Patient Information
Neulasta® (nu-las-tah)
(pegfilgrastim)
injection
Single-Dose Prefilled Syringe and Single-Dose Vial

What is Neulasta?

Neulasta is a prescription medicine that is used:

- in adults and children aged newborn and older 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.
- in adults and children aged newborn and older for acute radiation syndrome. The effectiveness of Neulasta for this use was only studied in animals, because it could not be studied in people.

Do not take Neulasta if you have had a serious allergic reaction to pegfilgrastim or filgrastim.

Before you receive Neulasta, tell your healthcare provider about all of your medical conditions, including if you:

- have a sickle cell disorder.
- have kidney problems.
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (derived from latex). You should not give Neulasta using the prefilled syringe if you have latex allergies.
- are pregnant or plan to become pregnant. It is not known if Neulasta will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Neulasta passes into your breast milk.

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

How will I receive Neulasta?

- **Neulasta is given as an injection under your skin (subcutaneous injection) by a healthcare provider. If your healthcare provider decides that the subcutaneous injections can be given at home by you or your caregiver, follow the detailed "Instructions for Use" that comes with your Neulasta for information on how to prepare and inject a dose of Neulasta using the single-dose prefilled syringe.**
- You and your caregiver will be shown how to prepare and inject Neulasta using the single-dose prefilled syringe before you use it.
- For children weighing less than 99 pounds (45 kg), your healthcare provider will prepare and give the dose of Neulasta.
- If you are receiving Neulasta because you are also receiving chemotherapy, the last dose of Neulasta should be injected at least 14 days before and 24 hours after your dose of chemotherapy.
- If you miss a dose of Neulasta, talk to your healthcare provider about when you should give your next dose.
- If you inject too much Neulasta, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of Neulasta?

Neulasta may cause serious side effects, including:

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Call your healthcare provider right away if you have pain in the left upper stomach area or your left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Call your healthcare provider or get emergency help right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** Allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate, and sweating. If you have any of these symptoms, stop using Neulasta and call your healthcare provider or get emergency medical help right away.
- **Sickle cell crises in people with sickle cell disorder.** You may have a severe sickle cell crisis, which could lead to death. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury**. Call your healthcare provider right away if you develop any of the following symptoms:
  - swelling of your face or ankles
  - blood in your urine or dark colored urine
  - you urinate less than usual
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood count during treatment with Neulasta.

- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood count during treatment with Neulasta. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with Neulasta.
- **Capillary Leak Syndrome (CLS).** Neulasta can cause fluid to leak from blood vessels into your body's tissues. 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 than usual
  - trouble breathing
  - swelling of your stomach area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness
- **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML).** If you have breast cancer or lung cancer, when Neulasta is used with chemotherapy and radiation therapy, or with radiation therapy alone, you may have an increased risk of developing a precancerous blood condition called MDS or a blood cancer called AML. Call your healthcare provider if you develop any symptoms of MDS and AML, including tiredness, fever, or easy bruising or bleeding.
- **Inflammation of the aorta (aortitis).** Inflammation of the aorta (the large blood vessel that carries blood from the heart to the body) has happened in people who receive Neulasta. Tell your healthcare provider if you develop fever, stomach (abdominal) pain, feeling tired, or back pain.

The most common side effects of Neulasta are pain in the bones, arms, and legs.

These are not all the possible side effects of Neulasta.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Neulasta single-dose prefilled syringes?

- Store Neulasta in the refrigerator between 36˚F to 46˚F (2˚C to 8˚C).
- **Do not** freeze.
- Keep Neulasta in the original carton to protect from light or physical damage.
- Do not shake Neulasta.
- Take Neulasta out of the refrigerator 30 minutes before use and allow it to reach room temperature, 68˚F to 77˚F (20˚C to 25˚C), before preparing an injection.
- Throw away (dispose of) any unused Neulasta that has been left at room temperature, 68˚F to 77˚F (20˚C to 25˚C), for more than 48 hours.

Keep Neulasta and all medicines out of the reach of children.

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. Do not use Neulasta for a condition for which it was not prescribed. Do not give Neulasta to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Neulasta that is written for health professionals.

What are the ingredients in Neulasta?

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

Manufactured by:
Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799
U.S. License No. 1080

Patent: http://pat.amgen.com/onpro/

For more information go to www.neulasta.com, or call 1-800-77-AMGEN (1-800-772-6436).
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This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 08/2025