

NIVESTIM®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NIVESTIM?

NIVESTIM contains the active ingredient filgrastim. NIVESTIM is used to encourage your bone marrow to produce more neutrophils, a type of white blood cell. You may have been prescribed NIVESTIM because you are receiving treatment for cancer, are receiving a bone marrow or stem cell transplant, are donating stem cells for another person, are suffering from severe chronic neutropenia (long term low white blood cell count) or are receiving medicines for HIV infection. For more information, see [Section 1. Why am I using NIVESTIM?](#) in the full CMI.

2. What should I know before I use NIVESTIM?

Do not use if you have ever had an allergic reaction to filgrastim or any of the ingredients listed at the end of the CMI, or any other products that are produced using the bacteria E. coli. Do not use NIVESTIM 24

hours before or after you receive your chemotherapy, radiotherapy, bone marrow transplant or stem cell transplant. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use NIVESTIM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NIVESTIM and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NIVESTIM?

NIVESTIM is given by injection, usually just below the skin (called a subcutaneous injection) and it is a simple procedure. More instructions can be found in Section [4. How do I use NIVESTIM?](#) in the full CMI.

5. What should I know while using NIVESTIM?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using NIVESTIM.

	<ul style="list-style-type: none"> • Keep all your doctor's appointments so that your health can be monitored. • Call your doctor straight away if you become pregnant. • Go straight to the hospital if you notice any signs or symptoms of infection.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine or lower the dosage without checking with your doctor. Do not use NIVESTIM to treat any other complaint unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or using any machines or tools until you know how NIVESTIM affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Keep NIVESTIM in a refrigerator at a temperature of 2°C to 8°C. • Keep your medicine in its pack until it is time

	to use it. Protect it from light.
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For more information, see Section [5. What should I know while using NIVESTIM?](#) in the full CMI.

6. Are there any side effects?

Side effects may include bone, back, muscle, joint, mouth or throat pain; swelling or stiffness of joints; muscle spasms; abdominal discomfort; diarrhoea; constipation; nausea; vomiting; severe nose bleeds; reddish or purplish bumps or blotches; mouth ulcers; numbness, tingling in the hands and feet; injection site reactions; cough; hair loss; headache; looking pale; loss of appetite; unusual weakness; difficulty sleeping. Serious side effects include rash, itching or hives; swelling of the face, lips, mouth or throat; difficulty swallowing or breathing; shortness of breath; wheezing; light-headedness, dizziness or fainting; rapid pulse or breathing, sweating; painful skin lesions; swelling; chest, abdominal or back pain; fever; tiredness; easy bruising or bleeding; left shoulder pain; frequent infections; coughing up blood or mucus; pain in the upper left side of the stomach; swelling of your stomach-area; reduced urination; blood in the urine. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NIVESTIM®

Active ingredient(s): *Filgrastim [rbe]*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NIVESTIM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NIVESTIM.**

Where to find information in this leaflet:

- [1. Why am I using NIVESTIM?](#)
- [2. What should I know before I use NIVESTIM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NIVESTIM?](#)
- [5. What should I know while using NIVESTIM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NIVESTIM?

NIVESTIM contains the active ingredient filgrastim (rbe). NIVESTIM belongs to a group of medicines called cytokines and is a copy of a substance normally present in your body, called Granulocyte Colony Stimulating Factor or G-CSF. Using gene technology, NIVESTIM is produced in a specific type of bacteria, called E. coli.

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 do this work better. NIVESTIM works by encouraging the bone marrow to produce more neutrophils.

NIVESTIM can be used:

- to increase the number of white blood cells after treatment with chemotherapy to help prevent infections;
- to increase the number of white blood cells after a bone marrow transplant to help prevent infections;
- before high-dose chemotherapy to make the bone marrow produce more stem cells which can be collected and given back to you after your treatment. These can be taken from you or from a donor. The stem cells will then go back into the bone marrow and produce blood cells;
- to increase the number of white blood cells if you suffer from severe chronic neutropenia to help prevent infections;
- in patients with advanced HIV infection which will help reduce the risk of infections.

2. What should I know before I use NIVESTIM?

Warnings

Do not use NIVESTIM:

- if you are allergic to filgrastim, any of the ingredients listed at the end of this leaflet, or any medicines or products that are produced using the bacteria E. coli.

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.

Always check the ingredients to make sure you can use this medicine.

- in the 24 hours before or after you receive your chemotherapy, radiotherapy, bone marrow transplant or stem cell transplant.

This is because these types of treatments may stop NIVESTIM from increasing the number of infection-fighting neutrophils.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- have a medical condition affecting the bone marrow or blood

- have a family history of a genetic disorder
- suffer from sickle cell disease (an inherited disease in which red blood cells are sickle shaped)
- have problems with your kidneys, liver, heart or other organs such as past problems with your spleen e.g. splenomegaly (enlarged spleen)
- have had previous treatment for cancer
- have any infections, cancers or tumours
- have a recent history of pneumonia (or other serious lung infections)
- have osteoporosis (weakening of the bones) or other bone diseases
- have HFI (hereditary fructose intolerance) - NIVESTIM contains sorbitol which may affect this condition
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

Use in Children

There is limited experience with the use of NIVESTIM in children. Your doctor will discuss the risks and benefits of using it in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, particularly those that may affect the blood. Also tell him/her about any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NIVESTIM and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NIVESTIM.

4. How do I use NIVESTIM?

How much NIVESTIM to use

- 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.

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

When to use NIVESTIM

- 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 to use NIVESTIM

- 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.

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.

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.

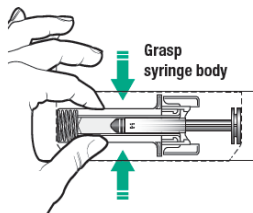
Things to do before you inject

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

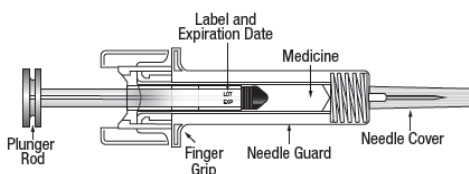
If you are unsure, check with your doctor, nurse or pharmacist.

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.

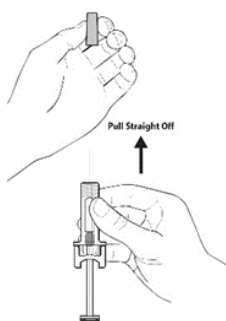
Do not use the NIVESTIM syringe if:

- 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.

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.

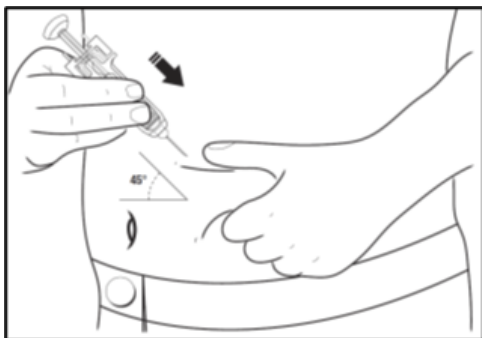


2. Pinch a large area of skin between your thumb and forefinger, to create a firm injection site.



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).

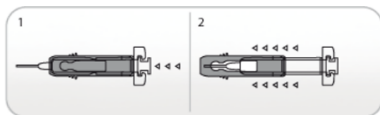


5. After the needle is in, pull back the plunger very slightly. If blood comes into the syringe, the needle has entered a blood vessel. Remove the needle.
6. Select another site, clean the new site with an alcohol swab and reinsert the needle. Again, pull back the plunger very slightly to check for blood.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

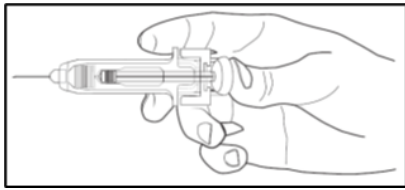


Use of Ultrasafe Passive Needle Guard for NIVESTIM 300 µg/0.5mL solution for injection and NIVESTIM 480 µg/0.5mL solution for injection

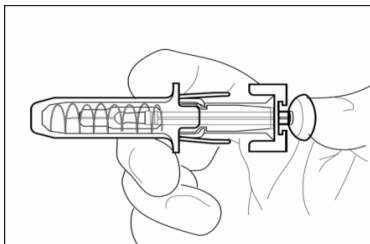
The pre-filled syringe has an UltraSafe Passive Needle Guard attached in order to protect from needle stick injury. When handling the pre-filled syringe, keep hands behind the needle.

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.

How long to use NIVESTIM for

- 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. Usually, the dose is then reduced to three injections per week 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.

If you forget to use NIVESTIM

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 NIVESTIM

If you think that you have injected more than the dose recommended by your doctor, you may need urgent medical attention.

Too much NIVESTIM may lead to neutrophil levels that are too high.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NIVESTIM?

Things you should do

- Remind any doctor, dentist, pharmacist or nurse you visit that you are using NIVESTIM, especially if you are about to be started on any new medicine.
- Keep all of your doctor's appointments so that your health can be monitored. Treatment with NIVESTIM leads to changes in the numbers of certain blood cells. Your doctor may order blood tests to check the levels of infection-fighting neutrophils and other blood cells. Blood tests may also be undertaken after you have completed your NIVESTIM treatment until your blood cells have returned to normal levels.

Call your doctor straight away if you:

- become pregnant during treatment with NIVESTIM.

Go straight to the hospital if you:

- **Notice any signs or symptoms of an infection.**
There are many ways an infection may show itself. You should watch for:
 - fever (a temperature of 38.2°C or greater, or as your doctor suggests)

- chills
- rash
- sore throat
- diarrhoea
- earache
- difficult or painful breathing, coughing or wheezing.

Things you should not do

- Do not stop using this medicine or lower the dosage without checking with your doctor.
- Do not use NIVESTIM to treat any other complaint unless your doctor tells you to.
- Do not give NIVESTIM to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NIVESTIM affects you.

You may experience dizziness after receiving NIVESTIM and it might affect your ability to drive or use machines.

Looking after your medicine

Keep NIVESTIM in a refrigerator at a temperature of 2°C to 8°C. Keep it in its carton protected from light.

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor as soon as possible if you have any problems while using NIVESTIM, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Some of these are known side effects of chemotherapy and may not be related to NIVESTIM:</p> <p>Muscle and Skeleton:</p> <ul style="list-style-type: none">• temporary bone pain, such as in the lower back or in the long bones of the arms or legs.	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<p>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 medication.</p> <ul style="list-style-type: none"> • back pain • pain, swelling, warmth or stiffness of joints • worsening of existing arthritis • muscle pain • muscle spasms <p>Gut and Digestion:</p> <ul style="list-style-type: none"> • abdominal discomfort • diarrhoea or constipation • nausea (feeling sick) and/or vomiting <p>Blood:</p> <ul style="list-style-type: none"> • pink, red or blue/purple spots or bumps on the skin 	

Side effects	What to do
<ul style="list-style-type: none"> • bleeding or bruising more than usual, severe nose bleeds • reddish or purplish blotches under the skin <p>Eyes, ears and mouth:</p> <ul style="list-style-type: none"> • sore throat • sore mouth, mouth ulcers <p>Nervous System:</p> <ul style="list-style-type: none"> • numbness • tingling in the hands and feet <p>Skin:</p> <ul style="list-style-type: none"> • redness, swelling or itching at the site of injection • skin disorders - worsening of existing symptoms • skin rash or red, itchy or sore spots • swelling of hands, legs, ankles, feet or any other part of the body <p>General:</p> <ul style="list-style-type: none"> • cough, breathlessness 	

Side effects	What to do
<ul style="list-style-type: none"> • hair loss • headache • tiredness, looking pale • loss of appetite • unusual weakness • difficulty sleeping 	

Serious side effects

Serious side effects	What to do
<p>General:</p> <ul style="list-style-type: none"> • chest pain • fever • general feeling of tiredness • easy bruising or bleeding • left shoulder tip pain • frequent infections • Dizziness or feeling light-headed • Faintness <p>Lungs and upper airways:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • coughing up blood or mucus, bleeding from the lung • breathing problems such as shortness of breath, rapid breathing <p>Gut, Digestion and Urine-related:</p> <ul style="list-style-type: none"> • pain in the upper left side of the stomach (abdomen) • swelling of your stomach-area (abdomen) and feeling of fullness • less frequent urination • blood in the urine <p>Skin:</p> <ul style="list-style-type: none"> • fever and painful skin lesions, most commonly on your arms, legs and sometimes on your face and neck • swelling or puffiness <p>Heart-related:</p> <ul style="list-style-type: none"> • fever, chest or abdominal pain, malaise and back pain. These 	

Serious side effects	What to do
<p>could be symptoms of inflammation of your aorta (the large vessel that transports blood from your heart to your body). Tell your doctor if you experience these symptoms.</p> <p>Symptoms of severe allergic reaction:</p> <ul style="list-style-type: none"> • pinkish, itchy swellings on the skin, also called hives or nettle rash • swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing • shortness of breath, wheezing • light-headedness, dizziness or fainting • rapid pulse, sweating 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What NIVESTIM contains

Active ingredient (main ingredient)	filgrastim (rbe)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• glacial acetic acid• polysorbate 80• sodium hydroxide• sorbitol water for injections

Do not take this medicine if you are allergic to any of these ingredients.

Each pre-filled syringe is affixed with a needle closed by a needle cover that contains epoxyprene, a derivative of natural rubber latex which may come into contact with the needle.

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

What NIVESTIM 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; (AUST R 160106).
- 300 micrograms of filgrastim in a volume of 0.5 mL; (AUST R 160108).
- 480 micrograms of filgrastim in a volume of 0.5 mL (AUST R 160107).

Who distributes NIVESTIM

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in December 2025.

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