approved 7-23-2007

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 *E coli*. G-CSF is a substance naturally 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.

What is Neulasta® used for?

Neulasta® is used to treat neutropenia (nu-tro-**peen**-ee-ah), a condition where the body makes too few neutrophils. Neutropenia can be caused by drugs used to treat cancer.

How does Neulasta® work?

Neulasta® works by helping your body make more neutrophils. To make sure Neulasta® is working, the doctor will ask that the patient have blood tests to count the number of neutrophils. It is important to follow the doctor's instructions about these tests.

Who should not take Neulasta®?

Do not take Neulasta® if you are:

- Allergic to Neulasta® (pegfilgrastim) or any of its ingredients, or to NEUPOGEN® (Filgrastim). See the end of this leaflet for a list of ingredients in Neulasta®.
- Allergic to other medicines made using the bacteria *E coli*. Ask your doctor if you are not sure.

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

Neulasta® can reduce the chance of infection, but it does not prevent all infections. An infection can still happen during the time when your neutrophil levels are low. You must be alert and look for some of the common signs or symptoms of infection, such as fever, chills, rash, sore throat, diarrhea, or redness, swelling, or pain around a cut or sore. If you notice any of these signs or symptoms during treatment with Neulasta®, tell your doctor or nurse immediately.

Occasionally a reaction may develop 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.

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.

Make sure your doctor knows about all medicines and all herbal and vitamin supplements you are taking before starting Neulasta®. If you are taking lithium, you may need more frequent blood tests.

The doctor, nurse, or caregiver will usually inject the dose of Neulasta® a day after the last dose of chemotherapy in each cycle. Neulasta® should only be injected on the day the doctor has determined and should not be injected until approximately 24 hours after receiving chemotherapy.

More information about Neulasta® is available in the Physician Package Insert. 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.

- **Serious Allergic Reactions.** Neulasta® can cause serious allergic reactions. These reactions can cause a rash over the whole body, shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, and sweating. 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 right away.

- **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.

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.

Some people experience redness, swelling, or itching at the site of injection. This may be an allergy to the ingredients in Neulasta®, or it may be a local reaction. If you notice signs of a local reaction, call your doctor.

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®.

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:

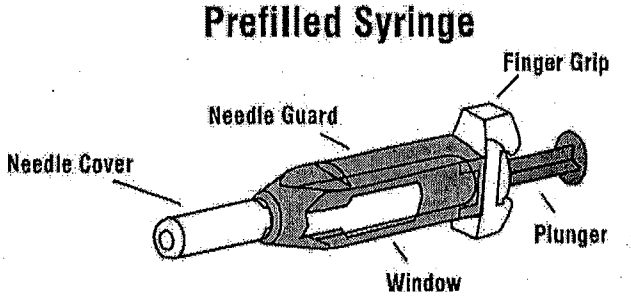
- The name Neulasta® appears on the carton and prefilled syringe label.
- The expiration date on the prefilled syringe has not passed. **You should not use a prefilled syringe after the date on the label.**
- The Neulasta® liquid should always be clear and colorless. Do not use Neulasta® if the contents 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

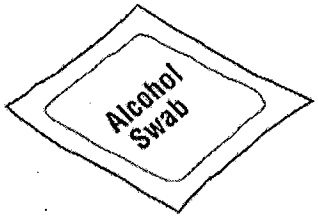
1. Find a clean, flat working surface, such as a table.
2. Remove the carton containing the prefilled syringe of Neulasta® from the refrigerator. Allow Neulasta® to reach room temperature (this takes about 30 minutes). Remove the syringe from the carton before injection. Each prefilled syringe should 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

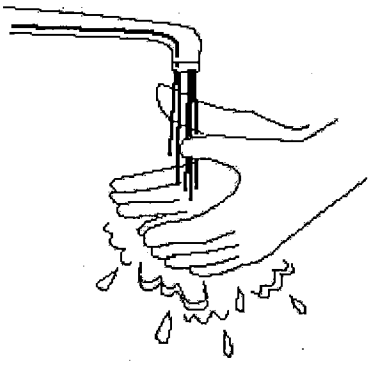
Alcohol Swab



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.

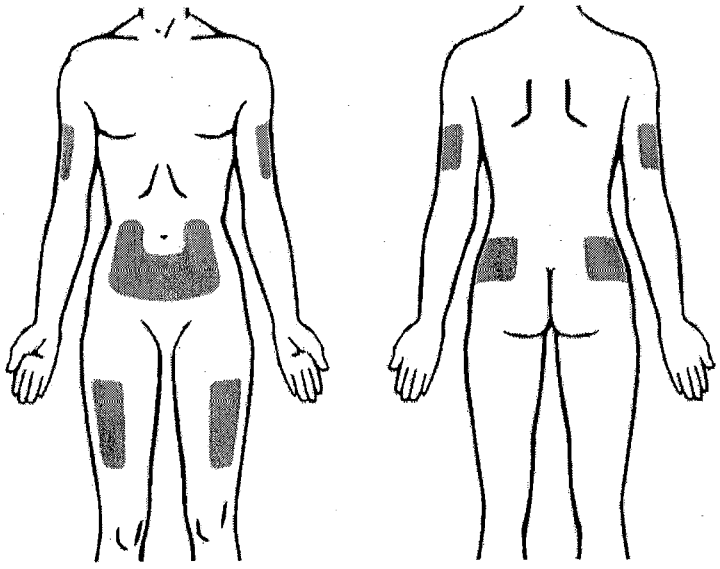
7. Check the syringe for air bubbles. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.

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

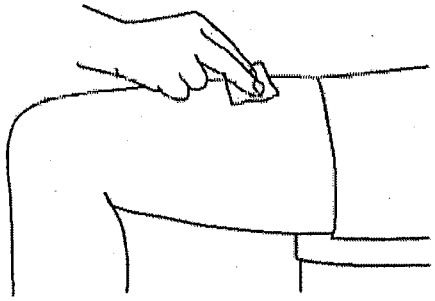
Selecting and preparing the injection site

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



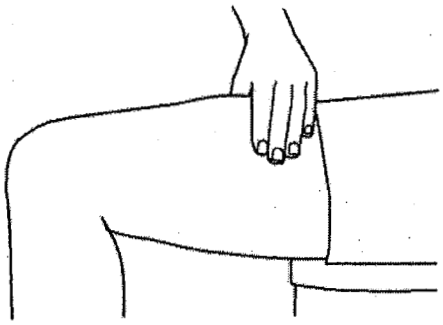
10. Clean the injection site with an alcohol swab.



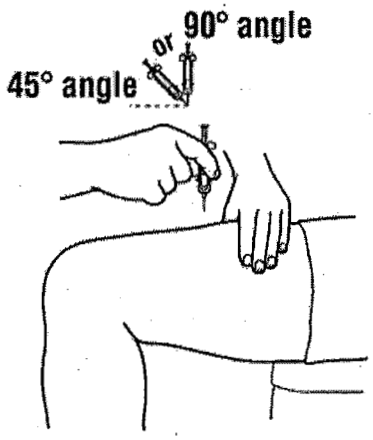
Injecting the dose of Neulasta®

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.

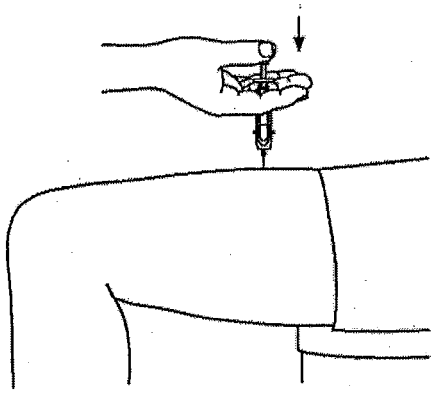
12. Hold the syringe in the hand you will use to inject Neulasta®. Use the other hand to pinch a fold of skin at the cleaned injection site. Note: Hold the syringe barrel through the needle guard windows when giving the injection.



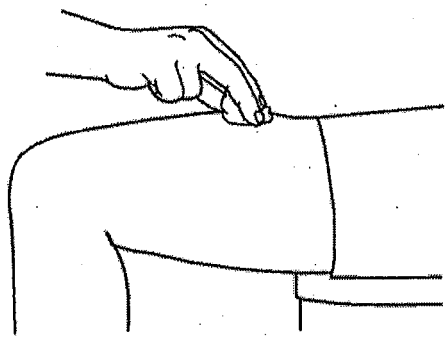
13. Holding the syringe like a pencil, use a quick "dart-like" motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.



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®.



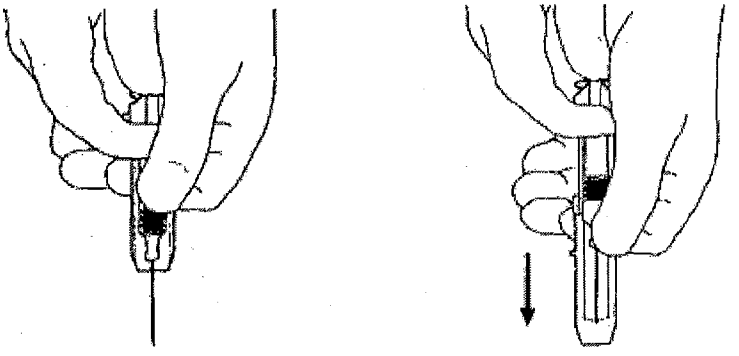
15. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.



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 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.

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.

[Amgen Logo]

Manufactured by:

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