

Patient Information
NYPOZI™ (ni-poz-ee)
(filgrastim-txid)
injection

What is NYPOZI?

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

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

Before you take NYPOZI, 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 pregnant or plan to become pregnant. It is not known if NYPOZI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NYPOZI 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 NYPOZI?

- **NYPOZI 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 NYPOZI is given at home, see the detailed "Instructions for Use" that comes with your NYPOZI for information on how to prepare and inject a dose of NYPOZI.**
- You and your caregiver should be shown how to prepare and inject NYPOZI before you use it, by your healthcare provider.
- Your healthcare provider will tell you how much NYPOZI to inject and when to inject it. Do not change your dose or stop NYPOZI unless your healthcare provider tells you to.
- You should not inject a dose of NYPOZI less than 0.3 mL (180 mcg) from a NYPOZI prefilled syringe. A dose less than 0.3 mL cannot be accurately measured using the NYPOZI prefilled syringe.
- If you are receiving NYPOZI because you are also receiving chemotherapy, your dose of NYPOZI 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 counts, and if necessary, adjust your NYPOZI dose.
- If you are receiving NYPOZI 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 NYPOZI to check your white blood cell count.
- If you miss a dose of NYPOZI, talk to your healthcare provider about when you should give your next dose.
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What are the possible side effects of NYPOZI?

NYPOZI 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.** NYPOZI 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 NYPOZI 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 NYPOZI. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** NYPOZI 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.** NYPOZI 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).**
 - NYPOZI 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 NYPOZI 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 NYPOZI.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with NYPOZI. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with NYPOZI. 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 NYPOZI.
- **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 filgrastim products. 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 NYPOZI 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 NYPOZI. 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 NYPOZI?

- Store NYPOZI in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze.**
- Keep NYPOZI in the original carton to protect it from light or physical damage. Do not leave NYPOZI in direct sunlight.
- Do not shake NYPOZI.
- Take NYPOZI out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- If not used right away, the prefilled syringe may be kept at room temperature between 68°F to 77°F (20°C to 25°C) for up to 24 hours. Throw away (dispose of) any NYPOZI that has been left at room temperature for more

than 24 hours.

- After you inject your dose, throw away (dispose of) any unused NYPOZI left in the prefilled syringe. **Do not save** unused NYPOZI in the prefilled syringe for later use.

Keep NYPOZI and all medicines out of the reach of children.

General information about the safe and effective use of NYPOZI:

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

What are the ingredients in NYPOZI?

Active ingredient: filgrastim-txid

Inactive ingredients: glacial acetic acid, polysorbate 80, sodium acetate, sorbitol, and water for injection

tanvex NYPOZI™
(filgrastim-txid) Injection

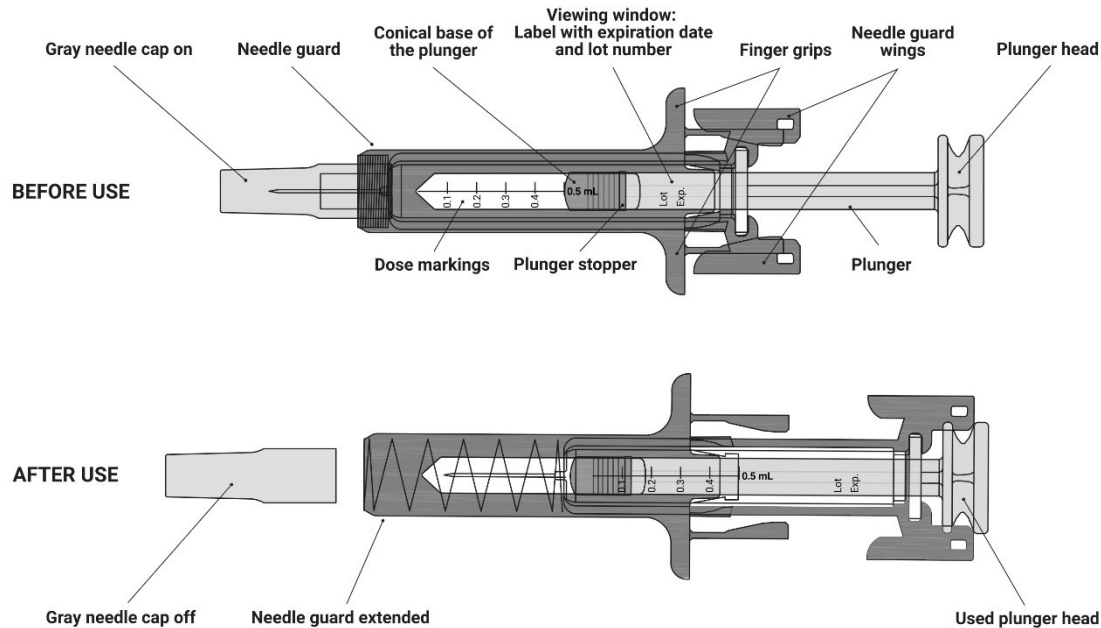
Manufactured by: Tanvex BioPharma USA, Inc., San Diego, CA 92121
Product of USA
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This Patient Information has been approved by the U.S. Food and Drug Administration.

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Instructions for Use
NYPOZI™ (ni-poz-ee) (filgrastim-txid) 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 NYPOZI before using these Instructions for Use.

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

Storing your NYPOZI prefilled syringe

- Store the NYPOZI prefilled syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze NYPOZI prefilled syringes.
- Keep the prefilled syringe in the original carton to protect it 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 NYPOZI left in the prefilled syringe. **Do not save** unused NYPOZI in the prefilled syringe for later use.
- Keep the NYPOZI 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 NYPOZI appears on the carton and prefilled syringe label.

- **Do not** inject a dose of NYPOZI less than 0.3 mL (180 mcg) from a NYPOZI prefilled syringe. A dose less than 0.3 mL cannot be accurately measured using the NYPOZI prefilled syringe.
- **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.
- The prefilled syringe has a needle guard that will be activated to cover the needle after the injection is given. The needle guard will help prevent needle stick injuries to anyone who handles the prefilled syringe.
- Avoid touching the syringe needle guard wings before use. Touching them may cause the syringe needle guard to be activated too early. 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

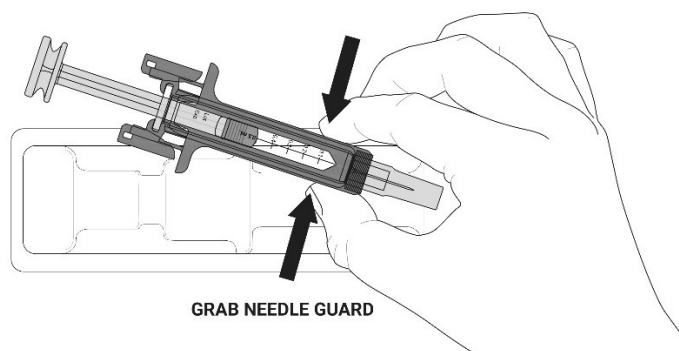
A Remove the prefilled syringe carton from the refrigerator.

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

Remove the syringe blister pack from the carton. On a clean, well-lit, flat surface, place the syringe blister pack 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.
- **Keep** the prefilled syringe in the blister pack until you are ready to use it.
- **Do not** leave the prefilled syringe in direct sunlight.
- **Do not** shake the prefilled syringe.

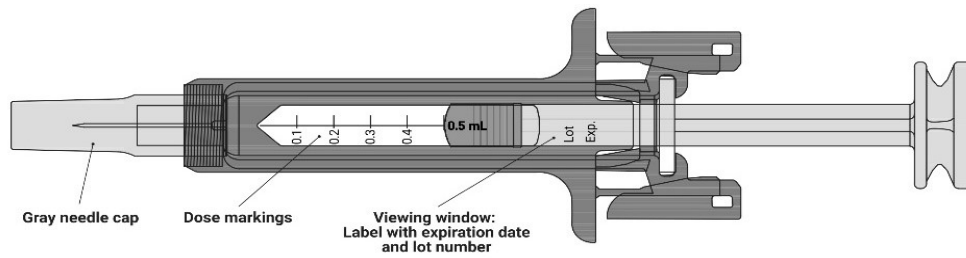
Open the blister pack by peeling away the cover. Grab the transparent needle guard to remove the prefilled syringe from the blister pack.



For safety reasons:

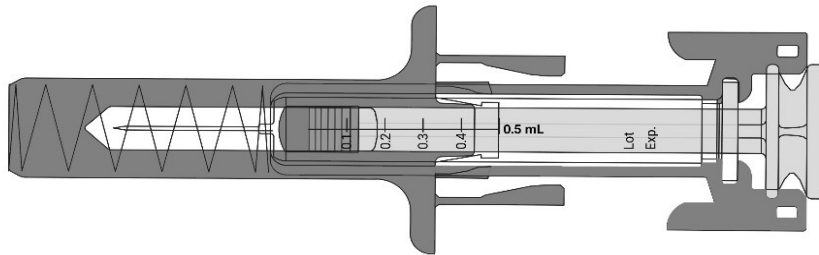
- **Do not** grab the plunger rod.
- **Do not** grab the gray needle cap.

B Inspect the medicine and prefilled syringe.



Turn the prefilled syringe so you can see through the viewing window and dose markings. Make sure the medicine in the prefilled syringe is clear and colorless to slightly yellowish.

Check to make sure that the plastic transparent needle guard is covering the barrel of the glass syringe. If the transparent needle guard is covering the gray needle cap (shown below), the needle guard has already been activated. **Do not** use the prefilled syringe if the needle guard has been activated.



Syringe with Activated Needle Guard

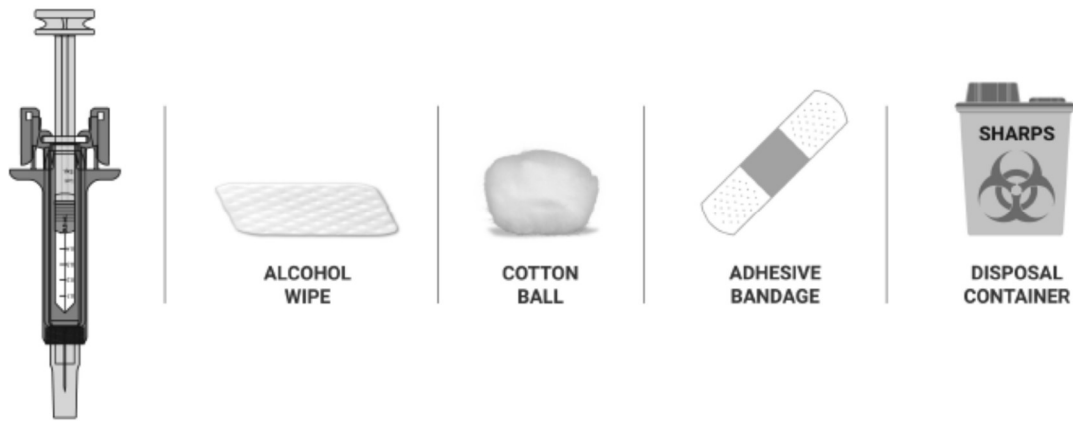
- **Do not** use the prefilled syringe if:
 - The medicine is cloudy or discolored or contains flakes or particles.
 - Any part appears cracked or broken.
 - The prefilled syringe has been dropped.
 - The gray needle cap is missing or not securely attached.
 - The expiration date printed on the label has passed.
- In all cases, use a new prefilled syringe and call your healthcare provider.

C Gather all materials needed for injection.

Wash your hands thoroughly with soap and water.

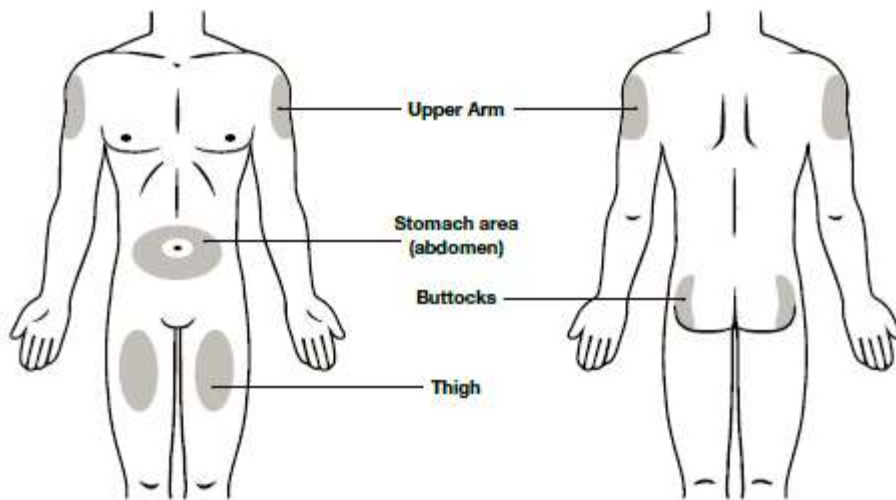
On a clean, well-lit work surface, place the:

- Prefilled syringe, and the following items, that are not included in the NYPOZI carton
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container or other appropriate 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)

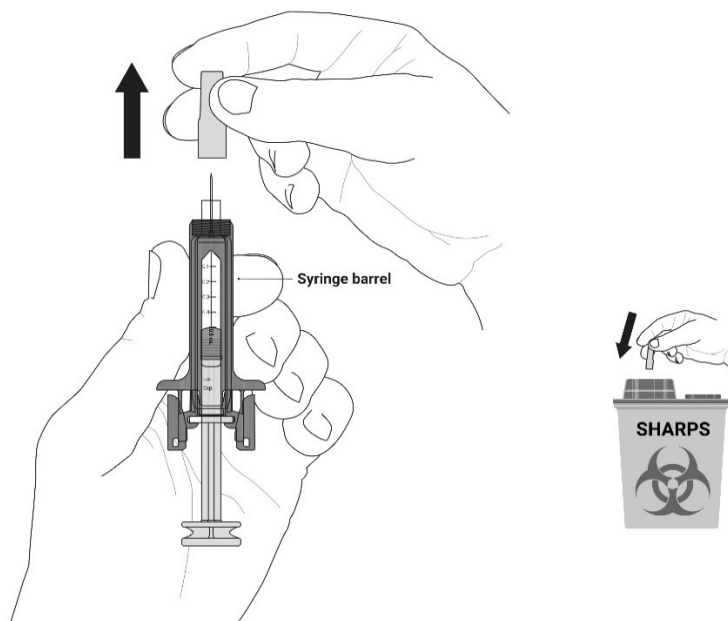
Clean your injection site with an alcohol wipe.

- Let your skin dry.
- **Do not** touch this cleansed 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, scaly or hard. Avoid injecting into areas with scars or stretch marks.

- E Hold the prefilled syringe by the syringe barrel (the clear plastic needle guard) with the needle pointing up. 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.

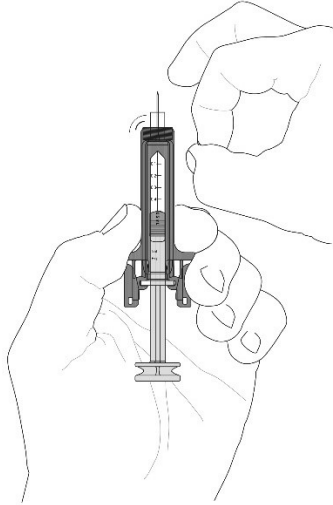
Important: Throw away the gray needle cap into the Sharps or other appropriate disposal container.



- F **Check your prescription before you inject your dose**

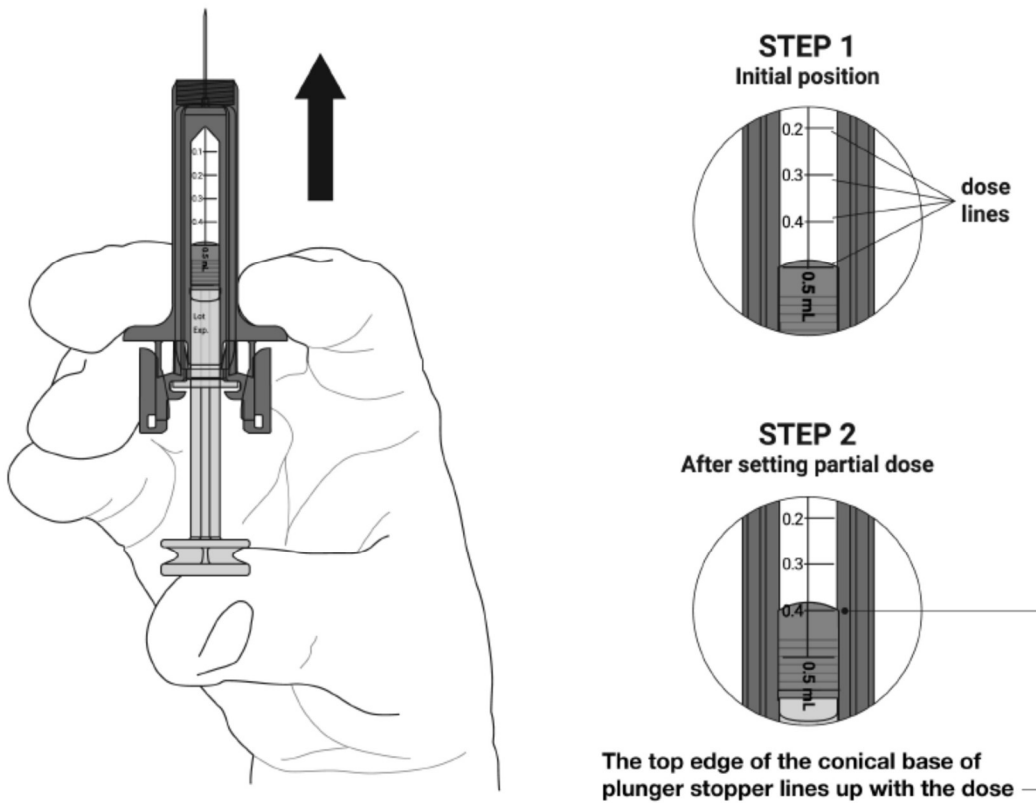
Your healthcare provider has prescribed either a “full” syringe dose or a “partial” syringe dose of NYPOZI.

- 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 NYPOZI, start with Step G below.**
- G Check the syringe for an air bubble. Point the needle up and gently tap the syringe with your fingers until the air bubble rises to the top of the syringe.



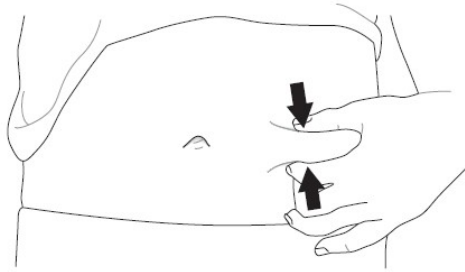
H Hold the syringe as shown below and press slowly on the plunger to push out the excess medicine until the top edge of the conical base of the plunger stopper lines up with the syringe marking for your prescribed dose. As you push the plunger rod up, air and extra medication is removed. Check to make 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**.

- See the figure below (**Step 2**) for an example of a dose of 0.4 mL. Your dose may be different than the example shown.
- Call your healthcare provider if you have problems measuring your prescribed dose.



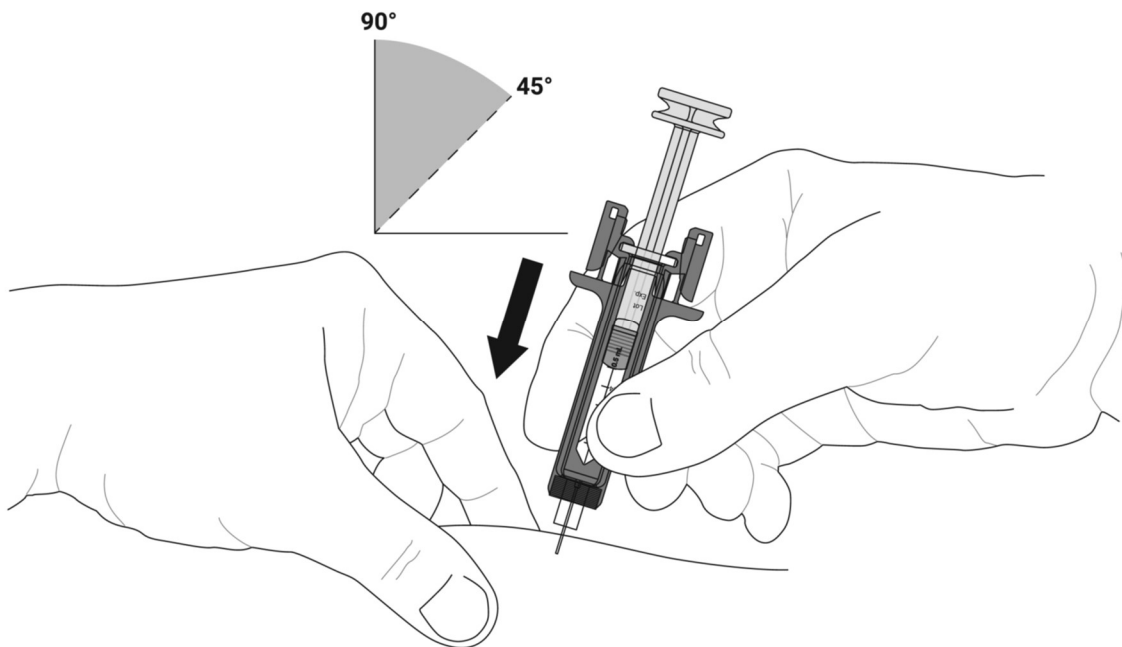
Step 3: Subcutaneous (under the skin) injection

I With one hand gently pinch the skin at the injection site to create a firm surface.

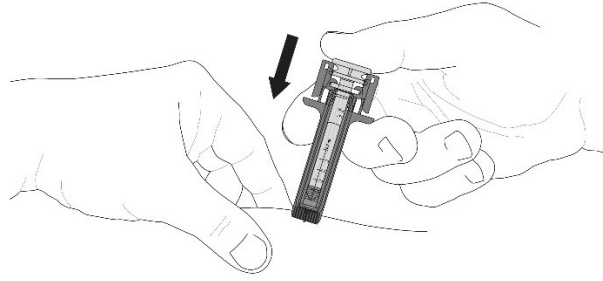


Important: Keep the skin pinched while injecting.

J Hold the pinch. With your other hand insert the needle into the skin at a 45 to 90 degree angle as shown.

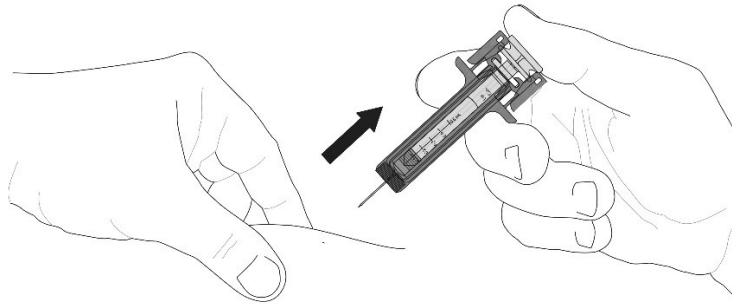


K Using slow and constant pressure, slowly press down on the plunger rod as far as it will go so that the plunger head is completely between the needle guard wings.



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

When done, keep the plunger fully pressed down while you carefully pull the needle straight out from the injection site.



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!**

Slowly release the plunger and allow the needle guard to automatically cover the exposed needle. Keep your hands away from the needle at all times.



M Discard (throw away) your used prefilled syringe.



- Put the used prefilled syringe in a FDA-cleared sharps or other appropriate disposal container right away after use. **Do not throw away (dispose of)** your NYPOZI 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, syringes, and prefilled 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.

tanvex_{NYPOZI™}
(filgrastim-txid) Injection

Manufactured by:
Tanvex BioPharma USA, Inc., San Diego, CA 92121
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