

NIVESTIM[®]

Filgrastim

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nivestim. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nivestim against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nivestim is used for

Nivestim solution for injection contains the active ingredient filgrastim.

Filgrastim is a copy of a substance normally present in your body, called Granulocyte Colony Stimulating Factor or G-CSF.

G-CSF is produced in the bone marrow and assists in the production of neutrophils, which are a type of white blood cell. Neutrophils help the body fight infections by surrounding and destroying the bacteria that cause them. G-CSF also helps neutrophils to be more effective. Nivestim does not cure the underlying illness but it is an important supportive therapy.

Your doctor may have prescribed Nivestim because:

- **you are receiving chemotherapy for cancer**

Some chemotherapy will reduce the number of neutrophils in your body. Although Nivestim is not a treatment for cancer, it does help the body to make new neutrophils, and this will reduce your chance of developing infections that might require treatment with antibiotics and/or hospital stays. Nivestim may also help to keep your chemotherapy treatment on schedule.

- **you are receiving a bone marrow or stem cell transplant**

Blood cells are produced in the bone marrow and arise from special 'parent' cells, called stem cells. Some chemotherapy has toxic effects on bone marrow, so your doctor may choose to collect stem cells from your bone marrow or blood before you receive your chemotherapy or from a donor's bone marrow or blood. These collected stem cells are then stored and may be given to you later to replace those lost during chemotherapy.

There are normally only a small number of stem cells in your blood; Nivestim is typically used to increase this number before stem cell collection. You may also receive Nivestim after a bone marrow or stem cell transplant, to help speed up your recovery.

- **you are donating stem cells for another person**

If you are aged between 16 and 60 years and have volunteered to donate your stem cells for another person, Nivestim may be used to increase the number of stem cells

in your blood before they are collected. Your stem cells can then be given to the person after he/she has received their chemotherapy.

- **you are suffering from severe chronic neutropenia**

Severe chronic neutropenia is a condition in which the body does not make enough neutrophils, increasing your risk of fever and/or infection. Nivestim helps the body to make and maintain the right number of infection-fighting neutrophils, decreasing the risk of infection and the need for antibiotics and/or hospital stays.

- **you are receiving medicines for HIV infection**

Some medicines used to treat HIV (Human Immunodeficiency Virus) infection, or its complications, can reduce the number of infection-fighting neutrophils in your blood. Your doctor may prescribe Nivestim if the number of neutrophils falls too low.

By boosting your neutrophil count, Nivestim will improve your body's ability to fight infection and may increase your chance of receiving the full dose of some of your HIV medicines. Nivestim is not a treatment for HIV infection.

Your doctor, however, may have prescribed Nivestim for another purpose.

Ask your doctor if you have any questions about why Nivestim has been prescribed for you.

Nivestim is not addictive.

This medicine is available only with a doctor's prescription.

Before you use Nivestim

When you must not use it

Do not use Nivestim if you have an allergy to:

- any medicine containing filgrastim
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use this medicine if have severe congenital neutropenia, also known as Kostmann's syndrome (an inherited lack of neutrophils).

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you have allergies to any other medicines or any other substances such as foods, preservatives or dyes

- you are pregnant or plan to become pregnant

It is not known whether Nivestim is harmful to an unborn baby when used by a pregnant woman. If there is a need to use Nivestim when you are pregnant your doctor will discuss the risks and

benefits to you and the unborn baby.

- **you are breast-feeding or plan to breast-feed**

It is not known whether Nivestim passes into breast milk. Breast-feeding is not recommended while you are taking Nivestim.

- **you have any other health problems, especially the following:**

- some cancers, including myelodysplastic syndrome and some leukaemias
- past problems with your spleen eg: splenomegaly (enlarged spleen)
- you have sickle cell disease (an inherited disease in which red blood cells are sickle shaped)
- you have osteoporosis (thinning of the bones) or other bone diseases
- you have rheumatoid arthritis
- you have previously had radiotherapy or chemotherapy as a treatment for cancer
- you have cancer where the tumour has got in to your bone marrow
- you have an infection in your bone marrow
- you have blood clotting problems and you are going to donate stem cells for another person
- you have HFI (hereditary fructose intolerance) - Nivestim contains sorbitol which may affect this condition.

- **you are taking blood-thinning medicines**

- **you are under 16 or over 60 years, if you are being prepared to be a stem cell donor**

If you have not told your doctor about any of the above, do so before you start to use Nivestim.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Nivestim. These medicines include:

- lithium
- some chemotherapy medicines e.g. fluorouracil.

These medicines may be affected by Nivestim or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

Nivestim should not be used 24 hours before and 24 hours after having chemotherapy.

Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Nivestim.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Nivestim

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, pharmacist or nurse for help.

Nivestim is given by injection, usually into the tissues just below the skin. This is called a subcutaneous injection and it is a simple procedure.

Your doctor, nurse or pharmacist may suggest that you or your carer be taught how to give a subcutaneous injection. This will allow you to have your Nivestim injection at home.

Nivestim is sometimes given by injection into a vein. This is called an intravenous injection and is generally given by a doctor or nurse.

How much to inject

Your doctor will tell you the strength of Nivestim you need and how much you require. How much you need will depend on the reason for your treatment, your body weight and the number of neutrophils in your blood.

For Nivestim to work properly, you have to use it exactly as your doctor has instructed.

Where to inject

The best injection sites are

- your abdomen, except for the area around the navel (belly button) or
- the front or side of your thighs.

The sites are shown in the picture below.



You should change the site of injection each time you inject, to avoid soreness at one site.

When to inject

For the best effect you should inject Nivestim at about the same time each day. Your doctor will tell you when to begin your treatment and when to stop.

How long to use it

Patients receiving chemotherapy or who have received a bone marrow or stem cell transplant are only required to use Nivestim for short periods of time until the number of infection-fighting neutrophils are restored (usually 1 to 3 weeks).

Stem cell donors should receive Nivestim treatment for 4 to 5 days.

Patients with severe chronic neutropenia are required to use Nivestim regularly and for a long period of time, to keep the number of infection-fighting neutrophils at a normal level.

Patients with HIV infection need to use Nivestim daily until their neutrophil numbers are normal. The number of injections per week may then be reduced to maintain the neutrophil numbers. Your doctor will tell you how many injections you need each week and on which days they should be given.

Do not use the Nivestim syringe if:

- The carton is open or damaged.
- The needle guard is missing, detached or has been activated.
- The medicine is cloudy or discoloured or the liquid has particles floating in it.
- Any part of the pre-filled syringe appears cracked or broken or any of the liquid has leaked out of the syringe.
- The pre-filled syringe has been dropped. The pre-filled syringe may be broken even if you cannot see the break.
- The needle cover is missing or not securely attached.
- The expiration date printed on the label has passed.

In all cases above, discard the pre-filled syringe and use a new pre-filled syringe.

Equipment required for administration

Make sure that you have all the materials you need for your injection:

- a new Nivestim pre-filled syringe
- an alcohol swab
- a puncture-resistant sharps container for disposing of used syringes safely.

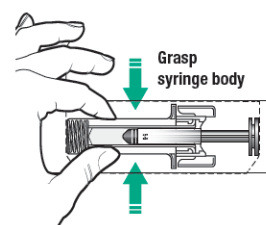
Things to do before you inject

Follow these instructions exactly to help avoid contamination and possible infection.

If you are unsure, check with your doctor, nurse or pharmacist.

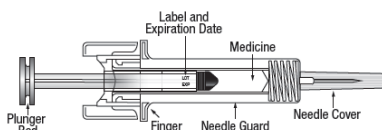
1. Find a clean, flat working surface, such as a table, where you can inject undisturbed.
2. Remove the carton containing the Nivestim pre-filled syringes from the refrigerator.
3. Remove the blister tray containing the pre-filled syringe from the carton. When the carton contains blister trays with more than one pre-filled syringe, tear off the blister tray containing one pre-filled syringe along the perforated part, and return the rest of the blister trays containing pre-filled syringes to the carton and return the carton to the refrigerator.
4. Open the blister tray containing the pre-filled syringe by peeling away the lid from the blister tray. Remove the pre-filled syringe from the blister tray by grasping from the syringe body.

- a. **Do not** grasp the grey needle cover or the plunger rod.



5. Check the syringe to make sure that the needle guard is covering the barrel of the pre-filled syringe. **Do not** push the needle

guard over the needle cover before the injection. This may activate or lock the needle guard. If the needle guard is covering the needle that means it has been activated.



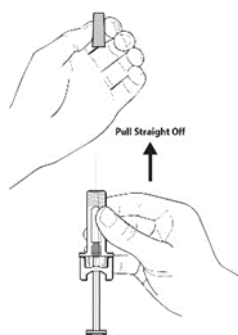
6. Check that the solution is clear, colourless and practically free from visible particles. **Do not** inspect the product through the plastic of the safety device.
7. Check the date on the syringe label to make sure that the medicine has not passed the expiry date.
8. For a more comfortable injection allow the pre-filled syringe to reach room temperature (approximately 25°C). This will take 15-30 minutes.
 - a. **Do not** warm Nivestim in any other way (e.g. do not warm it in the microwave or in hot water).
 - b. **Do not** shake the syringe.
 - c. **Do not** remove the needle cover until you are ready to inject
9. Make sure you have your puncture-resistant sharps container nearby.
10. Wash and dry your hands thoroughly.

How to prepare your injection – Nivestim Ready to Use Syringe

1. Hold the pre-filled syringe by the body of the needle guard with the needle cover pointing up – this helps reduce the amount of medicine that may leak out of the needle.
 - a. **Do not** hold by the plunger head, or plunger or needle cover.

- b. **Do not** pull back on the plunger at any time.
- c. **Do not** remove the needle cover from the pre-filled syringe until you are ready to inject your medicine.

2. Carefully remove the needle cover by holding the barrel and pulling the cover straight off and away from your body carefully without twisting it. Throw away the cover. **Do not** recap the needle. **Do not** push the plunger or touch the exposed needle or shake the syringe.



3. Check the dose (in mL) that your doctor has prescribed and locate the correct volume mark on the syringe barrel. Carefully push the plunger until the grey upper edge of the plunger reaches the correct volume mark. This will push the air and any excess liquid out of the syringe.
4. Double-check that you have the correct dose.

How to inject

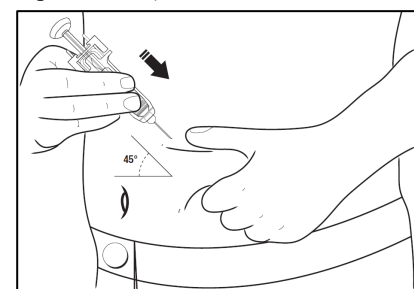
1. Clean the site where the injection is to be made with an alcohol swab, moving the alcohol swab in an expanding circle and allow the site to dry.



2. Pinch a large area of skin between your thumb and forefinger, to create a firm injection site.



3. With your other hand, pick up the pre-filled syringe and hold it as you would a pencil.
4. Use a quick “dart-like” motion to insert the needle directly into the skin (at an angle of 45° or as advised by your doctor, nurse or pharmacist).



5. After the needle is in, pull back the plunger very slightly. If blood comes into the syringe, the needle has entered a blood vessel. Remove the needle.
6. Select another site, clean the new site with an alcohol swab and reinsert the needle. Again, pull back the plunger very slightly to check for blood. If blood does

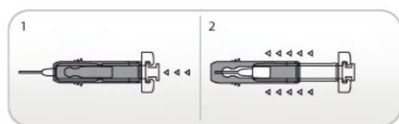
not appear in the syringe you are ready to inject.

7. Gently push down the plunger until all the contents of the pre-filled syringe have been emptied.
8. Withdraw the needle and using the alcohol swab apply pressure for several minutes to the injection site.
9. **Do not** put the needle cover back on the used syringe. You cannot reuse the syringe.
10. **Ensure needle guard covers the needle according to instructions for Active Needle Guard or Passive Needle Guard below.**
11. Discard the used syringe into an approved, puncture-resistant, sharps container.

Use of Active Ultrasafe Needle Guard for Nivestim 120 µg/0.2mL solution for injection

The pre-filled syringe has an UltraSafe Active Needle Guard attached in order to protect from needle stick injury. When handling the pre-filled syringe, keep hands behind the needle.

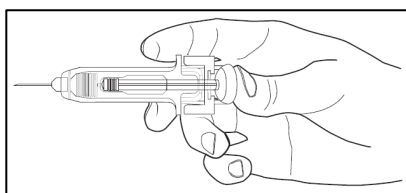
1. Perform the injection using the technique described above.
2. When you have completed the injection, slide the needle guard forward until the needle is completely covered (device 'clicks' into place).



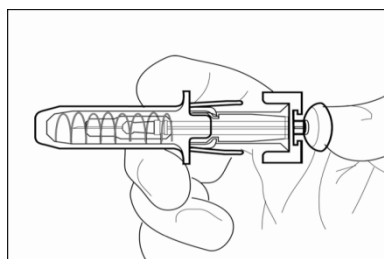
Use of Ultrasafe Passive Needle Guard for Nivestim 300 µg/0.5mL solution for injection and Nivestim 480 µg/0.5mL solution for injection

The pre-filled syringe has an UltraSafe Passive Needle Guard attached in order to protect from needle stick injury. When handling the pre-filled syringe, keep hands behind the needle.

1. Perform the injection using the technique described above.
2. Depress the plunger while grasping the finger flange until the entire dose has been given. The passive needle guard will NOT activate unless the ENTIRE dose has been given.



3. Remove needle from your skin, then let go of the plunger and allow syringe to move up until the entire needle is guarded and locks into place.



Do not change the dose or the way you inject Nivestim without consulting your doctor. Always follow your doctor's instructions.

If you forget to use your injection

If you miss your scheduled dose, inject it as soon as you can – provided that it is still on the same day.

If you miss a **whole day** before you remember to inject yourself, do not take a 'catch-up' dose or increase your next dose. Advise your doctor, nurse or pharmacist as soon as possible about the missed dose.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Nivestim. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Nivestim

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Nivestim.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Be alert for any signs or symptoms of infection.

There are many ways an infection may show itself. You should watch for fever (your body temperature is raised above normal), chills, rash, sore throat, diarrhoea, earache, difficult or painful breathing, coughing or wheezing.

If you develop any of these symptoms, see your doctor immediately or go to your nearest Accident and Emergency Centre.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that Nivestim is not helping your condition.

Keep all of your doctor's appointments so that your progress can be checked.

Treatment with Nivestim leads to changes in the numbers of certain blood cells. Your doctor will arrange for blood tests before treatment and then periodically during treatment to monitor these changes. Blood tests may also be undertaken after you have completed your Nivestim treatment until your blood cells have returned to normal levels.

Things you must not do

Do not use Nivestim to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not take other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Nivestim affects you.

However, Nivestim is not expected to affect your ability to drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Nivestim.

This medicine helps most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

You may also experience side effects caused by other medicines you are taking at the same time as Nivestim. Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you. Some of these are known side effects of chemotherapy and may not be related to Nivestim:

- bone pain, such as in the lower back or in the long bones of the arms or legs. This pain is usually relieved with non-prescription painkillers, like paracetamol. If you continue to have bone pain even after having taken this form of pain relief, you should speak to your doctor, as you may need a prescription medicine.
- pain, swelling, warmth or stiffness of joints
- worsening of existing arthritis
- muscle pain
- muscle spasms
- headache
- nausea (feeling sick) and/or vomiting
- diarrhoea or constipation
- abdominal discomfort
- pain in the chest, back, mouth or throat
- loss of appetite
- pain or difficulty in passing urine

- bleeding or bruising more than usual, nose bleeds
- cough
- sore mouth or throat, mouth ulcers
- hair loss
- redness, swelling or itching at the site of injection
- skin rash or red, itchy or sore spots
- skin disorders - worsening of existing symptoms
- reddish or purplish blotches under the skin
- pink, red or blue/purple spots or bumps on the skin
- tiredness, weakness, looking pale
- swelling of hands, legs, ankles, feet or any other part of the body
- swelling or puffiness
- trouble sleeping
- numbness
- tingling in the hands and feet

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- fever
- rapid pulse or sweating
- frequent infections
- coughing up blood, bleeding from the lung
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- pain in the upper left side of the abdomen
- left shoulder pain
- dizziness or light-headedness
- fever and painful skin lesions, often painful, most commonly on your arms, legs and sometimes on your face and neck
- blood in the urine

- tiredness, fever and easy bruising or bleeding
- chest pain
- breathlessness or difficulty breathing
- swelling of your stomach-area (abdomen) and feeling of fullness

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Nivestim

Storage

Keep Nivestim in a refrigerator at a temperature of 2°C to 8°C.

Brief exposure to freezing temperatures (up to 24 hours) will not harm Nivestim, nor will exposure to room temperature for up to fifteen (15) days in a single period.

Do not use Nivestim if it has been left out of the refrigerator for more than fifteen (15) days, or if it has been in the freezer for more than 24 hours, or if it has been frozen more than once.

Keep Nivestim in its carton protected from light.

Do not store Nivestim or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Once you have injected Nivestim, do not put the needle cover back on the used syringe.

Put the used syringe into an approved, puncture-resistant, sharps container. Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

Never put used syringes into your normal household rubbish bin.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

- polysorbate 80.

Nivestim does not contain lactose, gluten, tartrazine or any other azo dyes.

The needle cover and rubber closure for the syringe does not contain latex.

Supplier

Nivestim is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 363

www.pfizermedinfo.co.nz

Date of preparation

This leaflet was prepared in July 2023.

® = Registered Trademark

Product description

What it looks like

Nivestim is a clear, colourless solution and is supplied as ready to use syringes.

The single use, preservative free syringes are packed in cartons of 1, 5, or 10 and are available in the following strengths:

- 120 micrograms of filgrastim in a volume of 0.2 mL;
- 300 micrograms of filgrastim in a volume of 0.5 mL;
- 480 micrograms of filgrastim in a volume of 0.5 mL.

Ingredients

The active ingredient in Nivestim is filgrastim. Other ingredients are:

- water for injections
- sodium
- acetate
- sorbitol