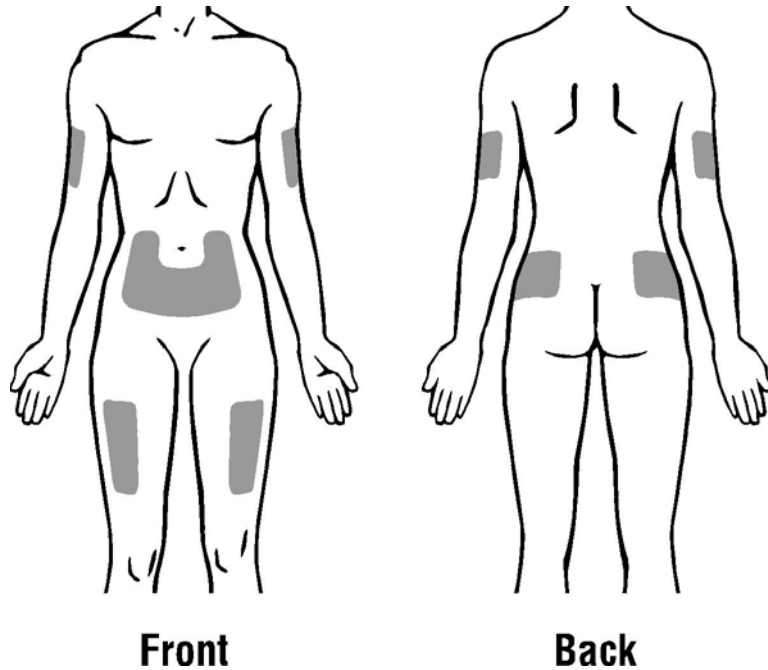
5. Remove the syringe from the package and the tray. Check to see that the plastic blue needle guard is covering the barrel of the glass syringe. **DO NOT** push the blue needle guard over the needle cover before injection. This may activate or lock the needle guard. If the blue needle guard is covering 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 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.

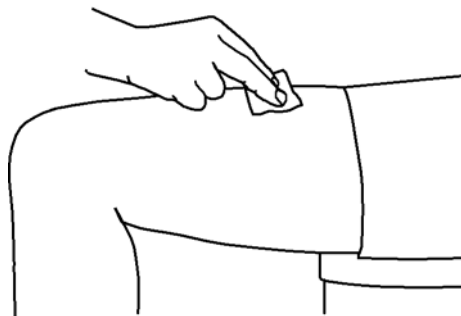
Selecting and preparing the injection site

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

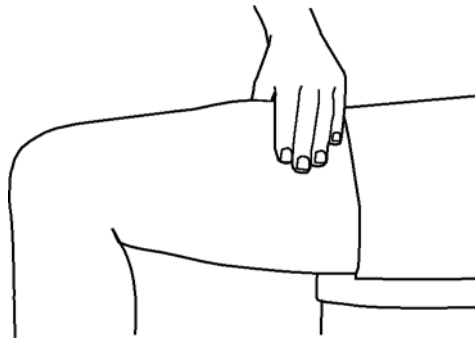


10. Clean the injection site with an alcohol swab.

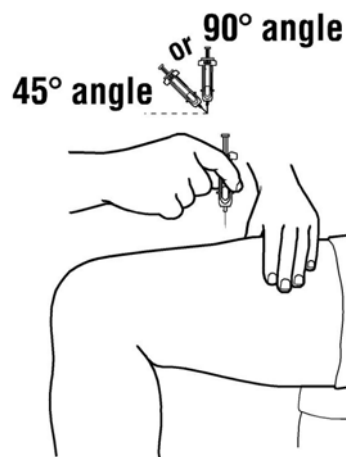


Injecting the dose of Neulasta

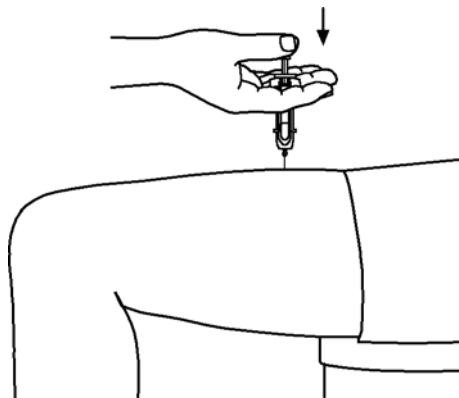
11. Pick up the prefilled syringe from your clean, flat working surface by grabbing the sides of the needle guard with your thumb and forefinger.
12. Hold the syringe in the hand you will use to inject Neulasta. Use the other hand to pinch a fold of skin at the cleaned injection site. Note: Hold the syringe barrel through the needle guard windows when giving the injection.



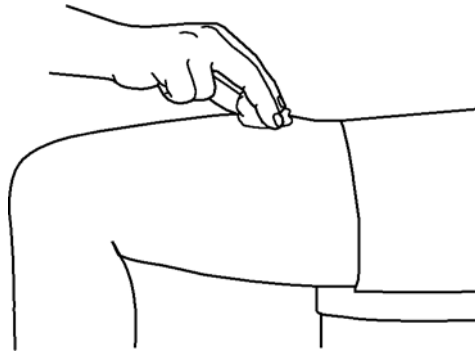
13. Holding the syringe like a pencil, use a quick “dart-like” motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.



14. After the needle is inserted, let go of the skin. Pull the plunger back slightly. If no blood appears, slowly push down on the plunger all the way, until all the Neulasta is injected. **If blood comes into the syringe, do not inject Neulasta, because the needle has entered a blood vessel.** Withdraw the syringe and discard it in the puncture-proof container. Repeat the steps to prepare a new prefilled syringe and choose and clean a new injection site. Remember to check again for blood before injecting Neulasta.



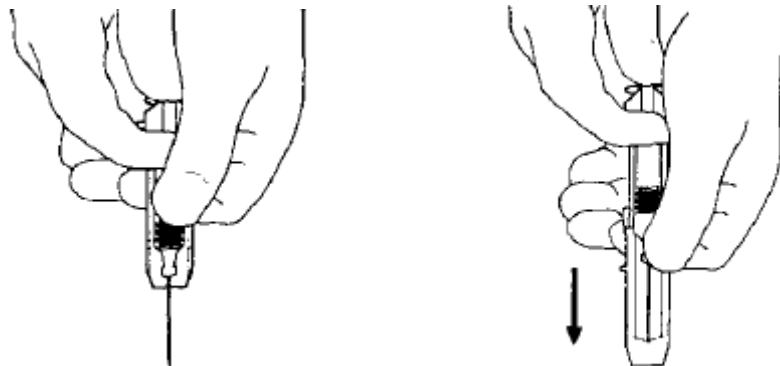
15. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.



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.

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Thousand Oaks, California 91320-1799

This product, its production, and/or its use may be covered by one or more US Patents, including US Patent Nos. 5,824,784; 5,582,823; 5,580,755, as well as other patents or patents pending.

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1-800-77-AMGEN (1-800-772-6436)

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