

Patient Information
NEUPOGEN® (nu-po-jen)
(filgrastim)
injection

What is NEUPOGEN?

NEUPOGEN 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 NEUPOGEN for this use was only studied in animals, because it could not be studied in people.

Do not take NEUPOGEN if you have had a serious allergic reaction to human G-CSFs such as filgrastim or pegfilgrastim products.

Before you take NEUPOGEN, tell your healthcare provider about all of your medical conditions, including if you:

- have a sickle cell disorder.
- have kidney problems.
- are receiving radiation therapy.
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (derived from latex). You should not give NEUPOGEN using the prefilled syringe if you have latex allergies. Ask your healthcare provider about using the vial if you have latex allergies.
- are pregnant or plan to become pregnant. It is not known if NEUPOGEN will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NEUPOGEN 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 NEUPOGEN?

- **NEUPOGEN injections can be given by a healthcare provider by intravenous (IV) infusion or under your skin (subcutaneous injection). Your healthcare provider may decide subcutaneous injections can be given at home by you or your caregiver. If NEUPOGEN is given at home, see the detailed "Instructions for Use" that comes with your NEUPOGEN for information on how to prepare and inject a dose of NEUPOGEN.**
- You and your caregiver should be shown how to prepare and inject NEUPOGEN before you use it, by your healthcare provider.
- Your healthcare provider will tell you how much NEUPOGEN to inject and when to inject it. Do not change your dose or stop NEUPOGEN unless your healthcare provider tells you to.
- If you are receiving NEUPOGEN because you are also receiving chemotherapy, your dose of NEUPOGEN should be injected **at least 24 hours before or 24 hours after** your dose of chemotherapy. Your healthcare provider will do blood tests to monitor your white blood cell count, and if necessary, adjust your NEUPOGEN dose.
- If you are receiving NEUPOGEN because you have been suddenly (acutely) exposed to an amount of radiation that can affect your bone marrow (Acute Radiation Syndrome), you will need to have blood tests about every 3 days during treatment with NEUPOGEN to check your white blood cell count.
- If you miss a dose of NEUPOGEN, talk to your healthcare provider about when you should give your next dose.

What are the possible side effects of NEUPOGEN?

NEUPOGEN 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 (abdomen) area or your left shoulder.
- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your healthcare provider or get emergency medical 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.** NEUPOGEN 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 NEUPOGEN 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 NEUPOGEN. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** NEUPOGEN 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
- **Capillary leak syndrome.** NEUPOGEN 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
- **Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML).**
 - Neupogen may increase the risk of developing a precancerous condition called MDS or a type of blood cancer called AML in people who were born with low white blood cell counts (congenital neutropenia).
 - If you have breast cancer or lung cancer, when NEUPOGEN is used with chemotherapy and radiation therapy, or with radiation therapy only, you may have an increased risk of developing MDS or AML.
 - Symptoms of MDS and AML may include tiredness, fever, and easy bruising or bleeding.
 - Call your healthcare provider if you develop any of these symptoms during treatment with NEUPOGEN.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with NEUPOGEN. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with NEUPOGEN. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with NEUPOGEN.
- **Inflammation of your blood vessels (cutaneous vasculitis).** Tell your healthcare provider right away if you develop purple spots or redness of your skin.
- **Inflammation of the aorta (aortitis).** Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body) has been reported in patients who received NEUPOGEN. 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 experienced in patients receiving NEUPOGEN include:

- Patients with cancer receiving chemotherapy: fever, pain, rash, cough, and shortness of breath
- Patients with acute myeloid leukemia receiving chemotherapy: pain, nose bleed, and rash
- Patients with cancer receiving chemotherapy followed by bone marrow transplant: rash
- Patients who are having their own blood cells collected: bone pain, fever, and headache
- Patients with severe chronic neutropenia: pain, decreased red blood cells, nose bleed, diarrhea, reduced sensation, and hair loss

These are not all the possible side effects of NEUPOGEN. 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 NEUPOGEN?

- Store NEUPOGEN in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep NEUPOGEN in the original carton to protect from light or physical damage. Do not leave NEUPOGEN in direct sunlight.
- Do not shake NEUPOGEN.
- Take NEUPOGEN out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any NEUPOGEN that has been left at room temperature for longer than 24 hours.
- After you inject your dose, throw away (dispose of) any unused NEUPOGEN left in the vials or prefilled syringes. **Do not** save unused NEUPOGEN in the vials or prefilled syringes for later use.

Keep NEUPOGEN out of the reach of children.

General information about the safe and effective use of NEUPOGEN.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NEUPOGEN for a condition for which it was not prescribed. Do not give NEUPOGEN 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 NEUPOGEN that is written for healthcare professionals.

What are the ingredients in NEUPOGEN?

Active ingredient: filgrastim

Inactive ingredients: acetate, polysorbate 80, sodium, sorbitol, and water for Injection

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

AMGEN[®]

Patent: <http://pat.amgen.com/neupogen/>

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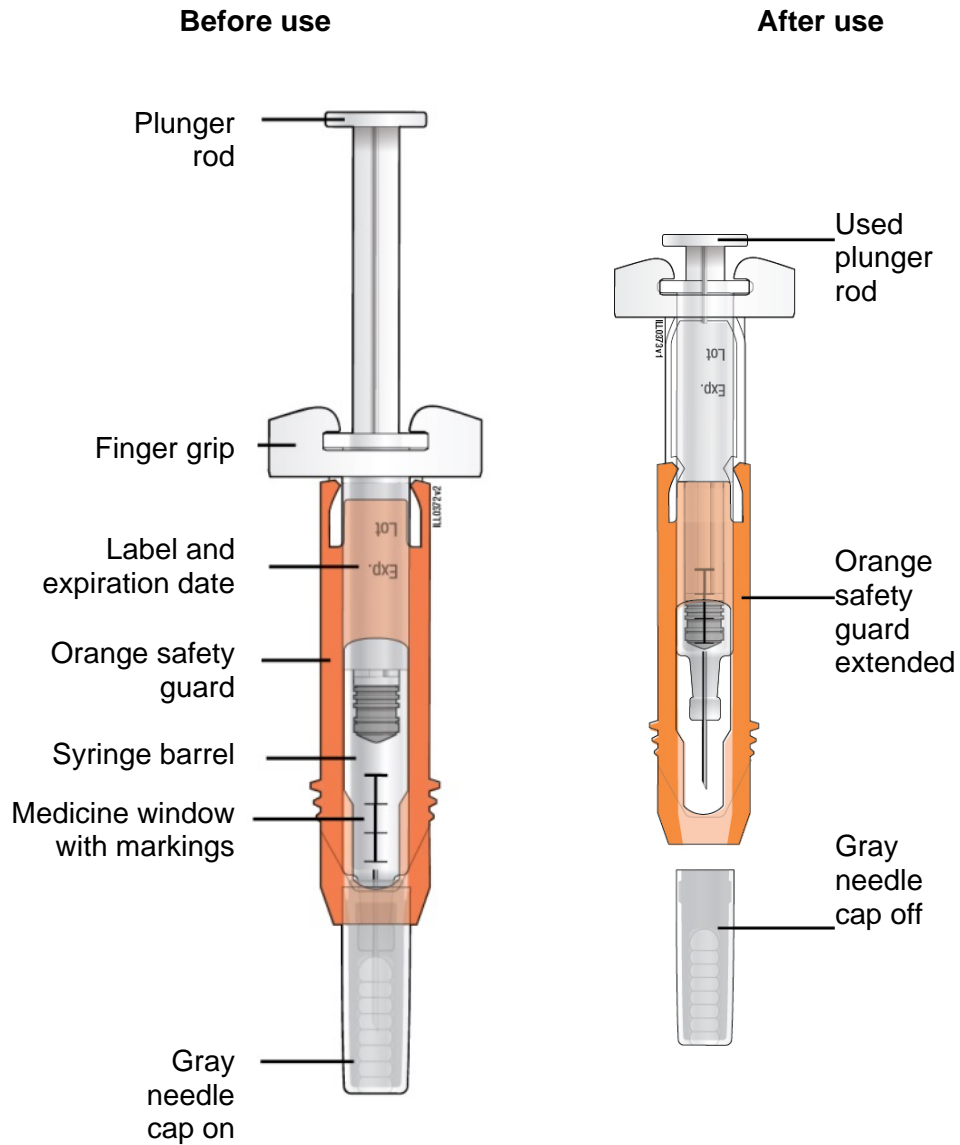
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This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 01/2021

Instructions for Use
NEUPOGEN® (nu-po-jen)
(filgrastim)
Injection
Single-Dose Prefilled Syringe

Guide to parts



Important: The needle is covered by the gray needle cap before use.

Important

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

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

Storing your prefilled syringe

- Store the prefilled syringe 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.
- Take the prefilled syringe out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any prefilled syringe that has been left at room temperature for longer than 24 hours.
- After you inject your dose, throw away (dispose of) any unused NEUPOGEN left in the prefilled syringe. **Do not** save unused NEUPOGEN in the prefilled syringe for later use.
- Keep the NEUPOGEN prefilled syringe out of the reach of children.

Using your 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 NEUPOGEN appears on the carton and prefilled syringe label.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe.
- **Do not** remove the gray needle cap 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.
- **Do not** slide the orange safety guard over the needle before you give the injection. This will “activate” or lock the orange safety guard. Use another prefilled syringe that has not been activated and is ready to use.
- **The gray needle cap on the prefilled syringe contains dry natural rubber (made from latex). Tell your healthcare provider if you are allergic to latex. You should not give NEUPOGEN using the prefilled syringe if you have latex allergies.**

Call your healthcare provider if you have any questions.

Step 1: Prepare

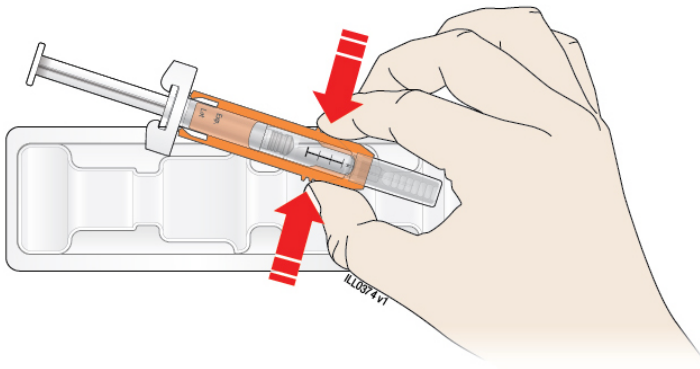
A Remove the prefilled syringe carton from the refrigerator.

Put the original carton with any unused prefilled syringes back in the refrigerator.

Remove the syringe tray from the carton. On a clean, well-lit surface, place the syringe tray at room temperature for **30** minutes before you give an injection.

- **Do not** use the prefilled syringe if the 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 tray by peeling away the cover. Grab the orange safety guard to remove the prefilled syringe from the tray.

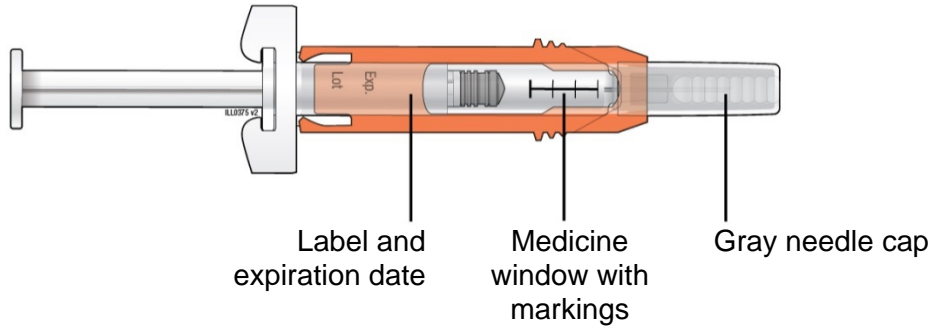


Grab Orange Safety Guard

For safety reasons:

- **Do not** grab the plunger rod.
- **Do not** grab the gray needle cap.

B Inspect the medicine and prefilled syringe.



Turn the prefilled syringe so you can see the medicine window and markings. Make sure the medicine in the prefilled syringe is clear and colorless.

- **Do not** use the prefilled syringe if:
 - The medicine is cloudy or discolored or contains flakes or particles.
 - Any part appears cracked or broken.
 - The prefilled syringe has been dropped.
 - The gray needle cap 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 your injection.

Wash your hands thoroughly with soap and water.

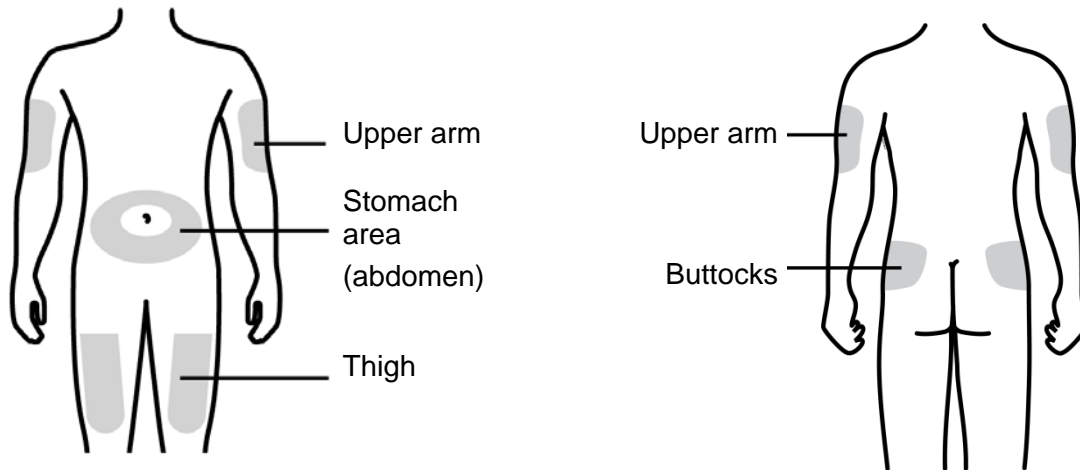
On a clean, well-lit work surface, place the:

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



Step 2: Get ready

D Prepare and clean your injection site.



You can use:

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

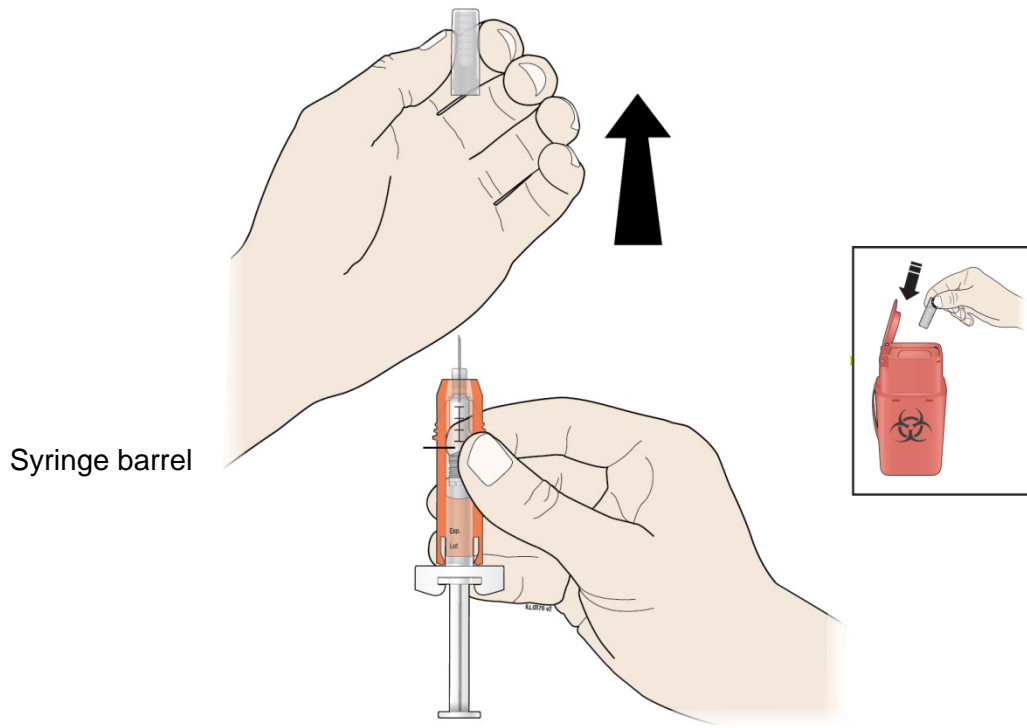
Clean your injection site with an alcohol wipe.

- Let your 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 area 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 syringe barrel. Carefully pull the gray needle cap straight off and away from your body.



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

Important: Throw the gray needle cap into the sharps disposal container.

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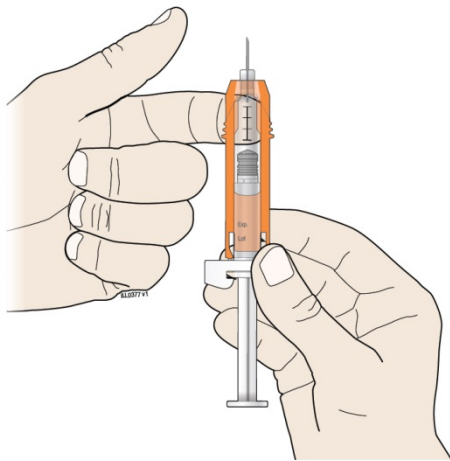


Check your prescription before you inject your dose.

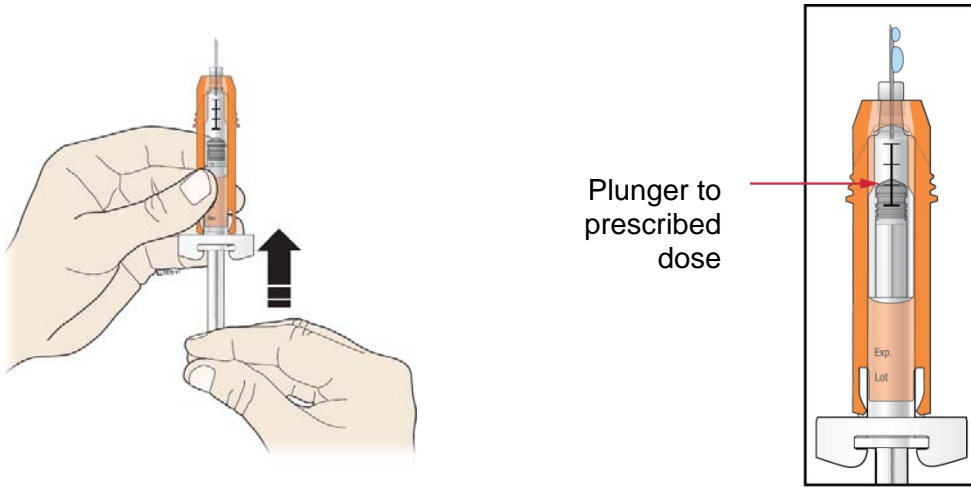
Your healthcare provider has prescribed either a “full” syringe dose or a “partial” syringe dose of NEUPOGEN.

- If you are prescribed a full dose, you will inject all of the medicine from your prefilled syringe. **For a full dose, go directly to Step 3: Subcutaneous (under the skin) injection.**
- If you are prescribed a partial dose of NEUPOGEN, start with Step G below.

G Point the needle up and tap gently until the air rises to the top.



H Slowly push the plunger rod up to the line on the syringe barrel that matches your prescribed dose.



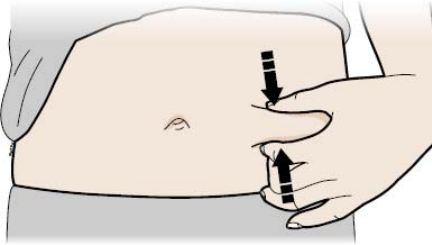
Important: Do not slide the orange safety guard over the needle before you give the injection. This will “activate” or lock the orange safety guard.

As you push the plunger rod up, air and extra medication is removed. Check to make sure the plunger lines up with the syringe markings for your prescribed dose. If you remove too much medicine, get a new prefilled syringe and start again at **Step 1**.

- Call your healthcare provider if you have problems measuring your prescribed dose.

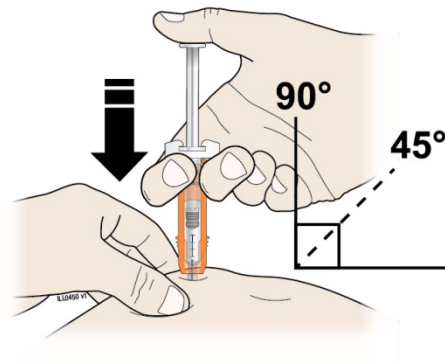
Step 3: Subcutaneous (under the skin) injection

I Pinch your injection site to create a firm surface.



Important: Keep skin pinched while injecting.

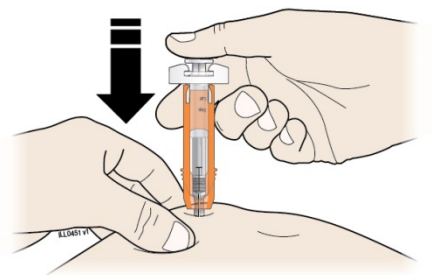
J Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.



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

- **Do not** pull back the plunger rod while the needle is inserted.

When done, gently pull the syringe off of your skin.

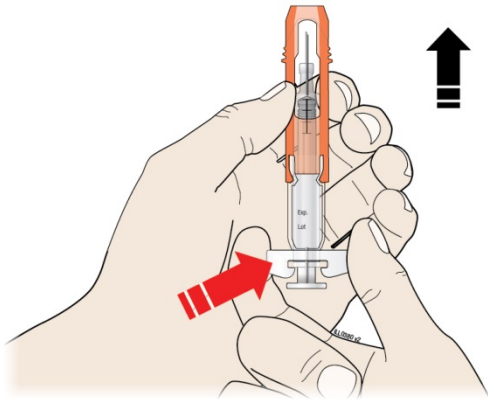


Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare provider right away.

Step 4: Finish

L  **Before you finish!**

For your safety, pull the orange safety guard until it clicks and covers the needle.



**GRAB
HERE**

Once extended, the orange safety guard will lock into position and will not slide back over the needle.

Keep your hands away from the needle at all times.

M Discard (throw away) the used prefilled syringe.



- Put the used prefilled syringe in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of)** the prefilled syringe in your household trash.
- If you do not have a FDA-cleared 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 state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** reuse the prefilled syringe.
- **Do not** recycle the prefilled syringe or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

N Examine the injection site.

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.



Manufactured by:

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
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Instructions for Use
NEUPOGEN® (nu-po-jen)
(filgrastim)
Injection
Single-Dose Vial

Important

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

Before you use a NEUPOGEN vial, read this important information:

Storing your NEUPOGEN vial

- Store the vial in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep the vial in the original carton to protect from light or physical damage.
- Take the vial out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any vial that has been left at room temperature for longer than 24 hours.
- After you inject your dose, throw away (dispose of) any unused NEUPOGEN left in the vial. **Do not** save unused NEUPOGEN in the vial for later use.
- Keep the NEUPOGEN vial out of the reach of children.

Using your vial

- **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 NEUPOGEN appears on the carton and vial label.
- **Only use the vial 1 time. Discard (throw away) the vial with any remaining NEUPOGEN liquid.**
- **Do not** use a vial after the expiration date on the label.
- **Do not** shake the vial.
- **Do not** use the vial if the medicine is cloudy or discolored or contains flakes or particles.

Call your healthcare provider if you have any questions.

Step 1: Prepare

A Remove the vial from the refrigerator.

On a clean, well-lit surface, place the vial at room temperature for **30** minutes before you give an injection.

- **Do not** try to warm the vial by using a heat source such as hot water or microwave.
- **Do not** leave the vial in direct sunlight.
- **Do not** shake the vial.
- Use the vial only 1 time.

B Inspect the vial.

Make sure the medicine in the vial is clear and colorless.

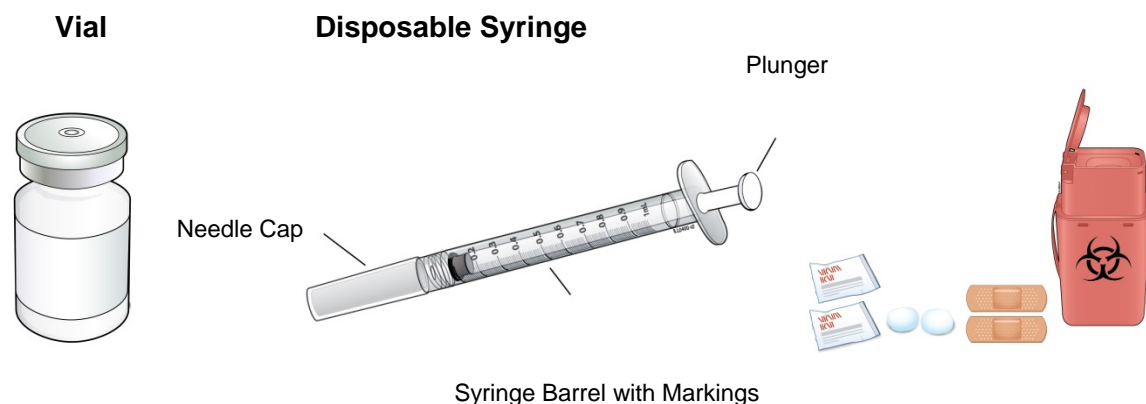
- **Do not** use the vial if:
 - The medicine is cloudy or discolored or contains flakes or particles.
 - The expiration date printed on the label has passed.
- In all cases, use a new vial and call your healthcare provider.

C Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.

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

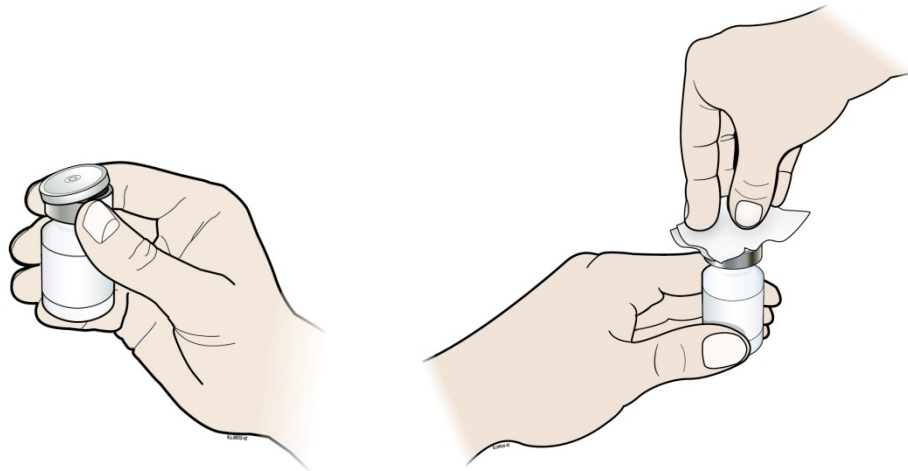
- Vial
- Disposable syringe and needle
- 2 alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



- **Only use the disposable syringes and needles that your healthcare provider prescribes.**
- **Only use the syringes and needles 1 time. Discard (throw away) any used syringes and needles.**
- You should only use a syringe that is marked in tenths of milliliters (mL).
- Your healthcare provider will show you how to measure the correct dose of NEUPOGEN. This dose will be measured in milliliters (mL).

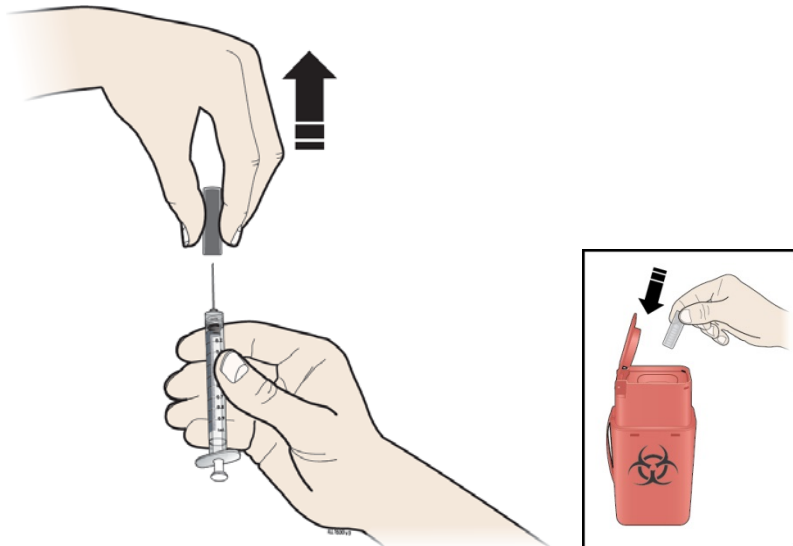
Step 2: Get Ready

D Take the cap off the vial. Clean the rubber stopper with one alcohol wipe.



E Check the carton containing the syringe. If the carton has been opened or damaged, do not use that syringe. Dispose of (throw away) that syringe in the sharps disposal container.

F Hold the syringe by the barrel with the needle cap pointing up. Carefully pull the needle cap straight off and away from your body.

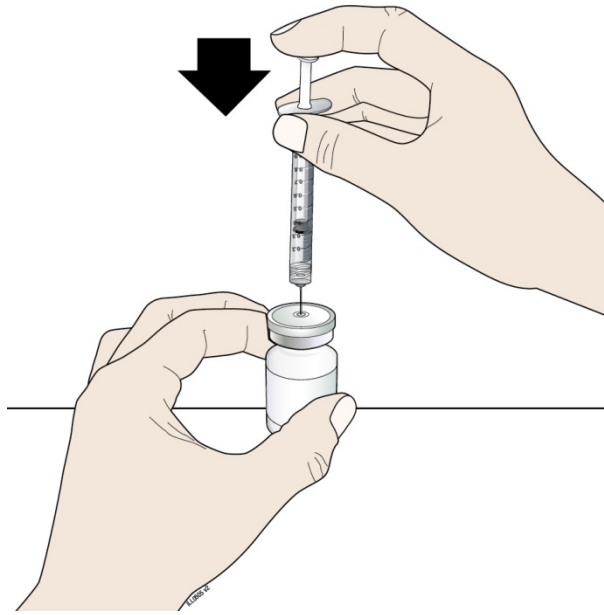


Pull back on the plunger and draw air into the syringe that is the same amount (mL) as the dose of NEUPOGEN that your healthcare provider prescribed.

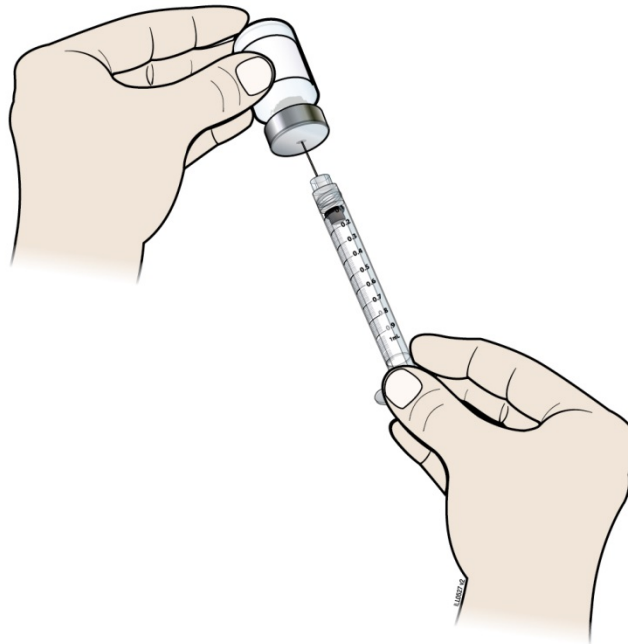
Important: Throw the needle cap into the sharps disposal container.

G Keep the vial on the flat working surface and insert the needle straight down through the rubber stopper. Do not insert the needle through the rubber stopper more than 1 time.

H Push the plunger down and inject all the air from the syringe into the vial of NEUPOGEN.

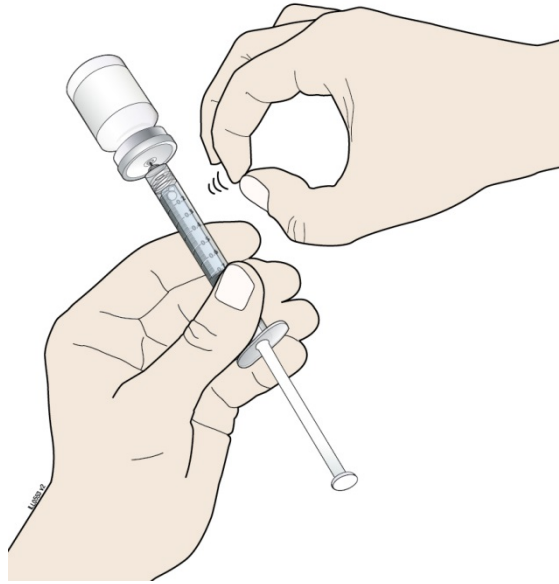


I Keep the needle in the vial and turn the vial upside down. Make sure that the NEUPOGEN liquid is covering the tip of the needle.



J Keep the vial upside down and slowly pull back on the plunger to fill the syringe barrel with NEUPOGEN to the correct marking amount (mL) of medicine that matches the dose your healthcare provider prescribed.

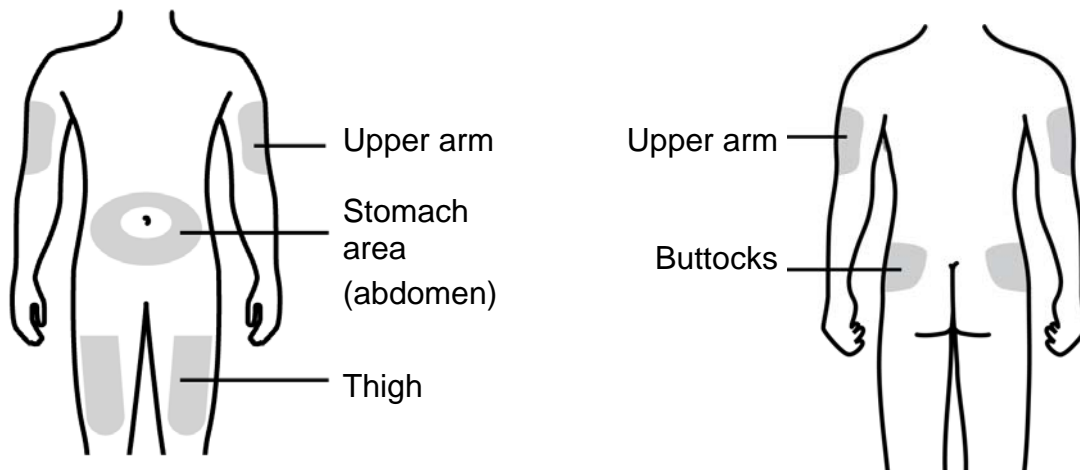
- K** Keep the needle in the vial and check for air bubbles in the syringe. If there are air bubbles, gently tap the syringe barrel with your finger until the air bubbles rise to the top. Slowly push the plunger up to push the air bubbles out of the syringe.



- L** Keep the tip of the needle in the liquid and again pull the plunger back to the number on the syringe barrel that matches your dose. Check again for air bubbles. The air in the syringe will not hurt you, but too large an air bubble can reduce your dose of NEUPOGEN. If there are still air bubbles, repeat the steps above to remove them.
- M** Check again to make sure that you have the correct dose in the syringe. It is important that you use the exact dose prescribed by your healthcare provider. Do not remove the needle from the vial. Lay the vial down on its side with the needle still in the vial.

Step 3: Select and Prepare the Injection Site

N Prepare and clean your injection site.



You can use:

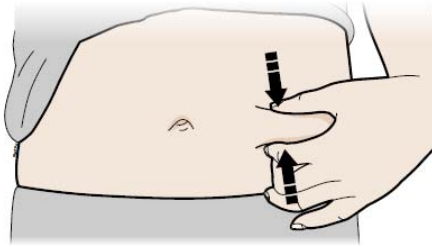
- Thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel (belly button)
- Upper outer area of your buttocks (only if someone else is giving you the injection)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean your injection site with a clean alcohol wipe.

- Let your 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 area 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.

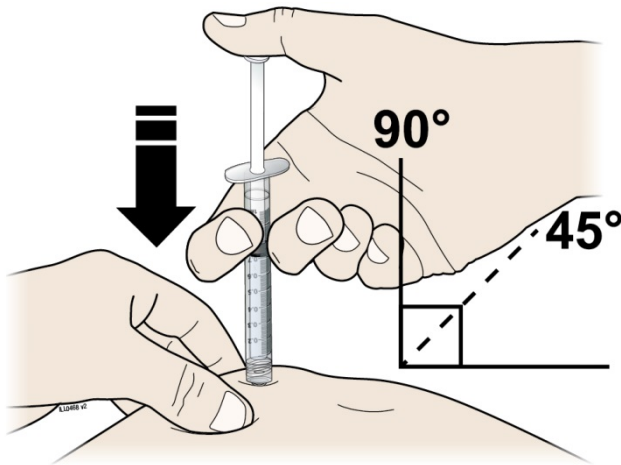
Step 4: Subcutaneous (under the skin) injection

- O Remove the prepared syringe and needle from the vial.
- P Pinch your injection site to create a firm surface.

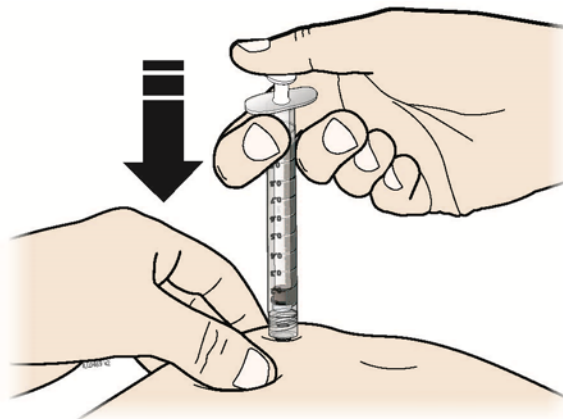


Important: Keep skin pinched while injecting.

- Q Hold the pinch. Insert the needle into the skin at a 45 to 90 degree angle.



- R Using slow and constant pressure, push the plunger until it reaches the bottom.



When done gently pull the syringe off of your skin.

Step 5: Finish

S Discard (throw away) the used syringe and vial.



- Put your used syringes, needles, and vials in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of)** needles, syringes and vials in your household trash.
- If you do not have an FDA-cleared 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,
 - is upright and stable during use,
 - is leak-resistant, and
 - is 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 state or local laws about how you should throw away used syringes and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** reuse the syringe or vial.
- **Do not** recycle the syringe, vial, or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

T Examine the injection site.

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.



NEUPOGEN® (filgrastim)

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