

Consumer Medicine Information

Neulastim[®]

pegfilgrastim

6 mg of pegfilgrastim in 0.6 mL (10 mg/mL) solution for injection

What is in this leaflet

This leaflet answers some common questions about NEULASTIM.

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 NEULASTIM against the benefits expected 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 NEULASTIM is used for

NEULASTIM solution for injection contains the active ingredient pegfilgrastim.

Using gene technology, pegfilgrastim is produced in a specific type of bacteria, called *E. coli*.

Pegfilgrastim is a long-acting form of recombinant human Granulocyte Colony Stimulating Factor (G-CSF). G-CSF is produced by the body in the bone marrow and assists in the production of neutrophils, which are a type of white blood cell. Neutrophils defend the body against infection by destroying bacteria in the blood.

NEULASTIM also helps neutrophils to be more effective.

Some chemotherapy medicines will reduce the number of neutrophils in your body. Although NEULASTIM is not a treatment for cancer, it is used following chemotherapy to increase the number of neutrophils. This will reduce your chance of developing infections that might require treatment with antibiotics and/or hospital stays. NEULASTIM may also help to keep your chemotherapy treatment on schedule.

NEULASTIM does not cure the underlying illness but it is an important supportive therapy.

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

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

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

Before you use NEULASTIM

When you must not use it

Do not use NEULASTIM if:

- 1. you have previously used pegfilgrastim (NEULASTIM) or filgrastim (NEUPOGEN® or ZARZIO®) and have had an allergic reaction to pegfilgrastim, filgrastim or any ingredients listed at the end of this leaflet**
- 2. you have had an allergic reaction to medicines or other products that are produced by gene technology using the bacteria *E. coli***
- 3. you are currently receiving chemotherapy or radiotherapy**
- 4. you have received chemotherapy within the last 24 hours**
This is because the chemotherapy medicine may stop NEULASTIM from increasing the number of infection-fighting neutrophils.
- 5. the package is torn or shows signs of tampering**
- 6. the expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.
- 7. the medicine has been left out of the refrigerator for more than 3 days.**

If you are not sure if you should be using NEULASTIM, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if:

- 1. you have allergies to any other medicines or any other substances such as foods, preservatives or dyes**
- 2. you are pregnant or plan to become pregnant**
Your doctor will discuss the possible risks and benefits of using NEULASTIM during pregnancy.
- 3. you are breast-feeding or plan to breast-feed**
Your doctor will discuss the possible risks and benefits of using NEULASTIM while breast-feeding.
- 4. you have any other health problems, especially the following:**
 - a medical condition affecting the bone marrow or blood
 - a family history of a genetic disorder called acute myeloid leukemia (AML), with cytogenetics t(15;17)
 - sickle cell disease [an inherited disease in which red blood cells are sickle (curved or tapered shaped)]
 - previous problems with your kidneys, liver, heart or other organs
 - previous radiotherapy or chemotherapy treatment for cancer
 - any infections, cancers or tumours.

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

Your doctor will decide whether it is safe for you to use NEULASTIM.

Taking other medicines

Tell your doctor if you are taking any other medicines, particularly those which may affect the blood. Tell your doctor about any medicines or herbal remedies that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with NEULASTIM. These medicines include some chemotherapy medicines, such as fluorouracil, methotrexate and sulfanilamide.

These medicines may be affected by NEULASTIM 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.

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

Ask your doctor or pharmacist if you are not sure about other medicines you are taking.

How to use NEULASTIM

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

They may differ from the information contained in this leaflet.

NEULASTIM can be administered by a doctor, nurse or by patients themselves.

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

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

Instructions for NEULASTIM pre-filled syringe

This section contains information on how to give yourself an injection of NEULASTIM using the ready-to-use pre-filled syringe. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. If you are unsure about anything, ask your doctor or nurse for help.

Things to do before you inject

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

- a new NEULASTIM ready-to-use pre-filled syringe
- the supplied needle
- an alcohol swab
- a puncture-resistant sharps container

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

1. Find a clean, flat working surface, such as a table, where you can inject undisturbed.
2. Remove the ready-to-use pre-filled syringe from the refrigerator. For a more comfortable injection, leave it at room temperature for approximately 30 minutes. Do not warm NEULASTIM in any other way (e.g. do not warm it in the microwave or in hot water). Do not leave the pre-filled syringe exposed to direct sunlight.
3. Do not shake the syringe. Shaking will cause NEULASTIM to clump and it will not work properly.
4. Do not remove the needle cover until you are ready to inject.
5. Check the expiry date on the label. Do not use it if the date has passed the last day of the month shown.
6. Check the appearance of the solution. The solution should be clear and colourless. If it is cloudy, coloured or if there are clumps or flakes, you must not use it.
7. You may notice a small air bubble in the pre-filled syringe. You do not have to remove the air bubble before injecting. Injecting the solution with the air bubble is harmless.
8. Wash and dry your hands thoroughly.

9. While keeping the needle cover on, grasp the needle cap and remove it carefully.
10. Remove the rubber cover from the glass syringe.
11. Connect the needle to the tip of the syringe and fasten it well. You may need to use a bit of force to do this.
12. Hold the syringe vertically with the needle pointing up – this helps reduce the amount of medicine that may leak out of the needle. Expel air from the syringe and needle by gently pressing the plunger upwards.
13. With one hand, squeeze firmly on the base of the needle cover with your thumb and forefinger (while taking care not to break the glass pre-filled syringe). Turn and pull the needle cover off while holding the syringe with your other hand, taking care not to touch the exposed needle.

The pre-filled syringe is now ready to use.

Where to inject

The best injection sites are the front or side of the thighs and the abdomen, except for the area around the navel (belly button). Change the injection site each time you inject to avoid tenderness at any one site.

How to inject

Always follow the instructions of your doctor, pharmacist or nurse - they may be different from those below.

14. 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.
15. Pinch a large area of skin between your thumb and forefinger, without squeezing it.
16. Pick up the syringe and hold it like a pencil.
17. Insert the needle directly into the skin (at an angle of between 45 and 90 degrees or as advised by your doctor, nurse or pharmacist).
18. After the needle is in, pull back the plunger very slightly. If blood comes into the syringe, the needle has entered a blood vessel. If this happens, remove the needle, choose a new injection site and repeat steps 13 – 16 again. 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.
19. If blood does not appear in the syringe, inject the NEULASTIM by gently pushing the plunger all the way in, while keeping your skin pinched.
20. Withdraw the needle and using the alcohol swab, apply pressure for several minutes to the injection site.
21. Do not put the needle cover back on the used needle. You cannot reuse the NEULASTIM pre-filled syringe. Unless your doctor, nurse or pharmacist advises you of another method of disposal, put the used syringe and needle into an approved, puncture-proof, sharps container.

How much to inject

Use NEULASTIM exactly as your doctor has prescribed.

The usual dose is one subcutaneous injection.

When to inject

NEULASTIM should be injected 24 hours after the end of each chemotherapy cycle. Your doctor will tell you when to begin your treatment and when to stop.

If you forget your injection

If you miss your scheduled dose, tell your doctor, nurse or pharmacist as soon as possible about your missed dose.

In case of an overdose

Immediately telephone your doctor, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to your nearest Accident and Emergency Centre if you think you or anyone else may have had too much NEULASTIM. 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 NEULASTIM

Things you must do

Tell all doctors, nurses and pharmacists who are treating you that you are using NEULASTIM.

Tell your doctor if you become pregnant while using NEULASTIM.

Be alert for any signs or symptoms of infection.

You should watch out for fever (your body temperature is raised above normal i.e. 37.6°C, or as advised by your doctor), chills, rash, sore throat, diarrhoea, ear ache, 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.

Blood tests

Keep all of your doctor's appointments so that your health can be monitored.

Your doctor may arrange for blood tests to check the levels of infection-fighting neutrophils and other blood cells.

Things you must not do

Do not stop taking NEULASTIM or change the dose without first checking with your doctor.

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

Do not use NEULASTIM to treat other complaints unless your doctor says to.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using NEULASTIM, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, NEULASTIM may have unwanted side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary. You may also experience side effects caused by other medicines you are taking at the same time as NEULASTIM.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor 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 NEULASTIM:

- bone pain. *This pain is usually relieved with non-prescription painkillers, like paracetamol. If you continue to have bone pain even after taking this form of pain relief, you should speak to your doctor, as you may need a prescription medicine.*
- joint pain, muscle pain, pain in the chest area
- headache
- nausea (feeling sick) and/or vomiting
- skin rash or red, itchy or sore spots
- pain at the site of injection

Tell your doctor immediately if you notice any of the following:

- blood in urine
- fever and painful skin lesions most commonly on your arms, legs and sometimes on your face and neck
- swelling of the hands, legs, ankles, feet or any other part of the body
- left shoulder pain
- pain in the upper left side of the abdomen
- tiredness, shortness of breath, easy bleeding and frequent infections.

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

- 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
- swelling of your stomach-area (abdomen) and feeling of fullness
- swelling or puffiness
- less frequent urination.
- faintness, rapid pulse, sweating, dizziness.

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.

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

After using NEULASTIM

Storage

Keep your NEULASTIM in the original container, protected from light, until it is time to use it.

Keep NEULASTIM in the refrigerator where the temperature stays between 2°C and 8°C.

Exposure to room temperature of up to three days will not harm NEULASTIM.

Do not freeze.

Do not use NEULASTIM if you think it has been frozen.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep NEULASTIM where young children cannot reach it.

Disposal

Once you have injected NEULASTIM do not put the needle cover back on the used needle.

Discard used syringe and needle into an approved puncture-resistant sharps container and keep it out of the reach of children.

Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

Never put the used syringes into your normal household rubbish bin.

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

Product Description

Availability

NEULASTIM is supplied as a solution for injection in a single-use pre-filled syringe with an injection needle.

What it looks like

NEULASTIM is a clear, colourless solution.

Ingredients

Active ingredient - pegfilgrastim

Inactive ingredients

NEULASTIM pre-filled syringes contain the inactive ingredients, sodium acetate, sorbitol, polysorbate 20 and water for injection.

Distributor

NEULASTIM is distributed by:

Amgen (New Zealand) Limited
Level 22, PwC Tower
15 Customs Street West
Auckland 1010
NEW ZEALAND

This leaflet was prepared in November 2020

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