Patient Information

NEUPOGEN® (nu-po-jen)

(filgrastim)

injection

What is NEUPOGEN?

NEUPOGEN is a man-made form of granulocyte colony-stimulating factor (G-CSF), which is made using the bacteria *Escherichia coli*. G-CSF is a substance produced by the body. It stimulates the growth of neutrophils (nu-tro-fils), a type of white blood cell important in the body’s fight against infection.

Who should not take NEUPOGEN?

Do not take NEUPOGEN if you have had an allergic reaction to human G-CSFs such as NEUPOGEN (filgrastim) or Neulasta® (pegfilgrastim) or other forms of filgrastim.

What should I tell my doctor before taking NEUPOGEN?

Before you take NEUPOGEN, tell your doctor if you:

- have a sickle cell disorder.
- have a problem with your kidneys, as you may need more frequent urine tests.
- are allergic to latex. The needle cap on the prefilled syringes contains dry natural rubber (derived from latex). You should not give NEUPOGEN 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 doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Why am I given NEUPOGEN if I was exposed to radiation?

Exposure to high levels of radiation damages bone marrow. Damage to the bone marrow can be deadly. NEUPOGEN increases your chance of survival.

Effectiveness of NEUPOGEN in increasing survival after radiation exposure was only studied in animals. NEUPOGEN given after deadly radiation levels could not be studied in people.

How will I receive NEUPOGEN?

- If you or your child is receiving NEUPOGEN because you or your child is also receiving chemotherapy, the last dose of NEUPOGEN should be injected at least 24 hours before your next dose of chemotherapy.
If you or your child is receiving NEUPOGEN because you or your child has been exposed to harmful doses of radiation, your healthcare provider will monitor your response to NEUPOGEN. Your healthcare provider will advise you when to discontinue NEUPOGEN.

What are the possible serious side effects of NEUPOGEN?

**NEUPOGEN may cause serious side effects, including:**

- **Spleen Rupture.** Your spleen may become enlarged and can rupture while taking NEUPOGEN. A ruptured spleen can cause death. Call your doctor right away if you or your child has pain in the left upper stomach (abdomen) area or your left shoulder.

- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your doctor or get emergency medical help right away if you or your child has 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 the whole body, shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, and sweating. If you or your child starts to have any of these symptoms, stop using NEUPOGEN and call your doctor or get emergency help right away. If you or your child has an allergic reaction during the injection of NEUPOGEN, stop the injection right away.

- **Sickle Cell Crises.** You may have a serious sickle cell crisis if you have a sickle cell disorder and take NEUPOGEN. Serious and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim. Call your doctor right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.

- **Kidney injury (glomerulonephritis).** Kidney injury has been seen in patients who received NEUPOGEN. Call your doctor right away if you experience puffiness in your face or ankles, blood in your urine or brown colored urine or you notice 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 often
  - trouble breathing
  - swelling of your stomach-area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness
- **Decreased platelet count (thrombocytopenia).** Your doctor will check your blood during treatment with NEUPOGEN. Tell your doctor if you have unusual bleeding or bruising while taking NEUPOGEN. This could mean a decrease of platelets, which reduces the ability of blood to clot.

- **Increased white blood cell count (leukocytosis).** Your doctor will check your blood during treatment with NEUPOGEN.

- **Inflammation of your blood vessels (cutaneous vasculitis).** Tell your doctor if you develop purple spots or redness of your skin.

The most common side effects of NEUPOGEN include aching in the bones and muscles.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of NEUPOGEN. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**HOW TO PREPARE AND GIVE A NEUPOGEN INJECTION**

NEUPOGEN should be injected at the same time each day. If you miss a dose, contact your doctor or nurse.

Always use the correct dose of NEUPOGEN. Too little NEUPOGEN may not protect you against infections, and too much NEUPOGEN may cause too many neutrophils to be in your blood. Your doctor will determine your/your child’s correct dose based on your/your child's body weight.

If you are giving someone else NEUPOGEN injections, it is important that you know how to inject NEUPOGEN, how much to inject, and how often to inject NEUPOGEN.

NEUPOGEN is available as a liquid in vials or in prefilled syringes. When you receive your NEUPOGEN, always check to see that:

- The name NEUPOGEN appears on the package and vial or prefilled syringe label.

- The expiration date on the vial or prefilled syringe label has not passed. **You should not use a vial or prefilled syringe after the date on the label.**

- The strength of the NEUPOGEN (number of micrograms in the colored dot on the package containing the vial or prefilled syringe) is the same as what your doctor prescribed.
The NEUPOGEN liquid in the vial or in the prefilled syringe is clear and colorless. **Do not use NEUPOGEN** if the contents of the vial or prefilled syringe appear discolored or cloudy, or if the vial or prefilled syringe appears to contain lumps, flakes, or particles.

**If you are using vials of NEUPOGEN, only use the syringe that your doctor prescribes.**

Your doctor or nurse will give you instructions on how to measure the correct dose of NEUPOGEN. This dose will be measured in milliliters. You should only use a syringe that is marked in tenths of milliliters, or mL (for example, 0.2 mL). The doctor or nurse may refer to an mL as a cc (1 mL = 1 cc). If you do not use the correct syringe, you/your child could receive too much or too little NEUPOGEN.

**Only use disposable syringes and needles. Use the syringes only once and dispose of them as instructed by your doctor or nurse.**

**IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, YOU SHOULD FOLLOW THESE INSTRUCTIONS.**

**Setting up for an injection**

Note: The needle cap on the prefilled syringes contains dry natural rubber (derived from latex); persons with latex allergies should not administer these products.

1. Find a clean flat working surface, such as a table.

2. Remove the vial or prefilled syringe of NEUPOGEN from the refrigerator. Allow NEUPOGEN to reach room temperature (this takes about 30 minutes). Vials or prefilled syringes should be used only once. **DO NOT SHAKE THE VIAL OR PREFILLED SYRINGE.** Shaking may damage the NEUPOGEN. If the vial or prefilled syringe has been shaken vigorously, the solution may appear foamy and it should not be used.
3. Assemble the supplies you will need for an injection:
   - NEUPOGEN vial and disposable syringe and needle
   - Or NEUPOGEN prefilled syringe with transparent (clear) plastic orange needle guard attached
   - Two alcohol swabs and one cotton ball or gauze pad
   - Puncture-proof disposal container
4. Wash your hands with soap and warm water.

HOW TO PREPARE THE DOSE OF NEUPOGEN IN VIALS OR PREFILLED SYRINGES

If you are using NEUPOGEN in a vial, follow the instructions in Section A. If you are using NEUPOGEN in a prefilled syringe, go to Section B.

Section A. Preparing the dose using NEUPOGEN in a vial

1. Take the cap off the vial. Clean the rubber stopper with one alcohol swab.

2. Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. Dispose of that syringe in the puncture-proof disposal container. If the syringe package is undamaged, open the package and remove the syringe.
3. Pull the needle cap straight off the syringe. Then, pull back the plunger and draw air into the syringe. The amount of air drawn into the syringe should be the same amount (mL or cc) as the dose of NEUPOGEN that your doctor prescribed.

4. 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 once.

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

6. Keeping the needle in the vial, turn the vial upside down. Make sure that the NEUPOGEN liquid is covering the tip of the needle.
7. Keeping the vial upside down, slowly pull back on the plunger to fill the syringe with NEUPOGEN liquid to the number (mL or cc) that matches the dose your doctor prescribed.

8. Keeping the needle in the vial, check for air bubbles in the syringe. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Then slowly push the plunger up to force the air bubbles out of the syringe.

9. Keeping the tip of the needle in the liquid, once again pull the plunger back to the number on the syringe 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.

10. 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 doctor. Remove the syringe from the vial but do not lay it down or let the needle touch anything. (Go to “Selecting and preparing the injection site”).
Section B. Preparing the dose using NEUPOGEN in a prefilled syringe

1. Remove the syringe from the package and the tray. Check to see that the plastic orange needle guard is covering the barrel of the glass syringe. **DO NOT push the orange needle guard over the needle cap before injection.** This may activate or lock the needle guard. If the orange needle guard is covering the needle that means it has been activated. **DO NOT use that syringe. Dispose of that syringe in the puncture-proof disposal container. Use a new syringe from the package.**

2. Hold the syringe barrel through the needle guard windows with the needle pointing up. Holding the syringe with the needle pointing up helps to prevent medicine from leaking out of the needle. Carefully pull the needle cap straight off.

3. Check the syringe for air bubbles. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.

4. Push the plunger up to the number (mL) on the syringe that matches the dose of NEUPOGEN that your doctor prescribed.

5. Check again to make sure the correct dose of NEUPOGEN is in the syringe.

6. Gently place the prefilled syringe with the window flat on your clean working surface so that the needle does not touch anything.

Selecting and preparing the injection site (for vials and prefilled syringes)

1. Choose an injection site. Four recommended injection sites for NEUPOGEN are:
   - The outer area of your upper arms
   - The abdomen, except for the two-inch area around your navel
   - The front of your middle thighs
   - The upper outer areas of your buttocks
Choose a new site each time you inject NEUPOGEN. Choosing a new site can help avoid soreness at any one site. Do not inject NEUPOGEN into an area that is tender, red, bruised, or hard or that has scars or stretch marks.

2. Clean the injection site with a new alcohol swab.

Injecting the dose of NEUPOGEN (for vials and prefilled syringes)

1. For injecting the dose of NEUPOGEN from a vial, remove the syringe and needle from the vial. For injecting the dose of NEUPOGEN from a prefilled syringe, pick up the prefilled syringe from the clean flat working surface by grabbing the sides of the needle guard with your thumb and forefinger.

2. Hold the syringe in the hand you will use to inject NEUPOGEN. Use the other hand to pinch a fold of skin at the cleaned injection site. Note: If using a prefilled syringe with a needle guard, hold the syringe barrel through the needle guard windows when giving the injection.
3. Holding the syringe like a pencil, use a quick “dart-like” motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.

4. Inject the prescribed dose subcutaneously as directed by your doctor, nurse, or pharmacist.
5. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.

6. Use the prefilled syringe with the needle guard or a syringe and vial only once. If you are using a syringe, DO NOT put the needle cap back on the needle. Discard the vial with any remaining NEUPOGEN liquid.
Activating the Needle Guard for the prefilled syringe after the injection has been given

1. After injecting NEUPOGEN from the prefilled syringe, do not recap the needle. Keep your hands behind the needle at all times. While holding the clear plastic finger grip of the syringe with one hand, grasp the orange needle guard with your free hand and slide the orange needle guard over the needle until the needle is completely covered and the needle guard clicks into place. **NOTE: If an audible click is not heard, the needle guard may not be completely activated.**

2. Place the prefilled syringe with the activated needle guard into a puncture-proof container for proper disposal as described below.

How should I dispose of used syringes, needles, and vials

- Put your used syringes, needles, and vials in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose 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
  - 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 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](http://www.fda.gov/safesharpsdisposal).
• Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

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

How should I store NEUPOGEN?
• Store NEUPOGEN in the refrigerator between 36°F to 46°F (2°C to 8°C).
• Avoid freezing NEUPOGEN. If frozen, thaw in the refrigerator before giving a dose. Throw away (dispose of) NEUPOGEN if it has been frozen more than 1 time.
• Store NEUPOGEN in the carton to protect from light until you are ready to use it.
• Do not leave NEUPOGEN in direct sunlight.
• Avoid shaking NEUPOGEN.
• NEUPOGEN can be left out at room temperature for up to 24 hours. Throw away (dispose of) NEUPOGEN that has been left at room temperature for longer than 24 hours.

What are the ingredients in NEUPOGEN?
Active ingredient: filgrastim
Inactive ingredients: acetate, polysorbate 80, sodium, and sorbitol