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2. Pegfilgrastim

Pegfilgrastim

Generic name: pegfilgrastim, pegfilgrastim-jmbd, pegfilgrastim-pbbk, pegfilgrastim-apgf, pegfilgrastim-fpgk, pegfilgrastim-cbqv, pegfilgrastim-bmez

Brand names: [Neulasta](#), Neulasta Onpro, [Fulphila](#), [Fylnetra](#), [Nyvepria](#), ... [show all 8 brands](#)

Dosage form: subcutaneous injection, autoinjector, on-body injector

Drug class: [Colony stimulating factors](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Jan 8, 2024.

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What is pegfilgrastim?

Pegfilgrastim ([Neulasta](#), Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca, Ziextenzo) is a man-made version of granulocyte colony-stimulating factor (G-CSF), which is a growth factor produced by your body. G-CSF stimulates your bone marrow to produce a type of white blood cell, called neutrophils. Neutrophils are important for fighting off infection.

Pegfilgrastim is used to reduce the risk of infection in some cancer patients and to increase your chances of surviving after exposure to high doses of radiation that affect your ability to make blood cells.

Pegfilgrastim is a leukocyte growth factor that works by binding to a receptor on immature cells called hematopoietic cells, which can develop into any type of blood cell. It makes them grow and turn into functioning neutrophils.

Pegfilgrastim is a pegylated or long-acting form of recombinant G-CSF, which means that it stays in your body for longer and doesn't need to be administered as often.

Pegfilgrastim is a type of biological drug. The original version of pegfilgrastim is called Neulasta and it was approved by the US Food and Drug Administration (FDA) in 2002.

Biosimilars of pegfilgrastim are also available. Biosimilar versions are highly similar to Neulasta and have the same effect on a person, but they are not identical. Biosimilars of pegfilgrastim include:

- Fulphila (pegfilgrastim-jmbd) approved in 2018
- Fylnetra (pegfilgrastim-pbbk) approved in 2022
- Nyvepria (pegfilgrastim-apgf) approved in 2020
- Stimufend (pegfilgrastim-fpgk) approved in 2022
- Udenyca (pegfilgrastim-cbqv) approved in 2018
- Ziextenzo (pegfilgrastim-bmez) approved in 2019

Neulasta and all of the biosimilar versions of pegfilgrastim are given by subcutaneous injection and available as a single-

dose prefilled syringe. The Neulasta brand can also be given by subcutaneous injection using an on-body injector called Neulasta Onpro. The Udenyca brand is also available as a prefilled autoinjector and an on-body injector called Udenyca Onbody.

What is pegfilgrastim used for?

Pegfilgrastim is a prescription medication used to decrease the risk of infection, demonstrated by the presence of febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs that are likely to cause febrile neutropenia.

Some brands (such as Neulasta and Udenyca) are also approved to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Pegfilgrastim is not approved for use in the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important information

Important information for patients receiving pegfilgrastim using an **on-body injection (Neulasta Onpro kit or Udenyca Onbody)**.

- See the Instructions for use for the on-body injector for detailed information.
 - Know the time that delivery of your dose is expected to start.
 - Avoid traveling, driving, or operating heavy machinery during hours 26 through hour 29 after the on-body injector is applied. Avoid activities and places that may interfere with monitoring during the 45 minutes (Neulasta Onpro) or 5 minutes (Udenyca Onbody) that the medication is expected to be delivered by the on-body injector, and for 1 hour after delivery.
- A caregiver should be with you the first time that you receive this medication with the on-body injector.
- Before your next scheduled dose, avoid the use of lotions, creams, or oils on your arms and stomach area (abdomen) to help keep the device on your skin.
- If placed on the back of the arm, a caregiver must be available to monitor the status of the on-body injector.
- If you have an allergic reaction during the delivery of the medication, remove the on-body injector by grabbing the edge of the adhesive pad and peeling off the on-body injector. Get emergency medical help right away.
- You should only receive a dose of the medication on the day your healthcare provider tells you.
- You should not receive your dose any sooner than 24 hours after you finish receiving your chemotherapy. The on-body injector is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector on your skin.
- Do not expose the on-body injector to the following because it may be damaged and you could be injured:
 - Diagnostic imaging (e.g., CT Scan, MRI, ultrasound, X-ray)
 - Radiation treatment
 - 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 from being accidentally removed.

- Keep the on-body injector at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves, and other common appliances. If the on-body injector is too close to electrical equipment, it may not work correctly and can lead to a missed or incomplete dose of your medication.
- The on-body injector is for adult patients only.
- If your on-body injector is not working properly, you may miss your dose or you may not receive your full dose. If you miss your dose or do not receive your full dose, you may have an increased risk of developing a fever or infection.
- Call your healthcare provider right away, as you may need a replacement dose if any of the following occur:
 - the on-body injector comes off before or during a dose delivery. Do not re-apply it.
 - the on-body injector is leaking.
 - the adhesive on your on-body injector becomes noticeably wet (saturated) with fluid, or there is dripping. This may mean that the medication is leaking out of your on-body injector. If this happens you may only receive some of your dose, or you may not receive a dose at all.
 - the on-body injector status light is flashing red.

Who should not take pegfilgrastim?

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

 [Pegfilgrastim pregnancy and breastfeeding warnings](#) (more detail)

What should I tell my doctor before receiving pegfilgrastim?

Before you receive this medication, 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 and are receiving the Neulasta, Stimufend, or Ziextenzo brands of pegfilgrastim. The needle cap on the prefilled syringe for these brands contains dry natural rubber (derived from latex). You should not use these brands if you have a latex allergy.

The needle caps on the prefilled syringes for Fulphila, Fylnetra, Nyvepria, and Udenyca are not made with natural rubber latex.

How should I receive pegfilgrastim?

Receiving pegfilgrastim using a single-dose prefilled syringe

- Pegfilgrastim 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 come with your medication for information on how to prepare and inject a dose.

- You and your caregiver will be shown how to prepare and inject this medication before you use it.
- You should not inject a dose of pegfilgrastim into children weighing less than 45 kg from a prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the prefilled syringe.
- If you are receiving this medication because you are also receiving chemotherapy, the last dose of it should be injected at least 14 days before and 24 hours after your dose of chemotherapy.

Receiving pegfilgrastim using a prefilled autoinjector

- Only adults can self-administer the Udenyca prefilled autoinjector.
- Ensure you receive training from your healthcare provider about how to administer the autoinjector. See the package instructions for detailed administration details.
- When a full dose has been administered you will hear a second click and the orange indicator will completely block the viewing window.

Receiving pegfilgrastim using an on-body injector

See the Instructions for use that come with your on-body injector for detailed information about how you will receive a dose of pegfilgrastim with the on-body injector, and how to remove and dispose of the on-body injector.

- See the section "Important information" above
- Pegfilgrastim is given as an injection under the skin (subcutaneous). Your healthcare provider will use a prefilled syringe with this medication in it to fill the on-body injector before applying it. The prefilled syringe and the on-body injector are provided to your healthcare provider as part of the Neulasta Onpro or Udenyca Onbody kit. The on-body injector will be applied to the stomach area (abdomen) or back of your arm by your healthcare provider. If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor it.
- Your healthcare provider should place the on-body injector 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 application area after it has been applied.
- The on-body injector is programmed to deliver your dose about 27 hours after your healthcare provider places it on your skin.
- The dose of pegfilgrastim will be delivered over about 45 minutes (Neulasta Onpro) or 5 minutes (Udenyca Onbody). 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 to make sure you receive your full dose and watch for symptoms of an allergic reaction.
- Your healthcare provider will show you how to monitor the on-body injector to make sure delivery has been completed.
- Keep the on-body injector 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 it.
- Only expose the on-body injector to temperatures between 41°F to 104°F (5°C to 40°C).

What happens if I miss a dose?

If you miss a dose of pegfilgrastim, talk to your healthcare provider about when you should give your next dose.

What should I avoid while using pegfilgrastim?

If you are receiving pegfilgrastim using an on-body injector, while the on-body injector is in place you should avoid:

- traveling, driving, or operating heavy machinery during hours 26 through hour 29 after the on-body injector is applied
- exposure to medical imaging studies (such as X-rays, MRI, CT scans or ultrasounds), radiation treatment, and oxygen-rich environments such as hyperbaric chambers
- sleeping on the on-body injector, or applying pressure on it. It may not work properly
- bumping the on-body injector or knocking it off your body
- using other materials to hold the on-body injector in place. Using other materials could cover audio or visual indicators or press the on-body injector against your skin, and lead to a missed dose or incomplete dose
- getting body lotion, creams, oils, and skin cleansing products near the on-body injector. These products may loosen the adhesive that holds the on-body injector onto your body
- using bathtubs, hot tubs, whirlpools, saunas, and direct sunlight. These may affect your medication
- peeling off or disturbing the on-body injector adhesive before you receive your full dose.

Dosing information

Pegfilgrastim dosing information for patients with cancer receiving myelosuppressive chemotherapy

- Pegfilgrastim 6 mg. Administer subcutaneously once per chemotherapy cycle.
- Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
- Use weight-based dosing for pediatric patients weighing less than 45 kg.

Body weight	Pegfilgrastim dose	Volume to administer
Less than 10kg	See below*	See below*
10-20kg	1.5mg	0.15ml
21-30kg	2.5mg	0.25ml
31-44kg	4mg	0.4ml

*For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of pegfilgrastim

Pegfilgrastim (Neulasta and Udenyca brands) dosing information for patients acutely exposed to myelosuppressive doses of radiation

- Administer two doses of pegfilgrastim 6 mg, subcutaneously, one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation, and a second dose one week after.
- Use weight-based dosing for pediatric patients weighing less than 45 kg; refer to the table above under pegfilgrastim dosing information for patients with cancer receiving myelosuppressive chemotherapy.

What are the possible side effects of pegfilgrastim?

Pegfilgrastim 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. This medication 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 this medication and call your healthcare provider or get emergency medical help right away.
- Sickle cell crises. You may have a serious sickle cell crisis, which could lead to death if you have a sickle cell disorder and receive this medication. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- Kidney injury (glomerulonephritis). This medication 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.
- Decreased platelet count (thrombocytopenia). Your healthcare provider will check your blood during treatment. Tell your healthcare provider if you have unusual bleeding or bruising during treatment. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- Capillary Leak Syndrome. Pegfilgrastim 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 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 and acute myeloid leukemia. 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 myelodysplastic syndrome (MDS) or a blood cancer called acute myeloid leukemia (AML). Symptoms of MDS and AML may include tiredness, fever, and easy bruising or bleeding. Call your healthcare provider if you develop these symptoms during treatment.
- Inflammation of the aorta (aortitis). Inflammation of the aorta (the large blood vessel that transports blood from the heart to the body) has been reported in patients who received pegfilgrastim. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.

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

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

 [Pegfilgrastim side effects](#) (more detail)

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Interactions

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

 [Pegfilgrastim drug interactions](#) (more detail)

Does pegfilgrastim interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

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Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant. It is not known if pegfilgrastim will harm your unborn baby.

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if pegfilgrastim passes into your breast milk.

Storage

The storage instructions for pegfilgrastim vary according to the brand you use.

Neulasta single-dose prefilled syringe storage instructions

- 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 it 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.

Fulphila, Fynetra, Nyvepria, Stimufend, Udenyca and Ziextenzo single-dose prefilled syringe storage instructions

- Store **Fulphila, Fynetra, Nyvepria, Stimufend, Udenyca, and Ziextenzo** in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Take **Fulphila, Fynetra, Nyvepria, Stimufend, and Udenyca** out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Take **Ziextenzo** out of the refrigerator for at least 15 to 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Avoid freezing. If **Fulphila, Fynetra, Nyvepria, Udenyca, or Ziextenzo** are accidentally frozen, allow the prefilled syringe to thaw in the refrigerator before injecting. If **Stimufend** is frozen then throw it away.
- Do not use a **Fulphila, Fynetra, Nyvepria, Udenyca, or Ziextenzo** prefilled syringe that has been frozen more than 1 time. Use a new **Fulphila, Fynetra, Nyvepria, Udenyca, or Ziextenzo** prefilled syringe.
- Keep the prefilled syringe in the original carton to protect it from light or physical damage.
- Do not shake the prefilled syringe.
- Throw away (dispose of) any pegfilgrastim that has been left at room temperature, 68°F to 77°F (20°C to 25°C) for more than:
 - **Fulphila:** 72 hours or frozen more than 1 time
 - **Fynetra:** 72 hours or frozen more than 1 time
 - **Nyvepria:** 15 days
 - **Stimufend:** 72 hours or frozen
 - **Udenyca:** 48 hours or frozen more than 1 time
 - **Ziextenzo:** 120 hours

Keep the pegfilgrastim prefilled syringe out of the reach of children.

Udenyca prefilled autoinjector

- Store in the refrigerator between 36°F to 46°F (2°C to 8°C). Do not freeze.
- Discard if stored at room temperature for more than 48 hours.

- Do not shake.

Udenyca Onbody kit (on-body injector)

- Store the kit in the refrigerator at 36°F to 46°F (2°C to 8°C) until 30 minutes before use.
- If the kit is stored at room temperature for more than 12 hours, do not use it. Start again with a new kit.
- Keep the prefilled syringe in the kit carton until used to protect it from light.
- Do not freeze the kit.
- Do not separate the components of the Udenyca Onbody kit until ready for use.

Neulasta Onpro kit (on-body injector)

- Store the kit in the refrigerator at 36°F to 46°F (2°C to 8°C) until ready for use. If the kit is stored at room temperature for more than 12 hours, do not use it. Start again with a new kit.
- Keep the prefilled syringe in the kit carton until used to protect it from light.
- Do not freeze the kit.
- Do not separate the components of the Neulasta Onpro kit until ready for use.

What are the ingredients in pegfilgrastim?

Neulasta

Active: pegfilgrastim

Inactive: acetate, polysorbate 20, sodium, and sorbitol in water for injection.

Fulphila

Active: pegfilgrastim-jmbd

Inactive: acetate, D-sorbitol, polysorbate 20, and sodium in water for Injection.

Fylnetra

Active: pegfilgrastim-pbbk

Inactive: acetic acid, polysorbate 20, sodium hydroxide, and sorbitol in water for injection.

Nyvepria

Active: pegfilgrastim-apgf

Inactive: acetate, polysorbate 20, sodium, and sorbitol in water for injection.

Stimufend

Active: pegfilgrastim-fpgk

Inactive: acetate, polysorbate 20, sodium, and sorbitol in water for injection, USP.

Udenyca

Active: pegfilgrastim-cbqv

Inactive: acetate, polysorbate 20, sodium, and sorbitol in water for injection.

Ziextenzo

Active: pegfilgrastim-bmez

Inactive: acetic acid, polysorbate 20, sorbitol, and water for Injection. Sodium hydroxide may be added as necessary to adjust pH.

Manufacturer

- Nelasta: Amgen Inc.
- Fulphila: Mylan Pharmaceuticals Inc.
- Fylnetra: Kashiv BioSciences, LLC.
- Nyvepria: Hospira, Inc.
- Stimufend: Fresenius Kabi USA, LLC.
- Udenyca: Coherus BioSciences, Inc.
- Ziextenzo: Sandoz Inc.

Pegfilgrastim Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There are 2 for pegfilgrastim.

Neulasta (pegfilgrastim) - Amgen Inc.



Formulation type	Strength
Pre-Filled Syringe	6 mg/0.6 mL

View [Neulasta](#) information in detail.

Neulasta Onpro (pegfilgrastim) - Amgen Inc.



Neulasta, Neulasta Onpro biosimilar products

Biosimilar products can only be dispensed in place of the **reference product** if the healthcare provider specifically prescribes the biosimilar product by name.

Pharmacy laws for biosimilar prescribing may vary by state

Fulphila (pegfilgrastim-jmdb) - Biocon Biologics Inc.



Fylnetra (pegfilgrastim-pbbk) - Kashiv BioSciences, LLC



Nyvepria (pegfilgrastim-apgf) - Hospira Inc., a Pfizer Company



Stimufend (pegfilgrastim-fpgk) - Fresenius Kabi USA, LLC



Udenyca (pegfilgrastim-cbqv) - Coherus BioSciences, Inc.



Udenyca Onbody (pegfilgrastim-cbqv) - Coherus BioSciences, Inc.



Ziextenzo (pegfilgrastim-bmez) - Sandoz Inc.



Popular FAQ

What is the difference between Fulphila and Neulasta?



What is the difference between Udenyca and Neulasta?



How is Fulphila injected / administered?



Is Fulphila a chemo drug?



What is the difference between Udenyca and Fulphila?



What does cbqv stand for in pegfilgrastim?



More FAQ

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- [How long do the side effects of the Neulasta \(pegfilgrastim\) shot last?](#)

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References

1. [National Library of Medicine Fulphila Product Label](#)
2. [National Library of Medicine Ziextenzo Product Label](#)
3. [National Library of Medicine Nyvepria Product Label](#)
4. [National Library of Medicine Fylnetra Product Label](#)
5. [National Library of Medicine Neulasta Product Label](#)
6. [Food and Drug Administration \(FDA\) Stimufend Product Label](#)
7. [Udenyca Product Label](#)

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Other brands

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only

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 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

 Drug history at FDA



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[Neulasta \(pegfilgrastim\) 6 mg prefilled syringe](#)



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