

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrNyvepria™ (pronounced **Nigh-VEP' ree-ah**)

Pegfilgrastim Injection

Read this carefully before you start taking **Nyvepria** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Nyvepria**.

Nyvepria is a biosimilar biologic drug (biosimilar) to the reference biologic drug Neulasta®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Your spleen may become enlarged and can rupture while taking Nyvepria. A ruptured spleen can cause death. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area.
- If you have a sickle cell trait or sickle cell disease, make sure that you tell your doctor before you start taking Nyvepria so that the potential risks and benefits can be discussed. In patients with sickle cell trait or sickle cell disease, severe sickle cell crises have been associated with the use of pegfilgrastim. Severe sickle cell crises, in some cases resulting in death, have also been associated with filgrastim, the parent compound of pegfilgrastim.

What is Nyvepria used for?

Nyvepria is used to treat neutropenia (nu-tro-**peen**-ee-ah). Neutropenia is a condition where the body makes too few white blood cells and which may be caused by drugs used to treat cancer. Neutropenia is the most serious common side-effect of chemotherapy. Neutropenia predisposes your body to infections and prevents you from fighting them. Your doctor has decided to prescribe Nyvepria for you to increase the number of neutrophils (**nu**-tro-fils), which will fight infections.

How does Nyvepria work?

Nyvepria works by stimulating the bone marrow to make white blood cells. To make sure Nyvepria is working, your doctor may ask that you have regular blood tests to count the number of white blood cells. It is important to follow the doctor's instructions about these tests.

What are the ingredients in Nyvepria?

Medicinal ingredients: pegfilgrastim

Non-medicinal ingredients: polysorbate 20, sodium acetate, sorbitol, and water for injection

Nyvepria comes in the following dosage forms:

Prefilled syringe with a BD UltraSafe Plus™ Passive Needle Guard containing 6 mg / 0.6 mL (10 mg/mL) of pegfilgrastim.

The Nyvepria syringe plunger stopper and needle cover are not made with natural rubber latex.

Do not use Nyvepria if:

- You are allergic to pegfilgrastim (Nyvepria), filgrastim, or any of the ingredients of Nyvepria. Check the section above called, “What are the ingredients in Nyvepria?” and the Product Monograph for the list of ingredients in Nyvepria.
- You are allergic to other medicine made using the bacteria *Escherichia coli*. Talk to your doctor if you have any questions about this information.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Nyvepria. Talk about any health conditions or problems you may have, including:

- Nyvepria can reduce the risk of infection, but it may not prevent all infections. An infection can still happen during the short time when your white blood cell levels are low. You and your caregivers must be alert and look for some of the common signs of infection, such as fever, chills, rash, sore throat, diarrhea, or redness, swelling, or pain around a cut or sore. If you notice any of these symptoms during treatment with Nyvepria, tell your doctor or nurse immediately.
- If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your doctor. Occasionally, a problem may develop at the injection site.
- If you have sickle cell trait or sickle cell disease, tell your doctor prior to treatment. If you develop left upper abdominal pain or pain at the tip of your shoulder, tell your doctor or nurse immediately.

Other warnings you should know about:

Your doctor will decide if you are able to give yourself a subcutaneous (i.e., under the skin) injection. Nyvepria should only be injected on the day the doctor has determined for you, and should not be injected until 24 hours after receiving your last dose of chemotherapy in each cycle.

If you are injecting someone else with Nyvepria, it is important that you inform yourself about Nyvepria to know how and when to give the Nyvepria injection.

Make sure your doctor knows about all medications you are taking before starting Nyvepria injections. Patients taking lithium may need more frequent blood tests.

More information about Nyvepria is available in the Product Monograph. Any questions should be discussed with your doctor.

Pregnancy or breast-feeding and Nyvepria

Nyvepria has not been studied in pregnant women, and its effects on developing babies are not known. It is possible that Nyvepria can get into human breast milk. If you are pregnant, plan to become pregnant, think you may be pregnant, or are breast-feeding, you should consult your doctor before using Nyvepria.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Nyvepria:

Drug interactions between Nyvepria and other drugs have not been studied. Drugs such as lithium may affect the release of neutrophils into the blood stream. You should discuss your treatment with your doctor before using Nyvepria.

How to take Nyvepria:

Usual dose:

The recommended dosage of Nyvepria is a single subcutaneous injection, just under the skin, of 6 mg / 0.6 mL (the contents of one prefilled syringe), administered once per cycle of chemotherapy. You must wait at least 24 hours after your course of cancer chemotherapy before injecting Nyvepria.

Overdose:

If you think you, or a person you are caring for, have taken too much Nyvepria, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

As there should be a two-week period between Nyvepria and your next course of cancer chemotherapy, if you miss a planned dose, consult your doctor before taking the missed dose.

How to Prepare and Give Nyvepria Injection

Nyvepria is available in a prefilled syringe. Nyvepria should be stored in its carton to protect it from light until use. If you are giving someone else Nyvepria injections, it is important that you know how to inject Nyvepria.

Before a Nyvepria injection is given, always check to see that:

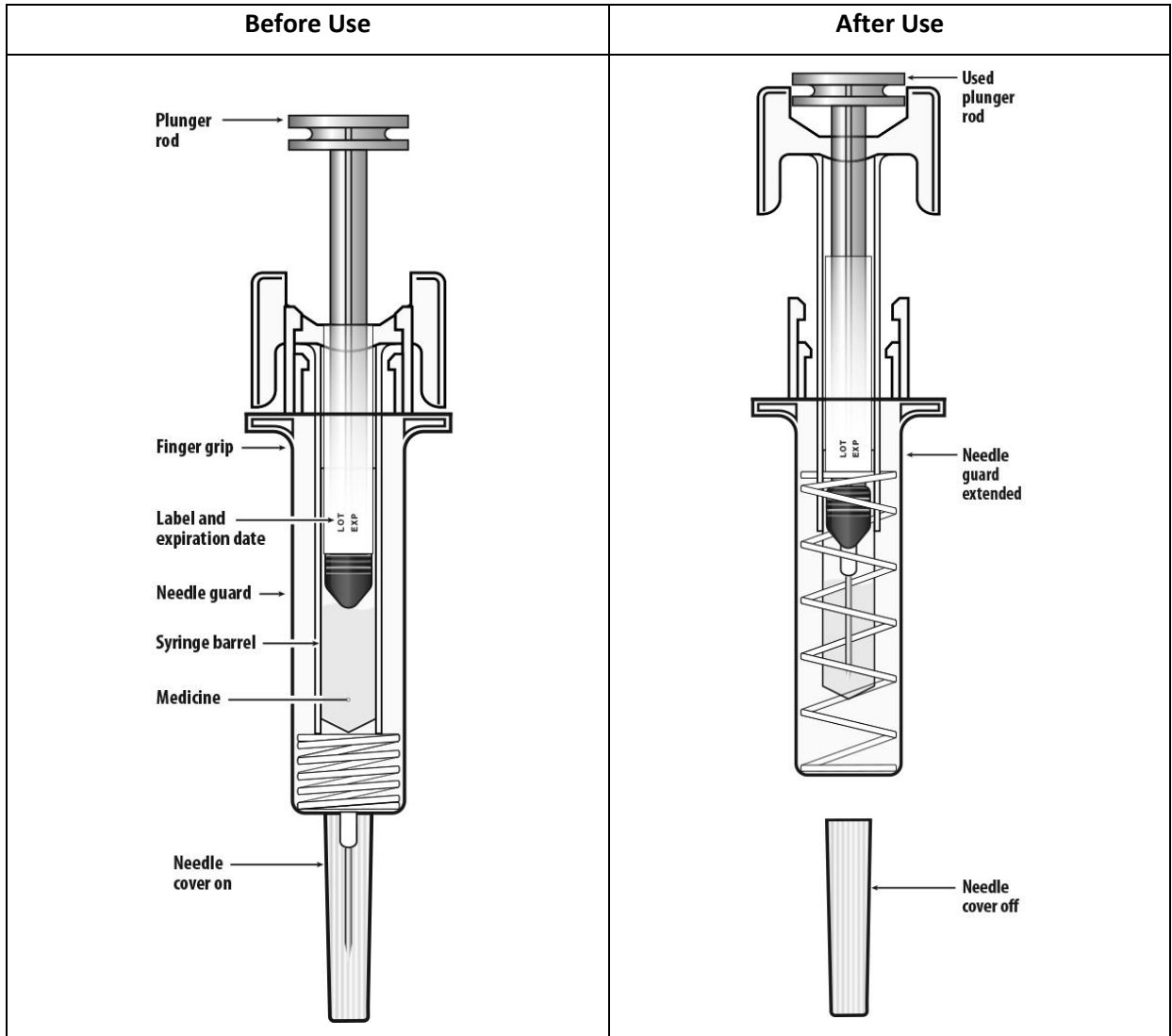
- The name Nyvepria appears on the carton and prefilled syringe label.
- The expiration date on the prefilled syringe has not passed. You should not use a prefilled syringe after the expiry date on the label.

- The Nyvepria liquid should always be clear and colourless. Do not use Nyvepria if the contents of the prefilled syringe appear discoloured or cloudy, or if the prefilled syringe appears to contain lumps, flakes, or particles.

IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, FOLLOW THESE INSTRUCTIONS EXACTLY.

Before you use a Nyvepria prefilled syringe, read this important information.

Guide to parts



Important: The needle is covered by the needle cover before use.

Read the Patient Medication Information for important information that you need to know about Nyvepria before using these Instructions for Use.

Before you use a Nyvepria prefilled syringe, read this important information.

Using the Prefilled Syringe

- **It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.**
- Make sure the name Nyvepria appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength is 6 mg.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe.
- **Do not** remove the needle cover from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if the carton is open or damaged.
- **Do not** use a prefilled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- The prefilled syringe has a needle guard that automatically activates to cover the needle after the injection is given. **Do not** use a prefilled syringe if the needle guard has been activated. Use another prefilled syringe that has not been activated and is ready to use.

Call your healthcare provider if you have any questions.

Step 1: Prepare

A. Remove the prefilled syringe carton from the refrigerator.

Remove the inner syringe carton from the outer prefilled syringe carton by peeling away the cover. On a clean, well-lit surface, place the inner syringe carton at room temperature for **30** minutes before you give an injection.

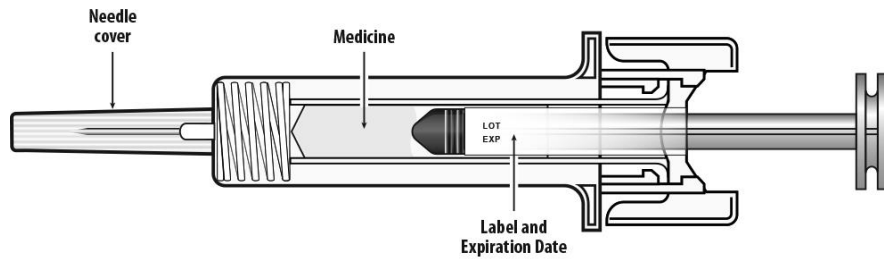
- **Do not** use the prefilled syringe if the inner syringe carton is damaged.
- **Do not** try to warm the prefilled syringe by using a heat source such as hot water or microwave.
- **Do not** leave the prefilled syringe in direct sunlight.
- **Do not** shake the prefilled syringe.

Open the inner syringe carton by peeling away the cover. Grab the needle guard to remove the prefilled syringe from the inner syringe carton.

For safety reasons:

- **Do not** grab the plunger rod.
- **Do not** grab the needle cover.

B. Inspect the medicine and prefilled syringe.



Make sure the medicine in the prefilled syringe is clear and colourless.

- **Do not** use the prefilled syringe if:
 - The medicine is cloudy or discoloured or contains flakes or particles.
 - Any part appears cracked or broken.
 - The prefilled syringe has been dropped.
 - The gray needle cover is missing or not securely attached.
 - The expiration date printed on the label has passed.

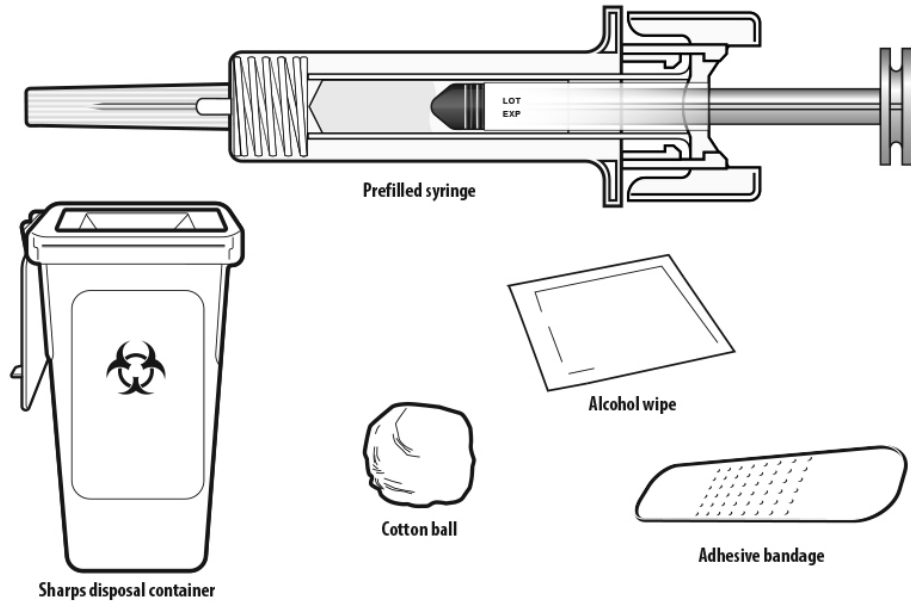
In all cases, use a new prefilled syringe and call your healthcare provider.

C. Gather all materials needed for the injection.

Wash your hands thoroughly with soap and water.

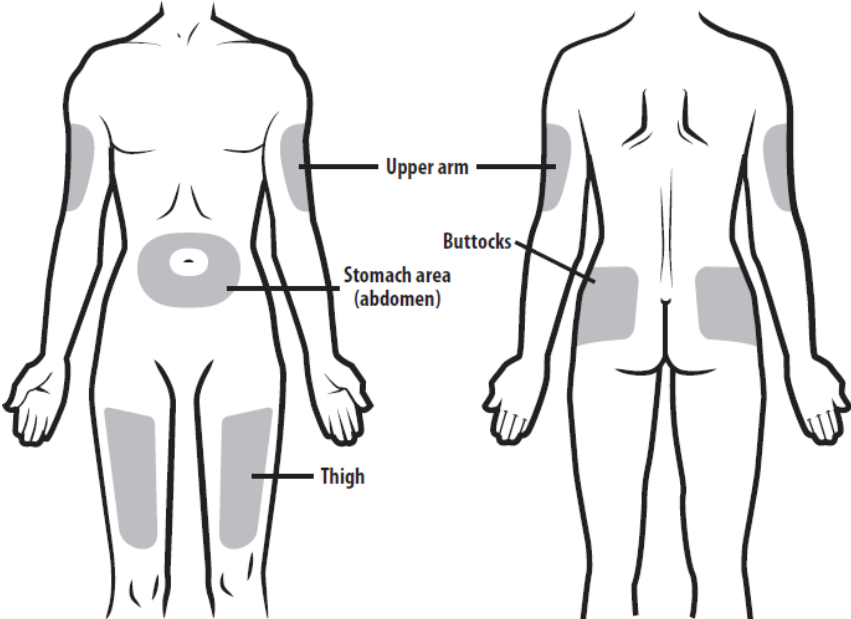
On a clean, well-lit work surface, place the:

- Prefilled syringe
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



Step 2: Get Ready

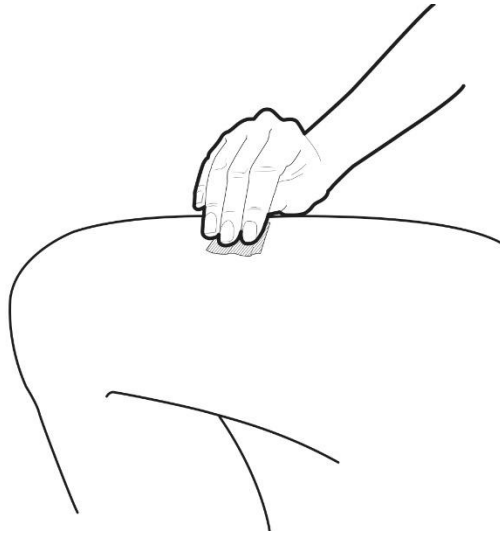
D. Prepare and clean the injection site(s).



You can use:

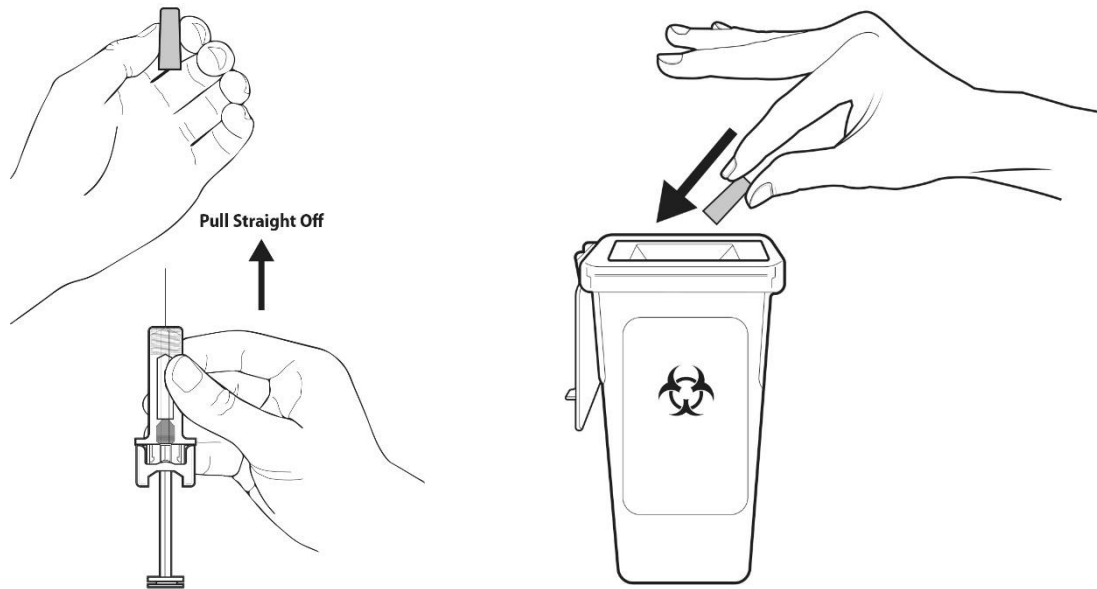
- Thigh
- Stomach area (abdomen), except for a 2-inch area right around the navel (belly button)
- Upper outer area of the buttocks (only if someone else is giving you the injection)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean the injection site with an alcohol wipe. Let the skin dry.



- **Do not** touch this area again before injecting.
- If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
- **Do not** inject into areas where the skin is tender, bruised, red or hard. Avoid injecting into areas with scars or stretch marks.

E. Hold the prefilled syringe by the needle guard. Carefully pull the needle cover straight off and away from the body. Throw away the needle cover into the sharps disposal container. **Do not recap.**



- **Do not** remove the needle cover from the prefilled syringe until you are ready to inject.
- **Do not** twist or bend the needle cover.
- **Do not** hold the prefilled syringe by the plunger rod.
- **Do not** put the needle cover back onto the prefilled syringe.

Important: Throw the needle cover into the sharps disposal container.

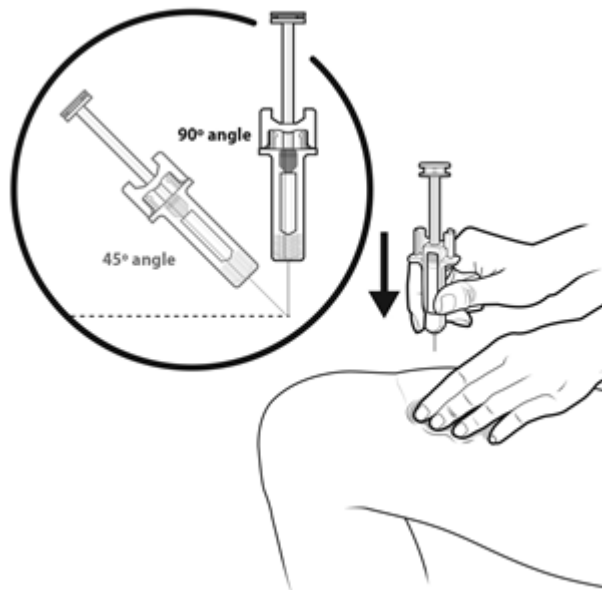
Step 3: Subcutaneous (under the skin) Injection

F. Pinch the injection site to create a firm surface.



Important: Keep skin pinched while injecting.

G. Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.

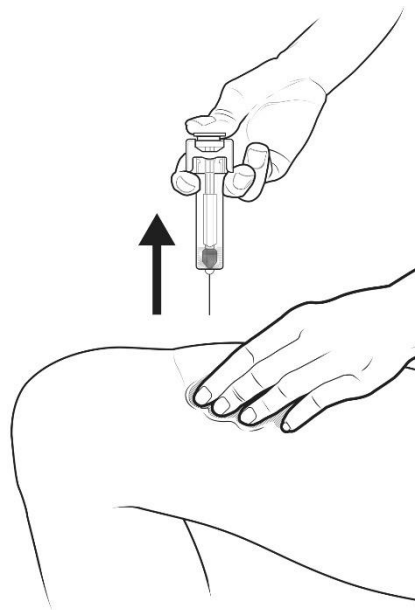


H. Using slow and constant pressure, push the plunger rod down until it reaches the bottom.

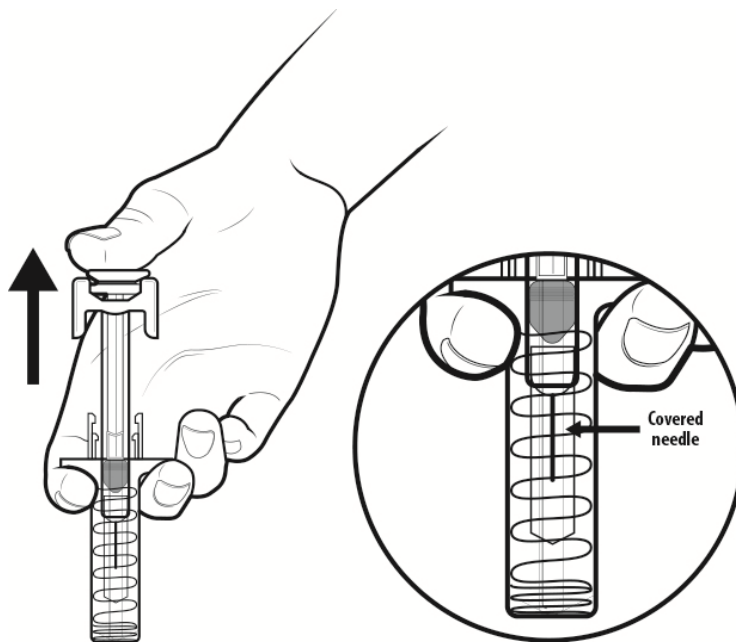


Step 4: Finish

I. When the syringe is empty, gently pull the syringe off the skin.

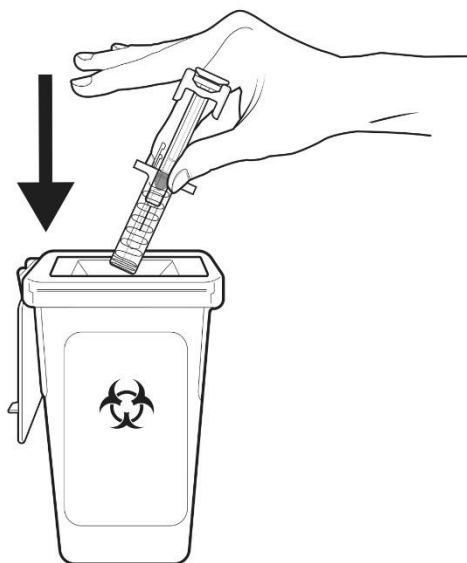


J. As you let go of the plunger rod, the needle guard will automatically slide over the needle until the needle is completely covered and the needle guard locks into place. **Do not recap the needle.**



Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare provider right away.

K. Throw away (dispose of) the syringe as instructed by your healthcare provider or by following the instructions below. There may be special provincial or local laws for the disposal of used needles and syringes.



- Put your used prefilled syringe in a sharps disposal container right away after use. **Do not throw away (dispose of)** syringes in your household trash.
- **Always keep the sharps disposal container out of the reach of children.**
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant and,
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be special provincial or local laws for disposal of used needles and syringes.
- Do not dispose of your used sharps container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

L. Examine the injection site.

If there is blood, press a cotton ball or gauze pad on the injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

What are possible side effects from using Nyvepria?

These are not all the possible side effects you may feel when taking Nyvepria. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Serious Warnings and Precautions**.

Spleen Rupture. Your spleen may become enlarged and can rupture while taking Nyvepria. A ruptured spleen can cause death. The spleen is located in the upper left section of your stomach area. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area. This pain could mean your spleen is enlarged or ruptured.

Serious Allergic Reactions. Serious allergic reactions can also happen. These reactions may cause a rash over the whole body, shortness of breath, wheezing, a drop in blood pressure (usually causing dizziness or lightheadedness), swelling around the mouth or eyes, fast pulse, or sweating. If you experience an allergic reaction during the injection of Nyvepria, the injection should be stopped immediately. If at any time a serious allergic reaction occurs, immediately call a doctor or emergency services (for example, call 911).

A serious lung problem called acute respiratory distress syndrome (ARDS). Call your doctor or seek emergency care right away if you have shortness of breath, trouble breathing or a fast rate of breathing.

Kidney injury (glomerulonephritis) has been seen in patients who received Nyvepria. Call your doctor immediately if you experience puffiness in your face or ankles, blood in your urine or brown coloured urine, or if you notice that you urinate less often than usual.

The most common side effect that you may experience is aching in the bones and muscles. If this occurs, it can usually be relieved with a non-acetylsalicylic acid over-the-counter pain reliever. Ask your doctor which is the most suitable one for you.

Some patients experience redness, swelling, or itching at the site of injection. This may be an allergy to the ingredients in Nyvepria, or it may be a local reaction. If you notice any of these signs or symptoms, call your doctor.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Bone Pain		√	
UNCOMMON			
Low platelet counts (thrombocytopenia) (including the following symptoms: easy bruising and increased bleeding).		√	
Allergic Reactions (including the following symptoms): rash over the whole body, shortness of breath, a drop in blood pressure (usually causing dizziness or lightheadedness), swelling around the mouth or eyes, fast pulse, weakness, sweating; severe redness or swelling or itching at injection site		√	√
Acute Respiratory Distress Syndrome (including the following symptoms: fever, shortness of breath, cough, or congestion in your lungs)		√	
VERY RARE			
Splenomegaly (including the following symptoms: pain in the left upper stomach area or left shoulder tip area)		√	
*FREQUENCY NOT KNOWN			
Splenic Rupture (including the following symptoms: left		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
upper abdominal pain or pain at the tip of your shoulder)			
Cutaneous Vasculitis (including the following symptoms: A rash in the skin surface that looks like purple or red spots or bumps, clusters of small dots, splotches or hives. Your skin may also be itchy.)		√	
Capillary Leak Syndrome (including the following symptoms): swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness		√	
Kidney Injury (glomerulonephritis) (including the following symptoms): puffiness in your face or ankles, blood in your urine or brown coloured urine, or if you notice that you urinate less often than usual.		√	√
**Abnormal number of immature bone marrow cells (myelodysplastic syndrome) that could lead to a type of cancer (acute myeloid leukemia) (including the following symptoms: fever, bone pain, bruising, difficulty breathing, bleeding and a general feeling of tiredness).		√	√

*Reported in the post-marketing setting where the incidence is not known.

**Adverse events in breast and lung cancer patients receiving chemotherapy and/or radiotherapy

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Do not use Nyvepria after the expiry date which is stated on the outer carton and the label of the prefilled syringe.

- Nyvepria should be stored in the refrigerator between 2°C to 8°C but not in the freezer. Avoid shaking.
- If Nyvepria is accidentally frozen, allow it to thaw in the refrigerator before giving the next dose. However, if it is frozen for a second time, do not use it and contact your doctor or nurse for further instructions.
- Nyvepria can be left out at room temperature (not above 25°C) for a single period of up to 15 days that ends within the labeled expiry date. Once Nyvepria has been out at room temperature, it should not be placed back into the refrigerator. Any Nyvepria syringes that have been out of the refrigerator for longer than 15 days should not be used and should be disposed of in accordance with local requirements.
- Keep Nyvepria in the carton to protect from light or physical damage. Do not leave Nyvepria in direct sunlight. Do not use if you notice it is cloudy or there are particles in it.
- If you have any questions about storage or how to carry Nyvepria when you travel, contact your doctor, nurse, or pharmacist.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

Keep out of reach and sight of children.

If you want more information about Nyvepria:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

[product-database.html](#)); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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