

Consumer Medicine Information

Neupogen[®]

Filgrastim

**300 mcg in 0.5 mL and 480 mcg in 0.5 mL (prefilled syringes) and 300 mcg in 1 mL (vials)
solution for injection**

What is in this leaflet

This leaflet answers some common questions about NEUPOGEN.

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 NEUPOGEN 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 NEUPOGEN is used for

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

Your doctor may have prescribed NEUPOGEN because:

- **you are receiving chemotherapy for cancer**
Some chemotherapy will reduce the number of neutrophils in your body. Although NEUPOGEN 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. NEUPOGEN 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; NEUPOGEN is typically used to increase this number before stem cell collection. You may also receive NEUPOGEN 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, NEUPOGEN 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. NEUPOGEN 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 NEUPOGEN if the number of neutrophils falls too low.

By boosting your neutrophil count, NEUPOGEN 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. NEUPOGEN is not a treatment for HIV infection.

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

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

NEUPOGEN is not addictive.

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

Before you use NEUPOGEN

When you must not use it

1. Do not use NEUPOGEN if you have an allergy to:

- any medicine containing Filgrastim
- any of the ingredients listed at the end of this leaflet
- any medicines or products that are produced using the bacteria E. coli.

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
- skin rash, itching or hives.

2. Do not use NEUPOGEN if the package is torn or shows signs of tampering

3. Do not use NEUPOGEN if 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.

If you are not sure if you should be using NEUPOGEN, talk to your doctor, nurse 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**
It is not known whether NEUPOGEN is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take NEUPOGEN when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
- 3. you are breast-feeding or plan to breast-feed**
It is not known whether NEUPOGEN passes into breast milk. Breast-feeding is not recommended while you are taking NEUPOGEN.
- 4. 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) - NEUPOGEN contains sorbitol which may affect this condition.
- 5. you are taking blood-thinning medicines**
- 6. 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 NEUPOGEN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with NEUPOGEN. These medicines include

- lithium (Lithicarb[®], Priadel[®])
- some chemotherapy medicines e.g. fluorouracil.

These medicines may be affected by NEUPOGEN 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.

NEUPOGEN 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 NEUPOGEN.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to have NEUPOGEN

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

They may differ from the information contained in this leaflet.

NEUPOGEN can be administered by the doctor, nurse or by patients themselves.

How much to have

Have NEUPOGEN exactly as your doctor has prescribed.

The usual dose varies from 1 mcg to 12 mcg per kg bodyweight depending on your condition. Your doctor or other health professional will tell you how much NEUPOGEN to use, how to inject it, how often you should inject it, and for how many days your NEUPOGEN therapy should be continued.

For NEUPOGEN to work properly, you have to use it exactly as you have been instructed.

How to have it

Intravenous administration

NEUPOGEN is sometimes given by injection into a vein - this is called an intravenous injection and is normally given by a doctor or nurse.

Subcutaneous administration

NEUPOGEN is often given by injection into the tissues just below the skin. This is called a subcutaneous injection and it is a simple procedure. In fact, 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 administer your NEUPOGEN at home.

Where to inject

The best injection sites are the abdomen and the front or side of the thighs. Change the injection site each time you inject to avoid soreness at any one site.

When to inject, and for how long

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

Patients receiving chemotherapy or who have received a bone marrow or stem cell transplant are only required to use NEUPOGEN for short periods of time until the number of infection-fighting neutrophils are restored (usually up to 14 days, but can be longer).

Stem cell donors would normally receive NEUPOGEN treatment for 4 to 7 days.

Patients with severe chronic neutropenia are required to use NEUPOGEN 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 NEUPOGEN 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.

Things to check before you inject

Before you inject NEUPOGEN always check that:

1. the syringe or vial has NOT been used before; and
2. the solution is not cloudy or discoloured and contains no clumps or flakes.

NEUPOGEN may appear frothy or bubbly if the syringe or vial has been shaken vigorously. This does not affect the way NEUPOGEN works but, before measuring your dose, you should allow the syringe or vial to sit undisturbed for a few minutes to reduce the froth or bubbles.

Before proceeding, make sure that you have all the materials you need to inject your NEUPOGEN; the syringe or vial, needle, alcohol swab and a puncture-proof container so you can dispose of used needles safely. If you are unsure, check with your doctor, nurse or pharmacist.

How to prepare your injection

Note: The instructions from your doctor or nurse on how to inject NEUPOGEN yourself may be different from the method given below. Follow the instructions of your doctor, pharmacist or nurse carefully.

NEUPOGEN prefilled syringes

Follow these instructions to help avoid contamination and possible infection.

1. Set up the equipment you will need and remove one NEUPOGEN prefilled syringe from the refrigerator 20 to 30 minutes before the injection is due, to allow it to reach room temperature. Use each syringe once only and DO NOT SHAKE.
2. Wash and dry your hands thoroughly, and find a clean, quiet place where you can inject undisturbed.
3. While keeping the needle cover on, grasp the needle cap and remove it carefully.
4. Remove the rubber cover from the glass syringe.
5. 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.
6. Hold the syringe vertically with the needle pointing up - this helps reduce the amount of medicine that may leak out of the needle.
7. 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.
8. 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.
9. Double-check that you have the correct dose.

NEUPOGEN vials

Follow these instructions to help avoid contamination and possible infection.

1. Set up the equipment you will need and remove the vial of NEUPOGEN from the refrigerator 20 to 30 minutes before the injection is due, to allow it to reach room temperature. Use each NEUPOGEN vial once only and DO NOT SHAKE THE VIAL.
2. Check that the syringe you are using is marked every tenth of a mL (i.e. 0.1, 0.2 mL, etc.) so that you can accurately inject the prescribed dose. Use disposable syringes and needles, and use them once only.

3. Wash and dry your hands thoroughly, and find a clean, quiet place where you can inject undisturbed.
4. Flip the protective cap off the vial. Do NOT remove the rubber stopper.
5. Wipe the top of the rubber stopper with an alcohol swab.
6. With the needle cap on, carefully pull back on the plunger. This will draw air into the syringe. The amount of air should be the same as your NEUPOGEN dose.
7. Carefully remove the needle cap, taking care not to touch the exposed needle. Gently push the needle through the rubber top of the NEUPOGEN vial.
8. Carefully push the plunger down. The air injected into the vial will allow NEUPOGEN to be easily withdrawn from the vial into the syringe.
9. Turn the vial and syringe upside down. Make sure the tip of the needle is in the solution. Slowly pull back on the plunger to draw the correct dose of NEUPOGEN into the syringe.
10. Check the syringe for air bubbles. The air is harmless, but a large air bubble will reduce the NEUPOGEN dose. To remove the air bubbles, gently push the solution back into the vial and measure the correct dose of NEUPOGEN.
11. Check that the correct dose of NEUPOGEN has been drawn into the syringe. Remove the needle from the vial.

How to inject

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

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. Spread the skin or pinch a large area of skin.
3. Pick up the syringe and hold it as you would a pencil. 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). 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. 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, inject the NEUPOGEN by gently pushing the plunger all the way in.
4. Withdraw the needle and using the alcohol swab apply pressure for several minutes to the injection site.
5. Do not put the needle cap back on the used syringe. Unless your doctor, nurse or pharmacist advises you of another method of disposal, put the used syringe into an approved, puncture-proof, sharps container and, if you are using NEUPOGEN vials, dispose of the used vial in the rubbish.

Do not change the dose or the way you inject NEUPOGEN without consulting your doctor or nurse.

If you forget your injection

Do not take two doses on the same day.

If you remember your NEUPOGEN dose later on in the day you are meant to take it, then take the dose.

If you remember the next day, skip the missed dose and take your next dose when you are meant to.

Advise your doctor, nurse or pharmacist as soon as possible about the missed dose.

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

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 taken too much NEUPOGEN. 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 NEUPOGEN

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are having NEUPOGEN.

Tell your doctor if you become pregnant while having NEUPOGEN.

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 taken 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 NEUPOGEN is not helping your condition.

Blood tests

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Treatment with NEUPOGEN 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 NEUPOGEN treatment until your blood cells have returned to normal levels.

Things you must not do

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

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

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

Do not use NEUPOGEN 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.

Things to be careful of

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

However, NEUPOGEN 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 having NEUPOGEN.

NEUPOGEN 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 treatment 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 NEUPOGEN. 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 NEUPOGEN:

- 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
- headache
- nausea (feeling sick) and/or vomiting
- diarrhoea or constipation
- abdominal discomfort
- 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
- tiredness, weakness, looking pale
- swelling of hands, legs, ankles, feet or any other part of the body
- swelling or puffiness
- trouble sleeping

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

- 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

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
- chest pain
- breathlessness or difficulty breathing

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 NEUPOGEN

Storage

Keep your NEUPOGEN in the original container until it is time to take it.

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

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 NEUPOGEN where young children cannot reach it, if possible.

Disposal

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

Product Description

Availability

NEUPOGEN is supplied as a solution for injection in a prefilled syringe or vial. Each vial or syringe is for single use only.

NEUPOGEN 300 mcg in 1 mL vials come in packs of 4

*NEUPOGEN 300 mcg in 0.5 mL prefilled syringe, in a pack of 1

*NEUPOGEN 480 mcg in 0.5 mL prefilled syringe, in a pack of 1

**Presentation not currently available.*

What it looks like

NEUPOGEN is a sterile, clear, colourless solution.

Ingredients

Active ingredient - filgrastim

NEUPOGEN prefilled syringe containing 300 mcg (30 million units) of filgrastim in 0.5 mL of solution.

NEUPOGEN prefilled syringe containing 480 mcg (48 million units) of filgrastim in 0.5 mL of solution.

NEUPOGEN vials containing 300 mcg (30 million units) of filgrastim in 1 mL of solution.

Inactive ingredients

NEUPOGEN prefilled syringes and vials contain the inactive ingredients; sodium acetate, sorbitol, polysorbate 80 and water for injection.

Distributor

NEUPOGEN is distributed by:

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

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