

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**NEUPOGEN**[®] (pronounced *nu-po-gen*)
filgrastim injection

Read this carefully before you start taking **NEUPOGEN** 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 **NEUPOGEN**.

Serious Warnings and Precautions

- 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 area or left shoulder tip area.
- If you have sickle cell trait or sickle cell disease, make sure that you tell your doctor before you start taking NEUPOGEN 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 NEUPOGEN, resulting in death in some cases.

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 predisposes your body to infections and prevents you from fighting them. Your doctor has decided to prescribe Neupogen for you to increase the number of neutrophils (*nu-tro-fils*), which will fight infections.

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.

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.

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.

What are the ingredients in NEUPOGEN?

Medicinal ingredients: filgrastim

Non-medicinal ingredients: acetate, polysorbate 80, sodium, sorbitol

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.

NEUPOGEN comes in the following dosage forms:

NEUPOGEN is available in 2 vial sizes: 1 mL and 1.6 mL. The preservative-free single use vials contain 300 mcg/mL of filgrastim.

NEUPOGEN is available in 2 prefilled syringe sizes: 0.5 mL and 0.8 mL. The preservative-free single use prefilled syringes contain 600 mcg/mL of filgrastim.

Do not use NEUPOGEN if you are:

- allergic to NEUPOGEN (filgrastim) or any of its ingredients.
- allergic to other medicines made using the bacteria *E coli*. Ask your doctor if you are not sure.

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

- If you have 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. 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 you/your child's neutrophil levels are low.
- If there is a lump, swelling, or bruising at an injection site that does not go away, call your doctor. There is a possibility that you could have a reaction at an injection site.
- If you have a sickle cell trait or sickle cell disease, 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.

Other warnings you should know about:

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.

Talk to your doctor if you experience unusual bleeding or bruising while taking NEUPOGEN following chemotherapy, as this could mean a decrease of platelets which reduces the ability of blood to clot.

If you have any questions, you should talk to your doctor.

Pregnancy or breastfeeding and NEUPOGEN

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 breastfeeding, you should tell your doctor before using NEUPOGEN.

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 NEUPOGEN:

Drug interactions between NEUPOGEN 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 NEUPOGEN.

How to take NEUPOGEN:

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. **Do not use a vial or prefilled syringe after the date on the label.**
- The NEUPOGEN liquid in the vial or in the prefilled syringe is clear and colourless. **Do not use NEUPOGEN** if the contents of the vial or prefilled syringe appear discoloured 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.

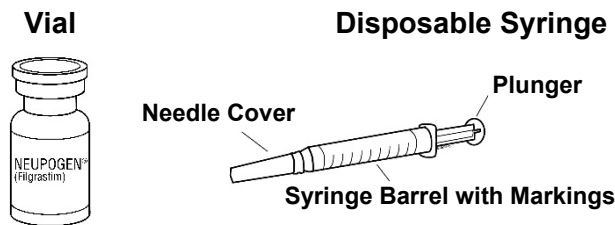
Your doctor or nurse will give you instructions on how to measure the correct dose of NEUPOGEN. This dose will be measured in milliliters. You should only use a syringe that is marked in tenths of milliliters, or mL (for example, 0.2 mL). The doctor or nurse may refer to an mL as a cc (1 mL = 1 cc). 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.

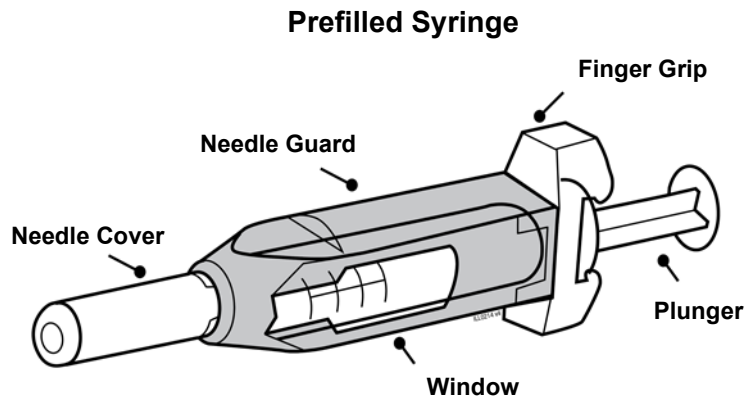
IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, YOU SHOULD FOLLOW THESE INSTRUCTIONS.

Setting up for an injection

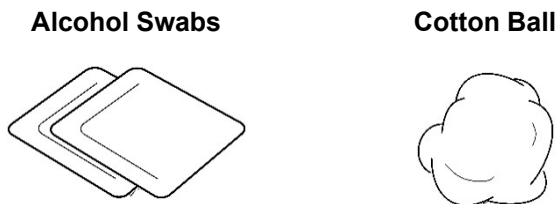
1. Find a clean flat working surface, such as a table.
2. Remove the vial or prefilled syringe of NEUPOGEN from the refrigerator. Allow NEUPOGEN to reach room temperature (this takes about 30 minutes). Vials or prefilled syringes should be used only once. **DO NOT SHAKE THE VIAL OR PREFILLED SYRINGE.** 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 sterile disposable syringe and needle:



- Or NEUPOGEN prefilled syringe with transparent (clear) plastic orange needle guard attached:

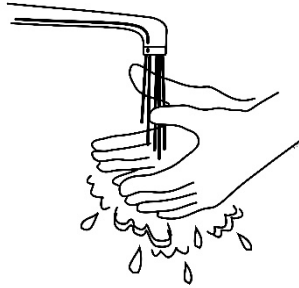


- Two alcohol swabs and one cotton ball or gauze pad



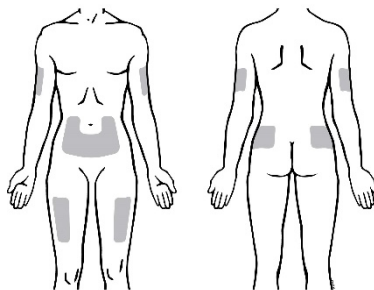
- Puncture-proof disposal container

4. Clean your work surface thoroughly and wash your hands with soap and warm water.



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

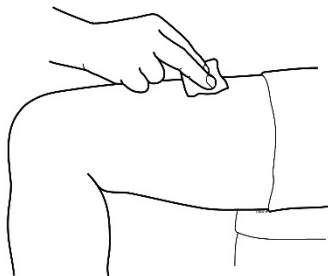
1. Choose an injection site. Four recommended injection sites for NEUPOGEN are:
 - The outer area of your upper arms
 - The abdomen, except for the two inch area around your navel
 - The front of your middle thighs
 - The upper outer areas of your buttocks



Front

Back

2. 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, hard or that has scars or stretch marks.
3. Clean the injection site with a new alcohol swab. Use a circular motion from the inside to the outside of the injection site.

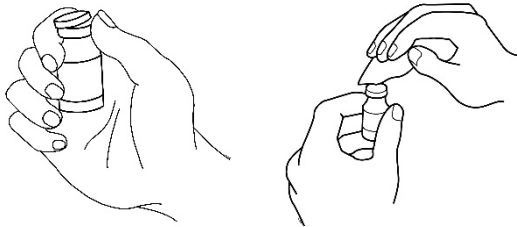


HOW TO PREPARE THE DOSE OF NEUPOGEN IN VIALS OR PREFILLED SYRINGES

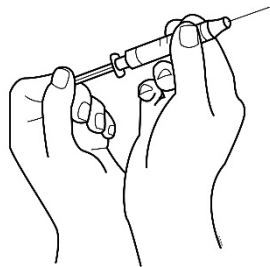
If you are using NEUPOGEN in a vial, follow the instructions in Section A. If you are using NEUPOGEN in a prefilled syringe, go to Section B.

Section A. Preparing the dose using NEUPOGEN in a vial

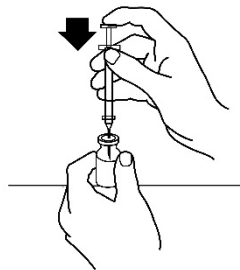
1. Take the cap off the vial. Clean the rubber stopper with one alcohol swab.



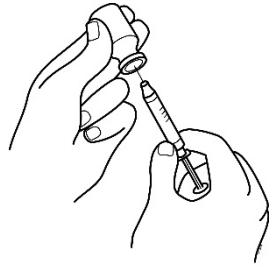
2. Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. Dispose of that syringe in the puncture-proof disposal container. If the syringe package is undamaged, open the package and remove the syringe.
3. Pull the needle cover straight off the syringe.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



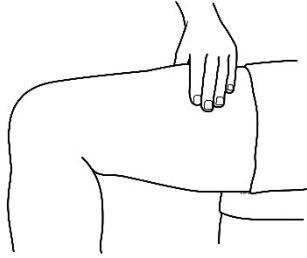
7. Keeping the vial upside down, slowly pull back on the plunger to fill the syringe with NEUPOGEN liquid to the number (mL or cc) that matches the dose your doctor prescribed.
8. Keeping the needle in the vial, check for air bubbles in the syringe. If there are air bubbles, gently tap the syringe with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

Section B. Preparing the dose using NEUPOGEN in a prefilled syringe

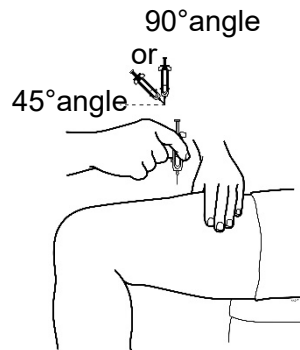
1. Remove the syringe from the package and the tray. Check to see that the plastic orange needle guard is covering the barrel of the glass syringe. **DO NOT** push the orange needle guard over the needle cover before injection. This may activate or lock the needle guard. If the orange needle guard is 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.

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

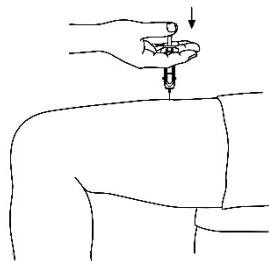
1. For injecting the dose of NEUPOGEN from a vial, slowly remove the syringe and needle from the vial. For injecting the dose of NEUPOGEN from a prefilled syringe, pick up the prefilled syringe from the clean flat working surface by grabbing the sides of the needle guard with your thumb and finger.
2. 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.



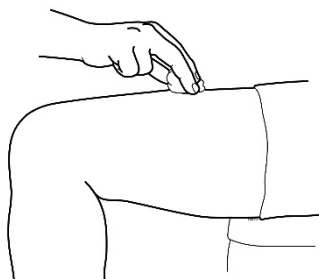
3. Holding the syringe like a pencil, use a quick “dart-like” motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.



4. After the needle is inserted, let go of the skin. Inject the prescribed dose subcutaneously as directed by your doctor, nurse or pharmacist.



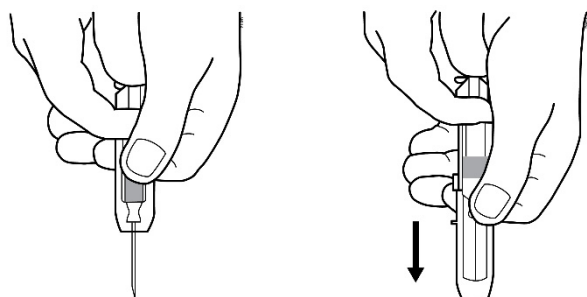
5. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.



6. Use the prefilled syringe with the needle guard or a syringe, needle and vial only once. If you are using a syringe needle, **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 provincial or 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.

Usual dose:

Your doctor will determine you/your child's correct dose based on you/your child's body weight.

Overdose:

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.

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

Missed Dose:

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

What are possible serious side effects from using NEUPOGEN?

These are not all the possible side effects you may experience when taking NEUPOGEN. If you experience any side effects not listed here, tell your healthcare professional.

- **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 you 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.
- **Sickle Cell Crisis.** Call your doctor or seek emergency care right away if you or your child experiences severe pain in bones, chest, gut or joints.
- **Kidney injury (glomerulonephritis)** 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 coloured urine, or if you notice that you urinate less often than usual.

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-acetylsalicylic acid 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. **If at any time a serious allergic reaction occurs, immediately call a doctor or emergency services (for example, call 911).**

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	
UNCOMMON $\geq 0.1\%$ and $< 1\%$			
Bone Pain		√	
Acute respiratory distress syndrome (including the following symptoms: fever, shortness of breath, cough, or congestion in your lungs)		√	√
Alveolar hemorrhage and hemoptysis (including the following symptoms: bleeding from the lungs and coughing of blood)		√	√
Low platelet counts (thrombocytopenia) (including the following symptoms: easy bruising and increased bleeding).		√	
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)		√	
RARE $\geq 0.01\%$ and $< 0.1\%$			
Extramedullary hematopoiesis (production of blood cell components [red blood cells, white blood cells, and/or platelets] outside of the typical site of production [bone marrow]). This may result in an enlarged spleen, liver, or pink, red, or blue/purple spots or bumps on the skin.		√	

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 RARE < 0.01%			
Splenomegaly (including the following symptoms: pain in the left upper stomach area or left shoulder tip area)		√	
Osteoporosis in children with severe chronic neutropenia (including decreased bone density, making them weak, more brittle and likely to break)		√	
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)		√	√
Cutaneous Vasculitis (including the following signs: inflammation of the blood vessels in the skin)		√	
Sweet's Syndrome (including the following symptoms: plum-coloured, raised, painful sores on the limbs and sometimes the face and neck with a fever)		√	
Kidney Injury (glomerulonephritis) (including the following symptoms: puffiness in the face or ankles, blood in urine or brown coloured urine, or urinating less often than usual).		√	√
*FREQUENCY NOT KNOWN			
Splenic rupture (including the following symptoms: left upper abdominal pain or pain at the tip of your shoulder)		√	
Pseudogout (including the following symptoms in patients treated for cancer: pain and swelling of the joints, similar to gout)		√	

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	
**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

- NEUPOGEN should be stored in the refrigerator at 2 °C to 8 °C (36 °F 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 14 days. Keep the container in the outer carton to protect from light. 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.

Keep out of reach and sight of children.

If you want more information about NEUPOGEN:

- 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 web site (www.amgen.ca), or by calling Amgen Canada Inc., at: 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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