

Pegfilgrastim-xxxx (Neulasta, Neulasta Onpro, Fulphila, Udenyca, Nyvepria, Ziextenzo)

About This Drug

Pegfilgrastim-xxxx belongs to a class of medicines called granulocyte colony-stimulating factors (G-CSF). G-CSF helps the body make more white blood cells. White blood cells help fight infection in your body. This drug is given as an injection under the skin (subcutaneously).

Possible Side Effects

- Bone pain
- Pain in your arms and/or legs

Note: Each of the side effects above was reported in 5% or greater of patients treated with pegfilgrastim-xxxx with or without other chemotherapy drugs. Not all possible side effects are included above.

Warnings and Precautions

- Enlargement and inflammation (swelling) of your spleen, which can very rarely rupture and be life-threatening. Signs of enlargement may be left-sided pain in your abdomen and/or shoulder.
- Trouble breathing because of fluid build-up around your lungs and/or inflammation (swelling) of the lungs
- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**
- Severe sickle cell crisis can happen in patients with sickle cell disorders treated with pegfilgrastim-xxxx, which can be life-threatening.
- Changes in your kidney function
- A rapid increase in your white blood cells
- A syndrome where fluid and protein can leak from your blood vessels into your tissues. This can cause a decrease in your blood protein level and blood pressure and fluid can accumulate in your tissues and/or lungs.
- Inflammation of the aorta - symptoms may include fever, abdominal pain, back pain and feeling tired.
- Decrease in the number of platelets. This may raise your risk of bleeding.

- Talk to your doctor about your risk of cancer. This drug may raise your risk of developing conditions such as myelodysplastic syndrome and acute leukemia.
- The on-body injector (OBI) uses acrylic adhesive. Caution should be used if you have an allergy to acrylic adhesives.
- Missed or partial doses of the medication have been reported from the on-body injector device not working properly. This could increase your risk of developing severely low white blood cells, which puts you at a risk of severe and life-threatening infections. If you have any problems with the on-body injector, contact your doctor and/or nurse right away.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

For patients with the pegfilgrastim on-body-injector (OBI) only:

- Avoid activities such as traveling, driving, or operating heavy machinery during hours 26-29 after it is placed.
- Do not use any other materials to hold it in place that could cover the audio/visual indicators or could press down the injector against your skin. Avoid peeling off the adhesive before the full dose of pegfilgrastim has been delivered.
- Keep your OBI dry for the last 3 hours before the dose should be delivered.
- If your OBI comes off before the full dose is delivered, do not try to reapply it. Instead, call your nurse and/or doctor right away.
- Notify your nurse and/or doctor right away if your OBI becomes saturated in fluid, or if there is dripping around the OBI. These could be signs of leaking and could increase the risk of a missed or incomplete dose of pegfilgrastim.
- It is recommended to avoid using lotions, creams, or oils on your arms or abdomen to help keep the device on your skin, especially before your next scheduled dose of the OBI.
- Keep the OBI at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves, and other appliances as it could interfere with the operation of the OBI and cause a missed or incomplete dose of pegfilgrastim.
- Do not expose the OBI to temperatures less than 41°F (5°C) or greater than 104°F (40°C).
- Avoid bumping or knocking your OBI off your body.
- Do not expose your OBI to medical imaging studies such as an X-ray (including airport X-ray scans), MRI, CT scan, or ultrasound. Avoid radiation treatments or oxygen rich places such as hyperbaric chambers. This could increase the risk of damage to your OBI or injury to yourself.
- Avoid sleeping on your OBI or applying pressure on it.
- Avoid using bathtubs, hot tubs, whirlpools, or saunas and avoid exposing your OBI to direct sunlight as this may affect pegfilgrastim.
- When dose delivery starts, it will take about 45 minutes to complete, and the OBI will flash a fast green light.
- Remove OBI after green light shines continuously.



- **Handling:** Wash your hands after before and after handling your OBI. Your caretakers should not handle your OBI with bare hands and should wear latex gloves.
- **Disposal:** Discuss with your nurse or your doctor how to dispose the OBI.

How to Take Your Medication

For pre-filled syringes only:

- Talk to your doctor, nurse, and/or pharmacist for proper preparation, dosing, and administration if you are self-injecting this medicine.
- Do not shake the medicine. You can take it out of the refrigerator 30 minutes before use to allow it to come to room temperature.
- Throw away any medicine that has been left at room temperature for too long (refer to specific product medication guide for more information). Throw away any medicine that has been frozen more than one time.
- **Missed dose:** If you miss a dose, contact your physician right away.
- **Handling:** Wash your hands after before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- The cap of the pre-filled syringe contains latex. Please speak to your doctor if you have a latex allergy. Caregivers with latex allergies should use caution.
- **Storage:** Store this medicine in the refrigerator between 36°F to 46°F (2°C to 8°C). Store this medicine in the original carton to protect it from light. Do not freeze. If accidentally frozen, allow syringe to thaw in refrigerator before use.
- **Disposal:** Discuss with your nurse or your doctor how to dispose of unused medicine/needles.

Treating Side Effects

- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.

Food and Drug Interactions

- There are no known interactions of pegfilgrastim-xxxx with food.
- Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.



When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Cough
- Wheezing and/or trouble breathing
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Tiredness that interferes with your daily activities
- Left-sided pain in your abdomen and/or shoulder
- Back pain
- Decreased urine, very dark urine, or blood in your urine
- Foamy or bubbly-looking urine
- Pain that does not go away or is not relieved by prescribed medicine
- Swelling of the hands, feet, or any other part of the body
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Red flashing light on your OBI and/or any other signs of your OBI not working properly
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** It is not known if this drug may harm an unborn child. For this reason, be sure to talk with your doctor if you are pregnant or planning to become pregnant while receiving this drug. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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