

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

#### **About This Medicine**

PEGFILGRASTIM (PEG fil gra stim) lowers the risk of infection in people who are receiving chemotherapy. It works by helping your body make more white blood cells, which protects your body from infection. It may also be used to help people who have been exposed to high doses of radiation. This medicine is given as an injection under the skin (subcutaneously).

This medicine may be used for other purposes; ask your care team if you have questions.

#### **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 people treated with pegfilgrastimxxxx. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

# **Warnings and Precautions**

- Enlargement and inflammation (swelling) of your spleen, which can very rarely rupture and be lifethreatening. Signs of enlargement may be left-sided pain in your abdomen and/or shoulder.
- Trouble breathing because of fluid build-up in your lungs caused by inflammation (swelling) of the lungs
- Allergic reactions, including anaphylaxis, are rare but may happen in some people. Signs of allergic
  reaction to this medicine 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 medicine. You
  should get urgent medical treatment.
- Severe sickle cell crisis can happen in people with sickle cell disorders treated with pegfilgrastimxxxx, 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 care team about your risk of cancer. This medicine 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 medicine 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 onbody injector, contact your care team right away.

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

## **Important Information**

#### For people 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 care team right away.
- Notify your care team 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, at about 27 hours after placement, 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 with soap and water, 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 care team how to dispose of the OBI.

#### **How to Take Your Medicine**

## For pre-filled syringes only:

- Talk to your care team 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 medicine guide for more information). Throw away any medicine that has been frozen more
  than one time.
- Overdosage: If you think you have taken too much of this medicine contact a poison control center
  or emergency room at once.
- **Missed dose:** If you miss a dose, contact your care team right away.
- **Handling:** Wash your hands with soap and water, 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 care team 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. Keep out of the reach of children and pets.
- **Disposal:** Discuss with your care team how to dispose of unused medicine/needles.

# **Treating Side Effects**

- Keeping your pain under control is important to your well-being. Please tell your care team if you
  are experiencing pain.
- Drink enough fluids to keep your urine pale yellow.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.



#### **Food and Medicine Interactions**

- There are no known interactions of pegfilgrastim-xxxx with food.
- Tell your care team 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 care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

#### When to Call Your Care Team

Call your care team 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
- Severe pain in the left side of your abdomen and/or shoulder
- Back pain
- · Chest 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. If you have an allergic
  reaction during the delivery of Neulasta with the OBI, remove the OBI right away by grabbing
  the edge of the adhesive pad and peeling off the OBI.
- Red flashing light on your OBI and/or any other signs of your OBI not working properly

# **Reproduction Warnings**

- **Pregnancy warning**: Talk with your care team if you are pregnant or planning to become pregnant while taking this medicine. Tell your care team right away if you think you might be pregnant.
- Breastfeeding warning: Talk with your care team about breastfeeding during treatment. You may need to stop breastfeeding.

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