PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]NEULASTA® (pronounced *nu-las-tah*)

pegfilgrastim injection

Read this carefully before you start taking **Neulasta** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Neulasta**.

Serious Warnings and Precautions

- Your spleen may become enlarged and can rupture while taking Neulasta. A ruptured spleen can cause death. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area.
- If you have a sickle cell trait or sickle cell disease, make sure that you tell your doctor before you start taking Neulasta so that the potential risks and benefits can be discussed. In patients with sickle cell trait or sickle cell disease, severe sickle cell crises have been associated with the use of Neulasta. Severe sickle cell crises, in some cases resulting in death, have also been associated with filgrastim, the parent compound of pegfilgrastim (Neulasta).

What is Neulasta used for?

Neulasta is used to treat neutropenia (nu-tro-**peen**-ee-ah). Neutropenia is a condition where the body makes too few white blood cells and which may be caused by drugs used to treat cancer. Neutropenia is the most serious common side-effect of chemotherapy. Neutropenia predisposes your body to infections and prevents you from fighting them. Your doctor has decided to prescribe Neulasta for you to increase the number of neutrophils (**nu**-tro-fils), which will fight infections.

Neulasta is a man-made, long-acting form of granulocyte colony-stimulating factor (G-CSF), a substance naturally produced by the body.

How does Neulasta work?

Neulasta works by stimulating the bone marrow to make white blood cells. To make sure Neulasta is working, your doctor may ask that you have regular blood tests to count the number of white blood cells. It is important to follow the doctor's instructions about these tests.

What are the ingredients in Neulasta?

Medicinal ingredients: pegfilgrastim

Non-medicinal ingredients: polysorbate 20, sodium acetate, sorbitol, water for injection.

The needle cover on the prefilled syringe contains a derivative of latex (dry natural rubber). If you know you are allergic to latex, talk to your healthcare provider before using Neulasta.

Neulasta comes in the following dosage forms:

Neulasta comes in prefilled syringes containing 6 mg of pegfilgrastim, the active substance.

Do not use Neulasta if you are:

- allergic to pegfilgrastim (Neulasta), filgrastim (Neupogen®), or any of the ingredients of Neulasta.
- allergic to other products made using the bacteria *Escherichia coli*. Talk to your doctor if you have any questions about this information.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Neulasta. Talk about any health conditions or problems you may have, including:

- If you have common signs 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 symptoms during treatment with Neulasta, tell your doctor or nurse immediately. Neulasta can reduce the risk of infection, but it may not prevent all infections. An infection can still happen during the short time when your white blood cell levels are low.

- If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your doctor. Occasionally a problem may develop at the injection site.

- If you have sickle cell trait or sickle cell disease, tell your doctor prior to treatment. If you develop left upper abdominal pain or pain at the tip of your shoulder, tell your doctor or nurse immediately.

Other warnings you should know about:

Your doctor will decide if you are able to give yourself a subcutaneous (ie, under the skin) injection. Neulasta should only be injected on the day the doctor has determined for you, and should not be injected until 24 hours after receiving your last dose of chemotherapy in each cycle. (If you are injecting someone else with Neulasta, it is important that you inform yourself about Neulasta to know how and when to give the Neulasta injection.)

Make sure your doctor knows about all medications you are taking before starting Neulasta injections. Patients taking lithium may need more frequent blood tests.

More information about Neulasta is available in the Product Monograph. Any questions should be discussed with your doctor.

Pregnancy or breast feeding and Neulasta

Neulasta has not been studied in pregnant women, and its effects on developing babies are not known. It is possible that Neulasta can get into human breast milk. If you are pregnant, plan to become pregnant, think you may be pregnant, or are breast feeding, you should consult your doctor before using Neulasta.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Neulasta:

Drug interactions between Neulasta and other drugs have not been studied. Drugs such as lithium may affect the release of neutrophils into the blood stream. You should discuss your treatment with your doctor before using Neulasta.

How to take Neulasta:

Neulasta is available in a prefilled syringe. Neulasta should be stored in its carton to protect it from light until use. If you are giving someone else Neulasta injections, it is important that you know how to inject Neulasta.

Before a Neulasta injection is given, always check to see that:

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

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

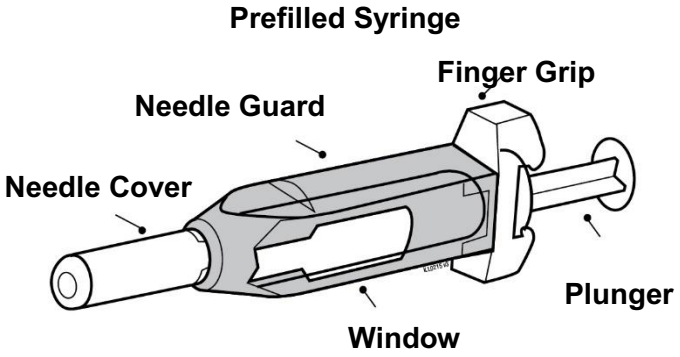
<u>Setting up for an injection</u>

1. Find a comfortable, well-lit working place for injecting Neulasta.

2. Remove the prefilled syringe of Neulasta from the refrigerator and check the date on the prefilled syringe to be sure that the Neulasta has not expired. **Do not use a prefilled syringe of Neulasta after the date on the label.**

3. Allow Neulasta to reach room temperature (this takes about 30 minutes). Neulasta should not be left at room temperature for more than 72 hours. Each prefilled syringe is designed to be used only once. DO NOT SHAKE THE PREFILLED SYRINGE. Shaking too hard or for too long may damage the Neulasta. If the prefilled syringe has been shaken vigorously, the solution may appear foamy and it should not be used.

4. Assemble the supplies needed for an injection:
    - Neulasta prefilled syringe with transparent (clear) blue plastic needle guard attached.



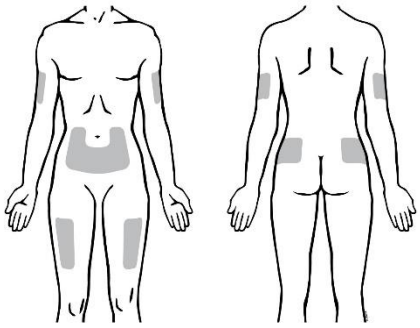
- alcohol swab and a cotton ball or gauze
- puncture-proof disposal container

5. Clean the work area.

6. Wash your hands thoroughly with soap and water before preparing for the injection.

Selecting and preparing the injection site

7. Find a site for injection prior to preparing the prefilled syringe. Alternate the injection site each time you inject Neulasta. The usual sites for injections are:
   - Back of the upper arms
   - Abdomen, except for the navel and waist
   - Upper thighs
   - Upper outer areas of the buttocks



8. Clean the injection site with an alcohol swab. Use a circular motion from the inside to the outside of the injection site.

Preparing the Neulasta prefilled syringe for injection

9. Remove the syringe from the package and the tray. Check to see that the plastic blue needle guard is covering the barrel of the 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 and discard it in the puncture-proof disposal container. Use a new syringe.

10. Hold the syringe with the needle pointing up. Carefully pull the needle cover straight off. Put the syringe needle cover into the disposal container. Take care not to touch the needle. Holding the syringe with the needle pointing up helps reduce the amount of medicine that may leak out of the needle.

11. Check the syringe for air bubbles. If there are bubbles, hold the syringe with the needle pointing upward and pull back on the plunger slightly to remove any Neulasta that may be inside the needle. Gently tap the syringe until the bubbles rise to the top of the syringe barrel. Then slowly push the plunger, forcing the bubbles but not the liquid out of the syringe.

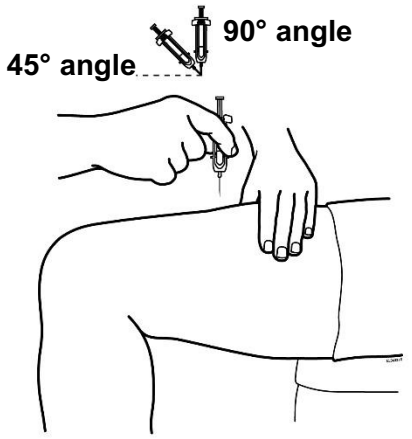
12. Do not lay the syringe down or allow the needle to touch anything.

Injecting the dose from a Neulasta prefilled syringe

13. Holding the syringe in one hand, use the other hand to pinch a fold of skin at the previously prepared injection site.

    NOTE: Hold the syringe barrel through the two needle guard windows when giving the injection.

14. Holding the syringe like a pencil, insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) to the skin.

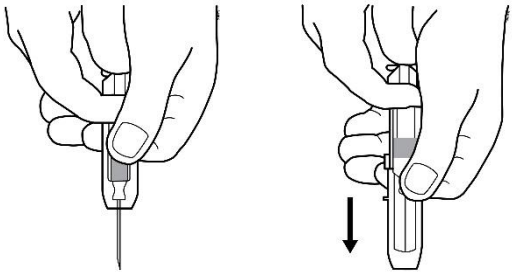


15. After the needle is in, let go of the skin. Inject the prescribed dose subcutaneously as directed by your doctor, nurse or pharmacist.

16. Pull the needle out of the skin, place the cotton ball or gauze over the injection site, and press for several seconds.

Activating the needle guard on used prefilled syringes

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



Disposing of syringes and needles

18. Dispose of the entire prefilled syringe as directed by your doctor, or by following these steps:

- Do not put the needle cover back on the used needle.
- Place all needle covers and used prefilled syringes in a labeled hard-plastic container with a screw-on cap, or a labeled metal container with a plastic lid, such as a coffee can. 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. When the container is full, tape around the cap or lid and dispose of the container according to your doctor's instructions.
- Do not use glass or clear plastic containers.
- Always store the container out of the reach of children.
- Please check with your doctor, nurse, or pharmacist for instructions on how to properly dispose of the filled container.
- **Do not throw the container in household trash. Do not recycle.**

Usual dose:

The recommended dosage of Neulasta is a single subcutaneous injection, just under the skin, of 6 mg (the contents of one prefilled syringe), administered once per cycle of chemotherapy. You must wait at least 24 hours after your course of cancer chemotherapy before injecting Neulasta.

Overdose:

If you think you, or a person you are caring for, have taken too much Neulasta, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

As there should be a two-week period between Neulasta and your next course of cancer chemotherapy, if you miss a planned dose, consult your doctor before taking the missed dose.

What are possible serious side effects of Neulasta?

These are not all the possible side effects you may experience when taking Neulasta. If you experience any side effects not listed here, tell your healthcare professional.

- **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.** Serious allergic reactions can also happen. These reactions may cause a rash over the whole body, shortness of breath, wheezing, a drop in blood pressure (usually causing dizziness or lightheadedness), swelling around the mouth or eyes, fast pulse, or sweating. If you experience an allergic reaction during the injection of Neulasta, the injection should be stopped immediately. **If at any time a serious allergic reaction occurs, immediately call a doctor or emergency services (for example, call 911).**
- **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.
- **Kidney injury (glomerulonephritis)** has been seen in patients who received Neulasta. Call your doctor immediately if you experience puffiness in your face or ankles, blood in your urine or brown coloured urine, or if you notice that you urinate less often than usual.

What are the most common side effects of Neulasta?

The most common side effect that you may experience is aching in the bones and muscles. If this occurs, it can usually be relieved with a non-acetylsalicylic acid over-the-counter pain reliever. Ask your doctor which is the most suitable one for you.

Some patients 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 any of these signs or symptoms, call your doctor.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNCOMMON ≥ 0.1% and < 1%			
Bone Pain		√	
Low platelet counts (thrombocytopenia) (including the following symptoms: easy bruising and increased bleeding).		√	
Allergic reactions (including the following symptoms: rash over the whole body, shortness of breath, a drop in blood pressure (usually causing dizziness or lightheadedness), swelling around the mouth or eyes, fast pulse, weakness, sweating; severe redness or swelling or itching at injection site)		√	√

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Acute respiratory distress syndrome (including the following symptoms: fever, shortness of breath, cough, or congestion in your lungs)		√	√
VERY RARE < 0.01%			
Splenomegaly (including the following symptoms: pain in the left upper stomach area or left shoulder tip area)		√	
***FREQUENCY NOT KNOWN**			
Splenic rupture (including the following symptoms: left upper abdominal pain or pain at the tip of your shoulder)		√	
Cutaneous Vasculitis (including the following symptoms: A rash in the skin surface that looks like purple or red spots or bumps, clusters of small dots, splotches or hives. Your skin may also be itchy.)		√	
Capillary Leak Syndrome (including the following symptoms: swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness)		√	
Kidney Injury (glomerulonephritis) (including the following symptoms: puffiness in the face or ankles, blood in urine or brown coloured urine, or urinating less often than usual).		√	√
**Abnormal number of immature bone marrow cells (myelodysplastic syndrome) that could lead to a type of cancer (acute myeloid leukemia) (including the following symptoms: fever, bone pain, bruising, difficulty breathing, bleeding and a general feeling of tiredness).		√	√

*Reported in the post-marketing setting where the incidence is not known.

**Adverse events in breast and lung cancer patients receiving chemotherapy and/or radiotherapy

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Neulasta should be stored in the refrigerator at 2° to 8°C (36° to 46°F), but not in the freezer. Keep the container in the outer carton to protect from light. Avoid shaking Neulasta. If Neulasta is accidentally frozen, allow it to thaw in the refrigerator before giving the next dose. However, if it is frozen a second time, do not use it and contact your doctor or nurse for further instructions. Neulasta can be left out at room temperature for up to 72 hours. Keep out of reach of children. For any questions about storage, contact your doctor or nurse.

Keep out of reach and sight of children.

If you want more information about Neulasta:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html: the manufacturer's web site (www.amgen.ca), or by calling Amgen Canada Inc., at: 1-866-502-6436.

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