

NEUPOGEN®

Filgrastim (rbe)

Consumer Medicine Information

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, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has prescribed NEUPOGEN after considering its likely benefit to you, as well as the potential risks.

If you have any concerns about taking this medicine, talk to your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NEUPOGEN is used for

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

Your doctor may have prescribed NEUPOGEN because:

- **You are receiving chemotherapy for cancer.**
Unfortunately, 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. This will reduce your chance of developing infections that might require antibiotics and/or hospital stays. It may even increase your chance of receiving your chemotherapy on time and at the right dose.
- **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 - or from a donor's bone marrow or blood - before you receive your chemotherapy. These collected stem cells are then stored and may be given back to you later, to replace those lost during chemotherapy. This procedure is called a bone marrow or stem cell transplant.
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 a patient after he/she has received their chemotherapy.

- **You are suffering from severe chronic neutropenia.**
Severe chronic neutropenia is a disease 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. This decreases 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 Immuno-deficiency 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.

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

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

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

Before you use NEUPOGEN

When you must not use it

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*.

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 NEUPOGEN at the same time as your chemotherapy or radiotherapy.

Do not use NEUPOGEN 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 NEUPOGEN from increasing the number of infection-fighting neutrophils.

Do not use NEUPOGEN after the expiry date (EXP) printed on the pack or if the

packaging is torn or shows signs of tampering.

Do not use NEUPOGEN if it has been left out of the refrigerator for more than three days.

If you are not sure whether you should use NEUPOGEN, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding or plan to breast feed.

Tell your doctor if you have or have had any of the following medical conditions:

- a medical condition affecting the bone marrow or blood
- family history of a genetic disorder
- sickle cell disease
- problems with your kidneys, liver, heart or other organs
- previous treatment for cancer
- any infections, cancers or tumours.

If you have not told your doctor about any of the above, tell him/her before you start using NEUPOGEN.

Taking other medicines

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

How to use NEUPOGEN

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

They may differ from the information contained in this leaflet.

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

NEUPOGEN is given by injection, usually into the tissues just below the skin. This is called a subcutaneous injection.

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 NEUPOGEN injection at home. NEUPOGEN is sometimes given by injection into a vein. This is called an intravenous injection and is given by a doctor or nurse.

How much to inject

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

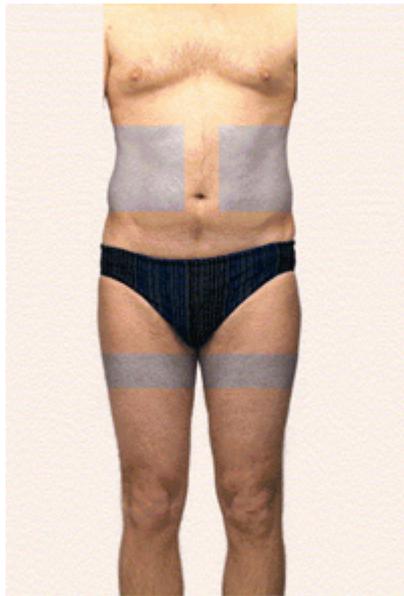
Your doctor will tell you the strength of NEUPOGEN you need and how much you require. How much you need will depend on the reason for your treatment, your body weight and the number of neutrophils in your blood.

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.



Change the injection site each time you inject to avoid soreness at any one site.

When to inject

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.

How long to use it

Your doctor will tell you how many injections you need each week and on which days they should be given.

- 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 1 to 3 weeks).
- Stem cell donors should receive NEUPOGEN treatment for 4 to 5 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. Usually, the dose is then reduced to three injections per week to maintain the neutrophil numbers.

Things to do before you inject

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

- a new NEUPOGEN syringe or vial
- a syringe and needle if using a NEUPOGEN vial
- an alcohol swab
- a puncture-resistant sharps container.

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

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

- Find a clean, flat working surface, such as a table, where you can inject undisturbed.
- Remove the syringe or vial from the refrigerator.

For a more comfortable injection, leave at room temperature for approximately 30 minutes.

Do not warm NEUPOGEN in any other way (e.g. do not warm it in the microwave or in hot water).

- Check that the syringe or vial has NOT been used before.
- Do not shake the syringe or vial. If the NEUPOGEN solution appears frothy or bubbly, allow the syringe or vial to sit undisturbed for a few minutes to reduce the froth or bubbles before measuring your dose.
- Do not remove the needle cover until you are ready to inject.
- Check the expiry date on the label. Do not use if the date has passed the last day of the month shown.
- 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.
- Wash and dry your hands thoroughly.

How to prepare your injection - NEUPOGEN Syringe

- Hold the syringe vertically with the needle pointing up - this helps reduce the amount of medicine that may leak out of the needle. Carefully remove the needle cover, taking care not to touch the exposed needle.
- 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. Double-check that you have the correct dose.**

How to prepare your injection - NEUPOGEN Vial

- Check that the syringe you are using is marked every tenth of a mL/cc (i.e. 0.1, 0.2, etc. mL/cc) so that you can accurately inject the prescribed dose. **Use disposable syringes and needles and use them once only.**
- Flip the protective cap off the vial. Do not remove the rubber stopper.
- Wipe the top of the rubber stopper with an alcohol swab.
- With the needle cover 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.
- Carefully remove the needle cover, taking care not to touch the exposed needle.
- Gently push the needle through the rubber top of the NEUPOGEN vial.
- Carefully push the plunger down. The air injected into the vial will allow NEUPOGEN to be easily withdrawn from the vial into the syringe.
- 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.

- 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. **Check that the correct dose of NEUPOGEN has been drawn into the syringe.** Remove the needle from the vial.

How to inject

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.



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



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° or as advised by your doctor, nurse or pharmacist).



Inject the NEUPOGEN by gently pushing the plunger all the way in.

- Withdraw the needle and using the alcohol swab apply pressure for several minutes to the injection site.
- Do not put the needle cover back on the used syringe. You cannot reuse the syringe.
- Discard the used syringe into an approved, puncture-resistant, sharps container.

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. Always follow your doctor's instructions.

If you forget 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.

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

If you inject too much (overdose)

If you inject more than the dose recommended by your doctor talk to your doctor, nurse or pharmacist immediately.

Too much NEUPOGEN may lead to neutrophil levels that are too high. Research has shown that doses almost 15 times greater than the most common dose do not immediately result in any harmful effects.

While you are using NEUPOGEN

Things you must do

Watch for any signs or symptoms of infection.

There are many ways an infection may show itself.

Symptoms of an infection include:

- 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.

Go straight to your hospital if you develop any of these symptoms.

If you are about to be started on any new medicine, tell your doctor, nurse and pharmacist that you are using NEUPOGEN.

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

If you become pregnant during treatment with NEUPOGEN, tell your doctor immediately.

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

Treatment with NEUPOGEN 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 NEUPOGEN treatment

until your blood cells have returned to normal levels.

Things you must not do

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

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

Side effects

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

All medicines can have 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 NEUPOGEN.

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

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

Tell your doctor, nurse 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 NEUPOGEN:

- temporary 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.
- abdominal discomfort
- bleeding or bruising more than usual, severe nose bleeds
- reddish or purplish blotches under the skin
- cough, breathlessness
- diarrhoea
- hair loss
- headache
- painful and swollen joints
- worsening of existing arthritis
- muscle pain
- redness, swelling or itching at the site of injection
- skin disorders - worsening of existing symptoms
- skin rash or red, itchy spots
- sore mouth, mouth ulcers
- tiredness, looking pale.

Tell your doctor as soon as possible if you notice any of the following:

- pain in the upper left side of the stomach (abdomen)
- left shoulder pain
- dizziness
- fever and painful skin lesions, often painful, most commonly on your arms, legs and sometimes on your face and neck

- blood in the urine.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- breathing problems such as shortness of breath, rapid breathing
- fever
- swelling or puffiness
- less frequent urination
- swelling of your stomach-area (abdomen) and feeling of fullness
- general feeling of tiredness.

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

Serious side effects are rare or uncommon.

If any of the following happen, stop taking NEUPOGEN and go straight to hospital, as you may need urgent medical attention:

- rash over a large area of the body, itching or hives
- shortness of breath, wheezing or difficulty breathing
- coughing up blood, bleeding from the lung
- swelling of the face, lips, tongue or other parts of the body
- faintness
- rapid pulse or sweating.

These are very serious side effects. If you have them you may have had a serious allergic reaction to NEUPOGEN. You may need urgent medical attention or hospitalisation

Tell your doctor if you notice anything that worries you or that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using NEUPOGEN

Storage

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

Exposure to freezing temperatures will not harm NEUPOGEN.

Exposure to room temperature of up to 3 days will not harm NEUPOGEN.

Keep your medicine in its pack until it is time to use it. Protect it from light.

Keep it where children cannot reach it.

Disposal

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

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

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

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

Dispose of the used vial in the rubbish or as directed by your doctor, nurse or pharmacist.

Product description

What it looks like

NEUPOGEN is a clear, colourless solution. It is supplied in pre-filled syringes or vials.

The syringes and vials are packed in cartons of 10 and are available in the following strengths:

- 300 micrograms of filgrastim in a volume of 0.5 mL, in a syringe;
- 480 micrograms of filgrastim in a volume of 0.5 mL, in a syringe;
- 300 micrograms of filgrastim in a volume of 1 mL, in a vial; and
- 480 micrograms of filgrastim in a volume of 1.6 mL, in a vial.

Ingredients

Active ingredient: filgrastim (rbe).

Inactive ingredients:

- sodium acetate
- sorbitol
- polysorbate 80
- Water for Injections.

The needle cover on the pre-filled syringe contains a derivative of latex.

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

Sponsor

Amgen Australia Pty Ltd
ABN 31 051 057 428
Level 7, 123 Epping Road,
North Ryde NSW 2113

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Australian Registration Numbers:

- 300 µg/0.5 mL syringe - AUST R 53580
- 480 µg/0.5 mL syringe -AUST R 53581
- 300 µg/1 mL vial - AUST R 53579
- 480 µg/1.6 mL vial - AUST R 53577

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