

NEUPOGEN®

(Filgrastim)

Information for Patients and Caregivers

This patient package insert provides information and instructions for people who will be receiving NEUPOGEN® and their caregivers. This patient package insert does not tell you everything about NEUPOGEN®. You should discuss any questions you have about treatment with NEUPOGEN® with your doctor.

What is NEUPOGEN®?

NEUPOGEN® is a man-made form of granulocyte colony-stimulating factor (G-CSF), which is made using the bacteria *E coli*. G-CSF is a substance naturally 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.

What is NEUPOGEN® used for?

NEUPOGEN® is used to treat neutropenia (**nu**-tro-**peen**-ee-ah), a condition where the body makes too few neutrophils. Neutropenia may be a long-standing condition where your body does not make enough neutrophils, or it may be caused by drugs used to treat cancer. In some cases, your body may make enough neutrophils, but as part of your treatment for cancer, your doctor may want to increase the number of certain blood cells (CD34 cells) and collect them. The cells are collected using a process called apheresis (**ay**-fer-**ree**-sis). These collected cells are given back to you after you receive very high doses of treatment for cancer to make your blood counts get back to normal more quickly.

How does NEUPOGEN® work?

NEUPOGEN® works by helping your body make more neutrophils. To make sure NEUPOGEN® is working, your doctor will ask that you have regular blood tests to count the number of neutrophils you have. It is important that you follow your doctor's instructions about getting these tests.

Who should not take NEUPOGEN®?

Do not take NEUPOGEN® if you are:

- Allergic to NEUPOGEN® (Filgrastim) or any of its ingredients. See the end of this leaflet for a list of ingredients in NEUPOGEN®.
- Allergic to other medicines made using the bacteria *E coli*. Ask your doctor if you are not sure.

What important information do I need to know about taking NEUPOGEN®?

NEUPOGEN® may reduce your chance of getting an infection, but does not prevent all infections. An infection can still happen during the short time when your/your child's neutrophil levels are low. You must be alert and look for some of the common signs or symptoms of infection, such as fever, chills, rash, sore throat, diarrhea, or redness, swelling, or pain around a cut or sore. If you/your child has any of these signs or symptoms during treatment with NEUPOGEN®, tell your doctor or nurse immediately.

There is a possibility that you could have a reaction at an injection site. If there is a lump, swelling, or bruising at an injection site that does not go away, call your doctor.

If you have a sickle cell disorder, make sure that you tell your doctor before you start taking NEUPOGEN®. If you have a sickle cell crisis after getting NEUPOGEN®, tell your doctor right away.

Make sure your doctor knows about all medicines, and herbal or vitamin supplements you are taking before starting NEUPOGEN®. If you are taking lithium you may need more frequent blood tests.

If you/your child are receiving NEUPOGEN® because you are also receiving chemotherapy, the last dose of NEUPOGEN® should be injected at least 24 hours before your next dose of chemotherapy.

There is more information about NEUPOGEN® in the Physician Package Insert. If you have any questions, you should talk to your doctor.

What are possible serious side effects of NEUPOGEN®?

- **Spleen Rupture.** Your spleen may become enlarged and can rupture while taking NEUPOGEN®. 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 or your child has pain in the left upper stomach area or left shoulder tip area. This pain could mean your or your child's spleen is enlarged or ruptured.
- **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 seek emergency care right away. If you or your child has an allergic reaction during the injection of NEUPOGEN®, stop the injection right away.
- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your doctor or seek emergency care right away if you or your child has shortness of breath, trouble breathing or a fast rate of breathing.

What are the most common side effects of NEUPOGEN®?

The most common side effect you/your child may experience is aching in the bones and muscles. This aching can usually be relieved by taking a non-aspirin pain reliever such as acetaminophen.

Some people experience redness, swelling, or itching at the site of injection. This may be an allergy to the ingredients in NEUPOGEN[®], or it may be a local reaction. If you are giving an injection to a child, look for signs of redness, swelling, or itching at the site of injection because they may not be able to tell you they are experiencing a reaction. If you notice any signs of a local reaction, call your doctor.

What about pregnancy or breastfeeding?

NEUPOGEN[®] has not been studied in pregnant women, and its effects on unborn babies are not known. If you take NEUPOGEN[®] while you are pregnant, it is possible that small amounts of it may get into your baby's blood. It is not known if NEUPOGEN[®] 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 tell your doctor before using NEUPOGEN[®].

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.

You must 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 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.

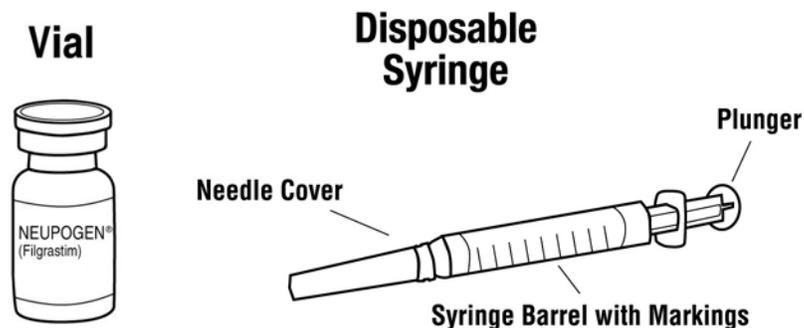
Your doctor or nurse will give you instructions on how to measure the correct dose of NEUPOGEN[®]. This dose will be measured in milliliters. You should only use a syringe that is marked in tenths of milliliters, or mL (for example, 0.2 mL). The doctor or nurse may refer to an mL as a cc (1 mL = 1 cc).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

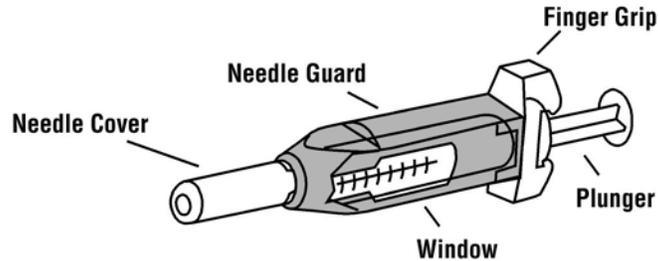
Setting up for an injection

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

Prefilled Syringe



- two alcohol swabs and one cotton ball or gauze pad

Alcohol Swabs



Cotton Ball



- 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

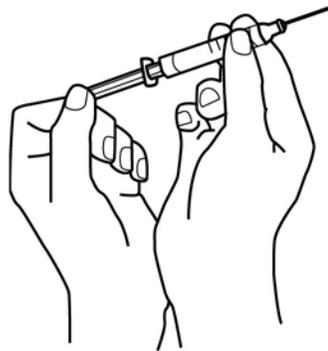
If you are using NEUPOGEN® in a vial, follow the instructions in Section A. If you are using NEUPOGEN® in a prefilled syringe, go to Section B.

Section A. Preparing the dose of NEUPOGEN® in a vial

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

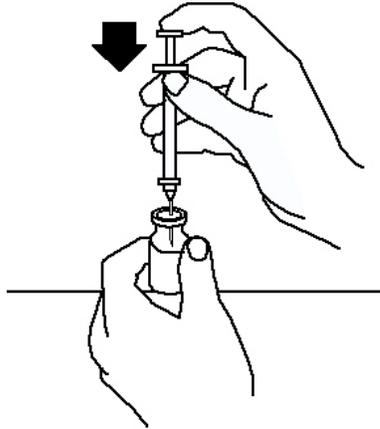


2. Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. Dispose of that syringe in the puncture-proof disposal container. If the syringe package is undamaged, open the package and remove the syringe.
3. Pull the needle cover straight off the syringe. 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.

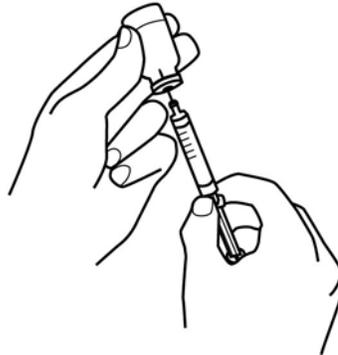


4. Keep the vial on your flat working surface and insert the needle straight down through the rubber stopper. Do not put the needle through the rubber stopper more than once.

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.



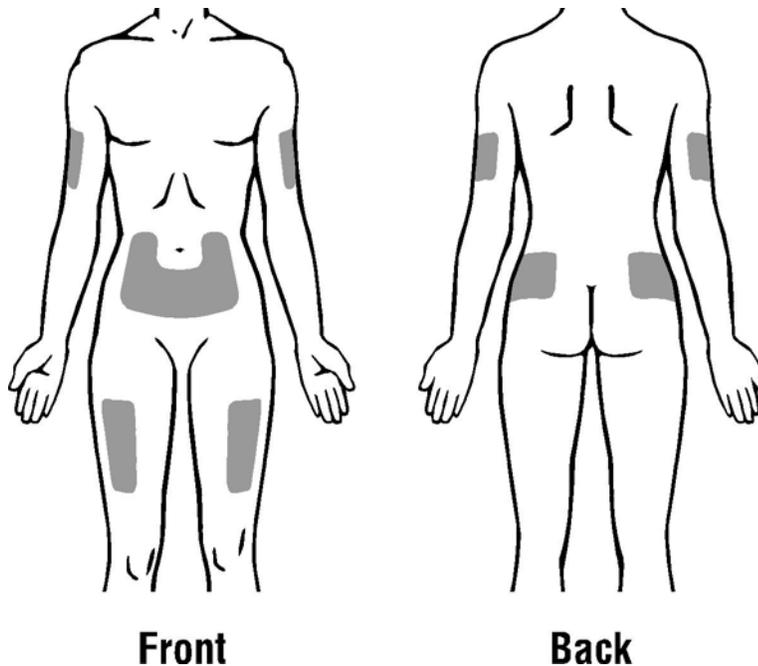
7. Keeping the vial upside down, slowly pull back on the plunger to fill the syringe with NEUPOGEN® liquid to the number (mL or cc) that matches the dose your doctor prescribed.
8. Keeping the needle in the vial, check for air bubbles in the syringe. If there are air bubbles, gently tap the syringe with 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 “Injecting the dose of NEUPOGEN®”).

Section B. Preparing the dose of 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 cover 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 cover 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

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



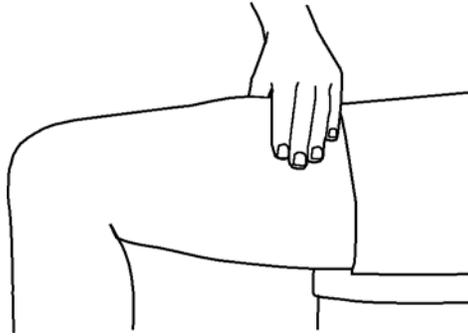
Choose a new site each time you inject NEUPOGEN[®]. Choosing a new site can help avoid soreness at any one site. Do not inject NEUPOGEN[®] into an area that is tender, red, bruised, or hard or that has scars or stretch marks.

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

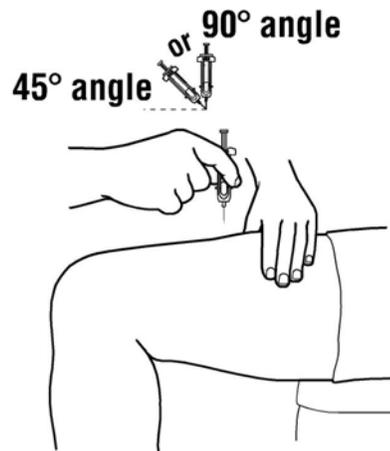


Injecting the dose of NEUPOGEN[®]

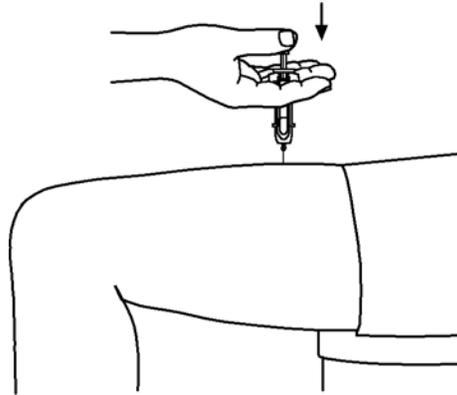
1. For injecting the dose of NEUPOGEN[®] from a vial, remove the syringe and needle from the vial. For injecting the dose of NEUPOGEN[®] from a prefilled syringe, pick up the prefilled syringe from your clean flat working surface by grabbing the sides of the needle guard with your thumb and forefinger.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



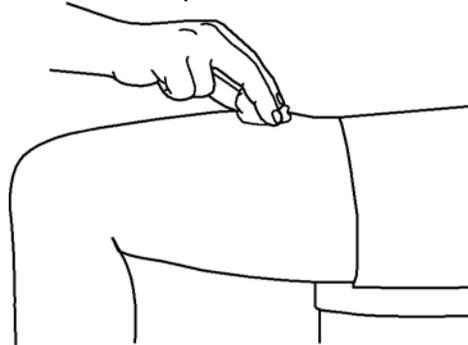
3. Holding the syringe like a pencil, use a quick “dart-like” motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.



4. After the needle is inserted, let go of the skin. Pull the plunger back slightly. If no blood appears, slowly push down on the plunger all the way, until all the NEUPOGEN[®] is injected. **If blood comes into the syringe, do not inject NEUPOGEN[®], because the needle has entered a blood vessel.** Withdraw the syringe and discard it in the puncture-proof container. Repeat the steps to prepare a new syringe (or get a new prefilled syringe) and choose and clean a new injection site. Remember to check again for blood before injecting NEUPOGEN[®].



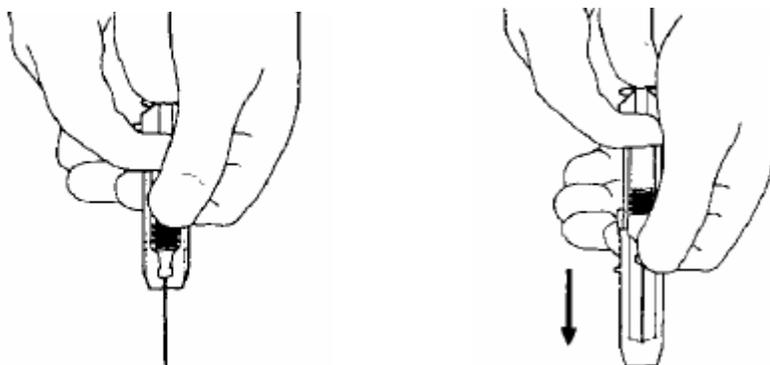
5. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.



6. Use a prefilled syringe with the needle guard or a syringe and vial only once. If you are using a syringe, DO NOT put the needle cover (the 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.

Disposal of syringes, needles, vials and needle guards

You should always follow the instructions given by your doctor, nurse, or pharmacist on how to properly dispose of containers with used syringes, needles, vials and needle guards. There may be special state and local laws for disposal of used needles and syringes.

- Place all used needles, needle covers, syringes, and vials (empty or unused contents) into a “Sharps” container given to you by your doctor or pharmacist or in a hard-plastic container with a screw-on cap, or a metal container with a plastic lid, such as a coffee can, labeled “used syringes.” If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. If a hard-plastic container is used, always screw the cap on tightly after each use.
- Do not use glass or clear plastic containers.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off. **Do not throw the container in the household trash. Do not recycle.**
- **Always** keep the container out of the reach of children.

How should NEUPOGEN® be stored?

NEUPOGEN® should be stored in the refrigerator at 2° to 8°C (36° to 46°F), but not in the freezer. Avoid shaking NEUPOGEN®. If NEUPOGEN® is accidentally frozen, allow it to thaw in the refrigerator before giving the next dose. However, if it is frozen a second time, do not use it and contact your doctor or nurse for further instructions.

NEUPOGEN® can be left out at room temperature for up to 24 hours. Do not leave NEUPOGEN® in direct sunlight. If you have any questions about storage or how to carry NEUPOGEN® when you travel, contact your doctor, nurse, or pharmacist.

What are the ingredients in NEUPOGEN®?

Each syringe and vial contains Filgrastim in a sterile, clear, colorless, preservative-free solution containing acetate, sorbitol, polysorbate 80, and sodium.

The needle cover on the single-use prefilled syringe contains dry natural rubber (latex), which should not be handled by persons sensitive to this substance.

[Amgen Logo]

Manufactured by:

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