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

What is Neulasta?

Neulasta is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection. 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 human G-CSFs such as pegfilgrastim or filgrastim products.

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.**
- You and your caregiver will be shown how to prepare and inject Neulasta before you use it.
- You should not inject a dose of Neulasta to children weighing less than 45 kg from a Neulasta prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the Neulasta prefilled syringe.
- 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.

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 care right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** Neulasta can cause serious allergic reactions. These 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.** You may have a serious sickle cell crisis if you have a sickle cell disorder and receive Neulasta. Serious sickle cell crises have happened in people with sickle cell disorders receiving Neulasta that has sometimes led to death. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** Neulasta can cause 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 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 than usual
  - trouble breathing
  - swelling of your stomach-area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness

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?

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

Keep the Neulasta prefilled syringe 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.

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

For more information go to www.neulasta.com, or call 1-800-77-AMGEN (1-800-772-6436). 1xxxxx v14

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Patient Information

Neulasta® (nu-las-tah) (pegfilgrastim) injection

On-body Injector for Neulasta

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:
    - 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

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 or call 1-844-696-3852 (1-844-MYNEULASTA).

What are the ingredients in Neulasta?

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

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

Neulasta® (pegfilgrastim)

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

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

www.neulasta.com

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