

YOUR
INTRODUCTION TO

Pr **NIVESTYM**[®]
(filgrastim injection)



Getting started on my NIVESTYM treatment

Starting any new treatment can be a challenge. This brochure has been designed to answer your questions and help you get the most out of your treatment.

Be sure to read this brochure to learn the basics about NIVESTYM, and remember to keep it handy to help you better understand your treatment. Also, it is important to be honest with your healthcare team about how you are doing on treatment. Speak to them when you have questions or concerns about your treatment plan.

What is NIVESTYM used for?

NIVESTYM is used to treat neutropenia, a condition where the body makes too few of one type of white blood cell that is important in the body's fight against infections—called a *neutrophil* (nu-tro-fil).

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.



How does NIVESTYM work?

NIVESTYM is not a chemotherapy, but it can sometimes be used in conjunction with chemotherapy. It is a man-made form of granulocyte colony-stimulating factor (G-CSF), a protein naturally produced by the body. It is artificially made from a type of *E. coli* bacteria and works by helping your body make more neutrophils, which are a type of white blood cell important in the body's fight against infection.



To make sure NIVESTYM 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 formats are available for NIVESTYM?

Prefilled syringes (600 mcg/mL):



- 300 mcg/0.5 mL in a single-use graduated prefilled syringe with a BD Ultrasafe Plus™ Passive Needle Guard
- 480 mcg/0.8 mL in a single-use graduated prefilled syringe with a BD Ultrasafe Plus™ Passive Needle Guard

The syringe plunger stopper and needle cover are not made with natural rubber latex

Vials (300 mcg/mL):



- 300 mcg/1 mL in a single-use vial
- 480 mcg/1.6 mL in a single-use vial

The vial stopper is not made with natural rubber latex

How will I receive NIVESTYM?



NIVESTYM is intended for subcutaneous injection or intravenous use and should not be given by any other route of administration. Your healthcare provider may decide that subcutaneous injections can be given at home by you or your caregiver.

If NIVESTYM is given at home, see the detailed “Instructions for Use” on pages 10–16 for information on how to prepare and inject a dose of NIVESTYM.



You should not inject a dose of NIVESTYM less than 0.3 mL (180 mcg) from a NIVESTYM prefilled syringe. A dose less than 0.3 mL cannot be accurately measured using the NIVESTYM prefilled syringe.



Your healthcare provider will tell you how much NIVESTYM to inject and when to inject it. Do not change your dose or stop NIVESTYM unless instructed by your healthcare provider.



If you are receiving NIVESTYM while receiving chemotherapy, your dose of NIVESTYM should be injected at least 24 hours before or 24 hours after your dose of chemotherapy.



If you miss a dose of NIVESTYM, talk to your healthcare provider as soon as possible about when you should take your next dose.



If you think you have received too much NIVESTYM, immediately contact your healthcare professional, hospital emergency department, or regional poison control. This is relevant even if you are not experiencing any symptoms.

How do I self-administer NIVESTYM?

Your healthcare provider should show you and your caregiver how to prepare and inject NIVESTYM before you use it.

See the detailed “Instructions for Use” on pages 10–16 for information on how to prepare and inject a dose of NIVESTYM.

Important safety information

What should I know before I take NIVESTYM?

Do not use NIVESTYM if you are allergic (hypersensitive) to filgrastim or any other ingredients found in the product, or to other medicines made using the bacteria *E. coli*. Ask your doctor if you are not sure.

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

- have pain in your left abdominal area or at the tip of your shoulder
- have osteoporosis (loss of calcium from the bones, which leads to the bones, becoming weak and fragile)
- are suffering from any other illness, especially any infections
- experience a cough, fever, and difficulty breathing
- have a sickle cell trait or sickle cell disease (an inherited blood disorder that affects red blood cells). In patients with sickle cell trait or sickle cell disease, severe sickle cell crises have been associated with the use of NIVESTYM, resulting in death in some cases
- are taking or have recently taken any other medications, including those obtained without a prescription
- are pregnant or plan to become pregnant. It is not known if NIVESTYM will harm your unborn baby
- are breastfeeding or plan to breastfeed. If you take NIVESTYM while you are pregnant, it is possible that small amounts of it may get into your baby's blood. It is not known if NIVESTYM passes into your breast milk

Tell your healthcare provider about all the medicines, vitamins, supplements, and alternative medicines you take.

Important safety information

What are the possible side effects of NIVESTYM?

NIVESTYM may cause side effects, including:



SPLEEN RUPTURE

Your spleen may become enlarged and can rupture while taking NIVESTYM.

A ruptured spleen can cause death. The spleen is located in the upper left section of the belly or stomach area. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area. This pain could mean your spleen is enlarged or ruptured.



SERIOUS ALLERGIC REACTIONS

NIVESTYM 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 NIVESTYM and call your doctor or seek emergency care right away. If you or your child has an allergic reaction during the injection of NIVESTYM, stop the injection right away.



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, trouble breathing, or a fast rate of breathing.



SICKLE CELL CRISIS

Call your doctor or seek emergency care right away if you experience severe pain in bones, chest, gut, or joints.



KIDNEY INJURY (GLOMERULONEPHRITIS)

Call your healthcare provider right away if you experience puffiness of the face or ankles, blood in the urine or brown-coloured urine, or if you notice that you urinate less often than usual.



The most common side effect you may experience is bone, joint, and/or muscle pain. This pain can usually be relieved by taking a non-acetylsalicylic acid (non-aspirin) pain reliever such as acetaminophen.

Other common side effects can be fatigue, headache, loss of appetite, diarrhea, cough, sore throat, elevation in liver enzymes, and reduction in platelets (cells involved in clotting), which increases the risk of bleeding or bruising.

Some people experience a lump, redness, swelling, bruising, or itching at the site of injection. This may be an allergy to the ingredients in NIVESTYM or it may be a local 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 healthcare provider or emergency services (for example, call 911).**

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

These are not all the possible side effects of NIVESTYM. Call your healthcare provider for medical advice about side effects.



How can I reduce my risk of infection?

Neutropenia is a condition that gives you a higher risk of infection. So, while you're taking NIVESTYM, try to avoid infections by doing the following:

1. Practise good personal hygiene



- **Wash your hands frequently**, especially before you eat and after you go to the bathroom
- **Carry hand sanitizer** (a small bottle) to disinfect your hands
- **Take a warm shower** (not hot) every day (to not dry out your skin)
- **Use a soft toothbrush** to clean your teeth and avoid irritating your gums

2. Protect your skin



- **Use moisturizing lotions** if your skin becomes dry or cracked
- **Wear rubber gloves** when you do the dishes, clean, or garden
- **Do not squeeze or scratch pimples**
- **Use an electric shaver** instead of a razor to avoid cutting your skin
- **Avoid burns** when you iron or cook
- **Clean any cut or scrape at once** with warm water and soap

3. Try to stay healthy overall



- **Get enough rest**
- **Eat a well-balanced diet**
- **Drink enough fluids**
- **Exercise** as often as you can
- **Stay away from anyone who has a cold**, the flu, or an infectious disease
- **Avoid crowds**, like those in shopping malls or on buses
- **Avoid uncooked eggs, raw or undercooked meats, poultry, fish, and seafood**
- **Remove plants from the living area**—live plants can be a source of germs
- **Avoid cleaning cat litter** boxes or birdcages

Recognize and report infections

Remember to report any symptoms of infection to your doctor or healthcare team.

The most common signs and symptoms of an infection include:

- fever and chills
- rash, swelling, and redness
- mouth sores, or red or white patches in the mouth
- sore throat
- severe cough or shortness of breath
- pain or burning when urinating, or foul-smelling urine
- diarrhea
- drainage, pus, redness, swelling or pain from a cut, sore, or incision

Do not take any medicines for a fever without checking first with your healthcare team.

Helpful Web Resources

www.cancer.ca (Canadian Cancer Society)

www.cancer.org (American Cancer Society)

www.standuptocancer.ca

Instructions for use

For single-use graduated prefilled syringe



1) Getting ready

- Find a clean, well-lit, flat work surface.
 - Gather your supplies:
 - 1 new NIVESTYM prefilled syringe (included in the carton)
 - 1 adhesive bandage (not included)
 - 1 alcohol wipe (not included)
 - 1 cotton ball or gauze (not included)
 - A disposal container for sharps (not included)
 - Wash your hands with soap and water
-

2) Preparing the prefilled syringe

- Take the carton containing NIVESTYM out of the refrigerator and leave it on your work surface for at least 30 minutes.
 - **Do not shake the prefilled syringe and do not leave it in direct sunlight.**
 - Remove the prefilled syringe from the carton and check:
 - the needle guard is covering the barrel of the syringe
 - the expiration date on the NIVESTYM prefilled syringe
 - the medicine and prefilled syringe to make sure the medicine is clear and colourless
-

3) Choosing and cleaning the injection site

- Choose an injection site:
 - Front of thighs
 - Stomach area, except for a **2-inch** area around your belly button
 - Outer upper arms, only if a caregiver is giving you the injection
 - Upper outer areas of the buttocks, only if a caregiver is giving you the injection
- Choose a different site for each injection of NIVESTYM.
-  • **Do not** inject into areas where the skin is tender, red, bruised, or hard. Avoid injecting into areas with scars or stretch marks.
- Clean your injection site with an alcohol wipe. Let dry.
-  • Do not touch injection site area again before injecting.

Do not use the NIVESTYM prefilled syringe if:

- the medicine is cloudy or discoloured, or contains flakes or particles
- any part of the prefilled syringe appears cracked or broken
- the prefilled syringe has been dropped
- the needle cover is missing or not securely attached
- the expiration date printed on the label has passed

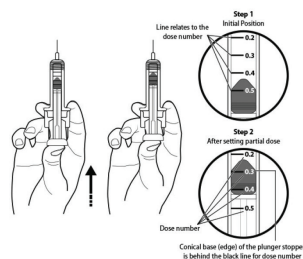
See the detailed "Instructions for Use" on pages 49–68 of the Consumer Information leaflet for information on how to prepare and inject a dose of NIVESTYM.

4) Inject your dose of NIVESTYM

- Hold the prefilled syringe by the needle guard with the needle cover pointing up. Carefully pull the needle cover straight off and away from your body.

Throw away the needle cover.

- If you were prescribed a partial dose, point the needle up and tap gently until the air rises to the top, and then slowly push up on the plunger rod to push out the extra air and medicine until the end of the conical base (edge) of the plunger stopper lines up with the syringe marking the prescribed dose.
- Be careful not to activate the needle guard before use. **Do not use a NIVESTYM prefilled syringe that has been activated.**

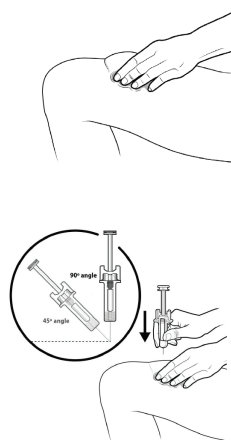


Example of a dose of 0.3 mL.
Your dose may be different than the example shown here.

- ✗ • Do not recap the needle.

- With one hand, gently pinch a fold of skin at the injection site. Hold the pinch.

- With the other hand, hold the prefilled syringe like you would hold a pencil. Use a quick "dart like" motion to insert the needle into the skin at a 45 to 90 degree angle.



Instructions for use

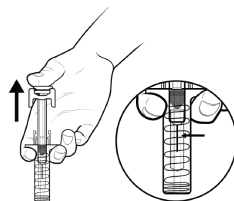
- Using a slow and constant pressure, press down on the plunger rod as far as it will go. Keep the plunger rod fully pressed down while you hold the syringe in place for 5 seconds.



- Keep the plunger rod fully pressed down while you carefully pull the needle straight out from the injection site.



- As you let go of the plunger, the needle guard will automatically slide over the needle until the needle is completely covered and the needle guard locks into place. **Do not recap the needle.**



5) Finishing up

- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds.

✗ Do not rub the injection site. You can cover the injection site with a small bandage, if needed.

- Throw away (dispose of) the syringe.
 - Put your used prefilled syringe in a sharps disposal container right away after use.
Do not throw away (dispose of) syringes in your household trash.
 - **Always keep the sharps disposal container out of the reach of children.**

See the detailed "Instructions for Use" on pages 49–68 of the Consumer Information leaflet for information on how to discard the prefilled syringe.



Instructions for use

For single-use vial

1) Getting ready

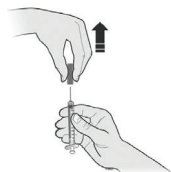
- Find a clean, well-lit, flat work surface.
 - Gather your supplies:
 - 1 new NIVESTYM single-use vial (included in the carton)
 - 1 disposable syringe and needle (not included)
 - Use only the disposable syringes and needles that your healthcare provider prescribes
 - 1 adhesive bandage (not included)
 - 2 alcohol wipes (not included)
 - 1 cotton ball or gauze (not included)
 - A disposal container for sharps (not included)
 - Wash your hands with soap and water
-

2) Preparing the vial

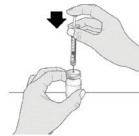
- Take the carton containing NIVESTYM out of the refrigerator and leave it on your work surface for at least 30 minutes.
 - X** ◦ **Do not** try to warm the vial by using a heat source such as hot water or a microwave.
 - X** ◦ **Do not shake the vial and do not leave it in direct sunlight.**
 - X** ◦ **Do not** shake the vial.
 - Remove the vial syringe from the carton and **make sure the medicine in the vial is clear and colourless.**
 - **Do not** use the vial if:
 - The medicine is cloudy or discoloured, or contains flakes or particles.
 - The expiration date printed on the label has passed.
-

3) Loading the syringe

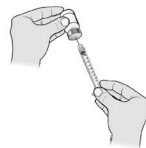
- a) Take the cap off the vial and clean the rubber stopper with 1 alcohol wipe.
 - b) Keep the vial on the flat work surface. Hold the syringe by the barrel with the needle pointing up. Carefully pull the needle cap straight off and away from your body.
Throw away the needle cap into the sharps container.
- X** • Do not recap the needle.



- c) Pull back the plunger and draw air into the syringe that is the same amount (mL) as the dose of NIVESTYM that your healthcare provider prescribed.
- d) Insert the needle straight down through the rubber stopper of the vial.
- Do not insert the needle through the rubber stopper more than 1 time.
- e) Push the plunger down and inject all the air from the syringe into the vial of NIVESTYM.



- f) Keep the needle in the vial and turn the vial upside down. Make sure that the NIVESTYM liquid is covering the tip of the needle.





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



- h) Keep the needle in the vial and check for air bubbles in the syringe. If there are any 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.
- i) 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. If there are still air bubbles, repeat the steps above to remove them.
- j) Check again to make sure you have the correct dose in the syringe. Do not remove the needle from the vial. Lay the vial down on its side with the needle still in the vial.

4) Choosing and cleaning the injection site

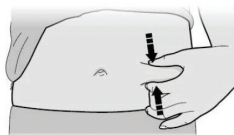
- Choose an injection site:
 - Front of thighs
 - Stomach area, except for a 2-inch area around your belly button
 - Outer upper arms, only if a caregiver is giving you the injection
 - Upper outer areas of the buttocks, only if a caregiver is giving you the injection
- Choose a different site for each injection of NIVESTYM.
-  • Do not inject into areas where the skin is tender, red, bruised, or hard. Avoid injecting into areas with scars or stretch marks.
- Clean your injection site with an alcohol wipe. Let dry.
-  • Do not touch injection site area again before injecting.

See the detailed "Instructions for Use" on pages 62–68 of the Consumer Information leaflet for information on how to prepare and inject a dose of NIVESTYM.

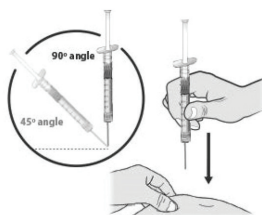
Instructions for use

5) Remove the prepared syringe and needle from the vial. Inject your dose of NIVESTYM

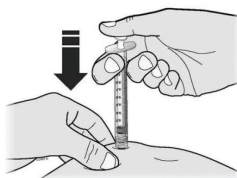
- With one hand, gently pinch a fold of skin at the injection site. Hold the pinch.



- With the other hand, hold the syringe like you would hold a pencil. Use a quick “dart like” motion to insert the needle into the skin at a 45 to 90 degree angle.



- Using a slow and constant pressure, press down on the plunger rod as far as it will go.



- When done, gently pull the syringe out of the injection site at the same 45 to 90 degree angle used to insert it.

6) Finishing up

- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You can cover the injection site with a small bandage, if needed.
- Discard (throw away) the used needle, syringe, and vial.
 - **Do not throw away (dispose of)** needles, syringes, and vials in your household trash.
 - **If you do not have a 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 labelled to warn of hazardous waste inside the container.
 - **Important: Always keep the sharps disposal container out of the reach of children.**

See the detailed “Instructions for Use” on pages 49–68 of the Consumer Information leaflet for information on how to discard the needle, syringe, and vial.



Preparing for my next appointment

It's important to ask questions and let your healthcare team know if you have any concerns about your treatment. Use the space below to write down anything you would like to bring up with your team at any of your next few visits.

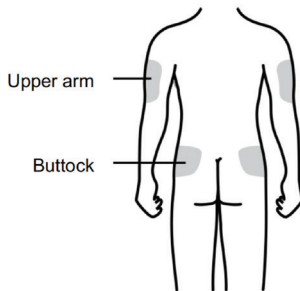
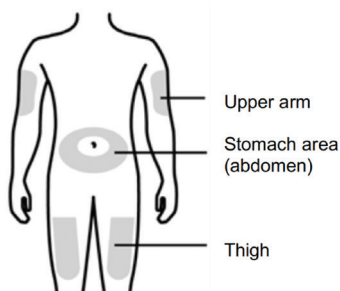
- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____
- 7. _____
- 8. _____
- 9. _____
- 10. _____

My healthcare team contact information

Name: _____	Phone number: _____
Name: _____	Phone number: _____
Name: _____	Phone number: _____
Name: _____	Phone number: _____
Name: _____	Phone number: _____

My injection tracker

If you will be self-injecting, see below for appropriate injection sites on your body, and use the injection tracker to help you rotate your sites and stay on top of your dosing.

[illegible]



Pfizer Liaison

Patient Support Program

Connecting you to resources that support your treatment and complement the care provided by your healthcare team

- Reimbursement navigation and assessment
- Coordination of insurance benefits
- Financial assistance*
- Treatment information

To enrol into Pfizer Liaison, contact us by phone, 1-844-616-6888 (toll-free); fax, 1-844-636-6888; or email, pfizerliaison@bayshore.ca.



For more information about NIVESTYM or to access other helpful resources, please visit mypfizer.ca

* Financial assistance cannot be guaranteed.



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