

NEUPOGEN® (filgrastim)

Patient Information Booklet

This booklet is intended only for patients who have been
prescribed NEUPOGEN®

WELCOME TO YOUR GUIDE TO NEUPOGEN® (filgrastim)

This is a simple guide to help you understand how to manage your treatment with NEUPOGEN®.



Please read both this patient booklet and the Patient Information Leaflet (PIL) found in your NEUPOGEN® pack or available at www.medicines.ie/medicines/list/all/page-1/per-page-25?query=neupogen



Visit the patient website www.amgencare.ie to read more information about NEUPOGEN® and neutropenia.



This medicine has been prescribed for you only. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours.



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

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.

For a list of side effects please see the Patient Information Leaflet (PIL).

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WHY HAVE I BEEN PRESCRIBED NEUPOGEN® AFTER CHEMOTHERAPY?

- White blood cells, the majority of which are called neutrophils, are one of the main cells that fight bacteria when it enters your body.¹
- Chemotherapy can cause a reduction in the number of neutrophils in your body. This is called neutropenia, which can sometimes lead to infection because you have fewer neutrophils available to fight off bacteria.¹
- Infection can be one of the most serious side effects of chemotherapy.² It may need to be treated in hospital and can disrupt your schedule for chemotherapy.



Chemotherapy works by killing fast-growing cancer cells.

Chemotherapy drugs can't tell the difference between cancer cells and fast-growing healthy cells. A possible side effect of chemotherapy is a low count of white blood cells, including neutrophils.²

Having a low neutrophil count is a condition known as neutropenia.

Neutropenia can raise your risk of developing certain types of infections. A low white blood cell count with fever, also known as febrile neutropenia, can be a sign of a serious infection.² You should call your doctor or nurse right away if you get a fever higher than 38°C.⁴



Infection may be a risk throughout your chemotherapy treatment.

Your treatment plan may consist of multiple chemotherapy cycles. The risk of infection may be present in every one of them. Helping to reduce that risk should be an important consideration for you and your doctor/nurse.

NEUPOGEN® can be used to increase the number of white blood cells after treatment with chemotherapy to help prevent infections:⁵



Before chemotherapy:

At natural levels, white blood cells help protect your body against infection.



With chemotherapy:

Chemotherapy can reduce your white blood cell count. This may put you at risk for certain types of infection.



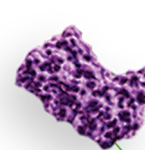
After chemotherapy:

NEUPOGEN® can help stimulate the production of neutrophils, shortening the time and reducing the depth of a low white blood cell count after chemotherapy. This can help your body fight infection.⁵

NEUPOGEN® can also be used:⁵

- to increase the number of white blood cells (neutrophils) 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 (neutrophils) if you suffer from severe chronic neutropenia to help prevent infections;
- in patients with advanced HIV infection to help reduce the risk of infection.

How does NEUPOGEN® work?⁵



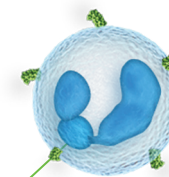
The body makes G-CSF

The body makes a natural protein called G-CSF [granulocyte colony stimulating factor] which acts in the bone marrow to boost the production of white blood cells called neutrophils.



NEUPOGEN® is a form of G-CSF

Like G-CSF, NEUPOGEN® acts in the bone marrow, where it helps boost the production of neutrophils.



NEUTROPHILS may mature faster

with NEUPOGEN®, ready for release into the blood stream to help fight bacteria and help reduce the risk of infection.

HOW IS NEUPOGEN® TAKEN?⁵

NEUPOGEN® is usually given as a daily injection into the tissue just under the skin (known as a subcutaneous injection). It can also be given as a daily slow injection into the vein (known as an intravenous infusion).

The usual dose varies depending on your illness and weight. Your doctor will tell you how much NEUPOGEN® you should take.

You will normally receive your first dose of NEUPOGEN® at least 24 hours after your chemotherapy and at least 24 hours after receiving your bone marrow transplant.

24h



Always use NEUPOGEN® exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

You must always use the dose of NEUPOGEN® that was prescribed to you:

- Do not increase the dose your doctor has given you.
- If you think you have injected more than you should, contact your doctor or nurse as soon as possible.
- If you have missed an injection, or injected too little, contact your doctor or nurse as soon as possible. Do not take a double dose to make up for any missed doses.



You, or people caring for you, can be taught how to give subcutaneous injections so that you can continue your treatment at home. However, you should not attempt this unless you have been properly trained first by your healthcare provider.

You will need to be treated with NEUPOGEN® until your white blood cell count is normal.

Regular blood tests will be taken to monitor the number of white blood cells in your body.

Your doctor or nurse will tell you how long you will need to take NEUPOGEN®.



For more information, please see the NEUPOGEN® Patient Information Leaflet and talk to your doctor/nurse.

HOW TO STORE NEUPOGEN®?⁵

Keep this medicine out of the sight and reach of children.



Store in a refrigerator (2°C – 8°C).

Accidental freezing will not harm NEUPOGEN®.



Keep the container in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the syringe label and carton after EXP. The expiry date refers to the last day of that month.



Do not use this medicine if you notice discolouration, cloudiness or particles, it should be a clear, colourless liquid.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help protect the environment.



It is important to tell your healthcare professional if you are having any problems with your medicine. For further information on NEUPOGEN® and possible side effects please read the Patient Information Leaflet.

STEP-BY-STEP GUIDE ON HOW TO INJECT NEUPOGEN® PRE-FILLED SYRINGE⁵

This section contains information on how to give an injection of NEUPOGEN®. **Important:** do not try to give yourself an injection unless you have received training from your doctor or nurse.

NEUPOGEN® is injected into the tissue just under the skin. This is known as a subcutaneous injection.

Equipment that you need

To give yourself a subcutaneous injection you will need:

- a new pre-filled syringe of NEUPOGEN®; and
- alcohol wipes or similar.

What do I do before I give myself a subcutaneous injection of NEUPOGEN®?

1. Remove one tray containing a syringe from the refrigerator and leave at room temperature for approximately 30 minutes, or hold gently in your hand for a few minutes. This will make the injection more comfortable. **Do not** warm NEUPOGEN® in any other way (for example, do not warm it in a microwave or in hot water).
2. Do not shake the pre-filled syringe.
3. Place the tray in your hand and peel the paper off the tray.
4. Flip the tray to place the pre-filled syringe onto your palm.
5. **Do not** remove the needle cover until you are ready to inject.
6. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
7. Check the appearance of NEUPOGEN®. It must be a clear and colourless liquid. If there is discolouration, cloudiness or particles in it, you must not use it.
8. **Wash your hands thoroughly.**
9. Find a comfortable, well-lit, clean surface and put all the equipment you need within reach.

How do I prepare my NEUPOGEN® injection?

Before you inject NEUPOGEN® you must do the following:

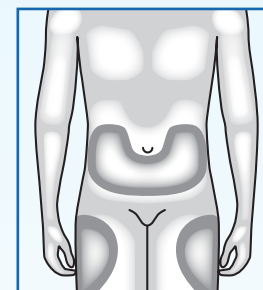
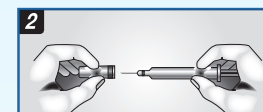
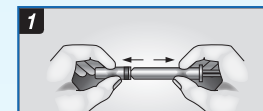
1. To avoid bending the needle, securely grasp the pre-filled syringe by the glass barrel. Gently pull the cover from the needle without twisting as shown in pictures 1 and 2.
2. Do not touch the needle or push the plunger.

3. 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.
4. You can now use the pre-filled syringe.

Where do I give my injection?

The best places to inject are the top of your thighs and the abdomen. If someone else is injecting you, they can also use the back of your upper arms.

You may change the injection site if you notice the area is red or sore.



How do I give my injection?

1. Disinfect your skin by using an alcohol wipe and pinch (without squeezing) the skin between your thumb and forefinger.
2. Put the needle fully into the skin as shown by your nurse or doctor.
3. Push the plunger with a slow constant pressure, always keeping your skin pinched, until the syringe is empty.
4. Remove the needle and let go of your skin.
5. If you notice a spot of blood you may gently dab it away with a cotton ball or tissue. Do not rub the injection site. If needed, you may cover the injection site with a plaster.
6. Only use each syringe for one injection. Do not use any NEUPOGEN® that may be left in the syringe.

Remember: if you have any problems, please do not be afraid to ask your doctor or nurse for help and advice.

Disposing of used syringes

- Do not put the cover back on used needles, as you may accidentally prick yourself.
- Keep used syringes out of the reach and sight of children.
- Syringes should not be thrown out in the household rubbish. Your pharmacist will know how to dispose of used syringes or syringes no longer needed.

WHAT YOU NEED TO KNOW BEFORE AND WHILE YOU USE NEUPOGEN®⁵



Please tell your doctor, pharmacist or nurse before starting treatment if you have:

- Sickle cell anaemia, as NEUPOGEN® may cause sickle cell crisis.
- An allergy to natural rubber (latex). The needle cover on the syringe may be made from a type of natural rubber and may cause allergic reactions.
- Osteoporosis (bone disease).

Please tell your doctor immediately during treatment with NEUPOGEN®, if you:

- Experience an allergic reaction (hypersensitivity) including weakness, drop in blood pressure, difficulty breathing, swelling of the face (anaphylaxis), skin rash, itchy rash (urticaria), swelling of the face, lips, mouth, tongue or throat (angioedema) and shortness of breath (dyspnoea).
- Experience kidney injury (glomerulonephritis). Kidney injury has been seen in patients who received NEUPOGEN®. Call your doctor right away if you experience puffiness in your face or ankles, blood in your urine or brown-coloured urine or you notice you urinate less than usual.
- Get left upper belly (abdominal) pain, pain below the left rib cage or pain at the tip of your left shoulder (these may be symptoms of an enlarged spleen (splenomegaly), or possibly rupture of the spleen).
- Notice unusual bleeding or bruising (these may be symptoms of a decrease in blood platelets (thrombocytopenia), with a reduced ability of your blood to clot).
- Experience fever, abdominal pain, malaise, back pain and increased inflammatory markers. Inflammation of aorta (the large blood vessel which transports blood from the heart to the body) has been reported rarely in cancer patients and healthy donors.
- If you experience a cough, fever and difficulty breathing (dyspnoea) as this can be a sign of Acute Respiratory Distress Syndrome (ARDS).
- If you have any of the following or combination of the following side effects: swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness. These symptoms generally develop in a rapid fashion - These could be symptoms of a condition called "Capillary Leak Syndrome" which causes blood to leak from the small blood vessels into your body and needs urgent medical attention.
- If you have a combination of any of the following symptoms: fever, or shivering, or feeling very cold, high heart rate, confusion or disorientation, shortness of breath, extreme pain or discomfort and clammy or sweaty skin - These could be symptoms of a condition called "sepsis" (also called "blood poisoning"), a severe infection with whole-body inflammatory response which can be life threatening and needs urgent medical attention.
- If you are being treated for severe chronic neutropenia and you have blood in your urine (haematuria). Your doctor may regularly test your urine if you experience this side effect or if protein is found in your urine (proteinuria).

WILL I HAVE ANY SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been experienced by some patients taking NEUPOGEN®⁵:



Very common side effects (may affect more than 1 in 10 people):

- Decrease of platelets which reduces the ability of blood to clot (thrombocytopenia)
- Low red blood cell count (anaemia)
- Headache
- Diarrhoea
- Vomiting
- Nausea
- Unusual hair loss or thinning (alopecia)
- Tiredness (fatigue)
- Soreness and swelling of the digestive tract lining which runs from the mouth to the anus (mucosal inflammation)
- Fever (pyrexia)

Common side effects (may affect up to 1 in 10 people):

- Inflammation of the lung (bronchitis)
- Upper respiratory tract infection
- Urinary tract infection
- Decreased appetite
- Trouble sleeping (insomnia)
- Dizziness
- Decreased feeling of sensitivity, specially in the skin (hypoesthesia)
- Tingling or numbness of the hands or feet (paraesthesia)
- Low blood pressure (hypotension)
- High blood pressure (hypertension)
- Cough
- Coughing up blood (haemoptysis)
- Pain in your mouth and throat (oropharyngeal pain)
- Nose bleeds (epistaxis)
- Constipation
- Oral pain
- Enlargement of the liver (hepatomegaly)
- Rash
- Redness of the skin (erythema)
- Muscle spasm
- Pain when passing urine (dysuria)
- Chest pain
- Pain
- Generalised weakness (asthenia)
- Generally feeling unwell (malaise)
- Swelling in the hands and feet (oedema peripheral)
- Increase of certain enzymes in the blood
- Changes in blood chemistry
- Transfusion reaction

THIS IS NOT A FULL LIST OF POSSIBLE SIDE EFFECTS, WARNINGS AND PRECAUTIONS.

Please refer to the patient information leaflet found in your NEUPOGEN® pack or available on www.medicines.ie/medicines/list/all/page-1/per-page-25?query=neupogen for a complete list of possible side effects. If you have any questions or concerns about side effects, please talk to your doctor, nurse or pharmacist.

SIGNS OF INFECTION

As infection can be one of the most serious side effects of chemotherapy, it is important that you know what the symptoms of infection are.

If you have any of the following signs of infection, report them to your doctor immediately:⁶



- Temperature (fever) of 38°C or higher
- Chills and sweats
- Change in cough or new cough
- Sore throat or new mouth sore
- Shortness of breath
- Nasal congestion
- Stiff neck
- Burning or pain with urination
- Unusual vaginal discharge or irritation
- Increased urination
- Redness, soreness, or swelling in any area, including surgical wounds and ports
- Diarrhea
- Vomiting
- Pain in the abdomen or rectum
- New onset of pain
- Changes in skin, urination, and mental status



Steps to help reduce the risk of infection

Protect yourself during your treatment with chemotherapy

Once you begin chemotherapy, the following steps and precautions can help you avoid getting an infection:⁶



- Clean your hands frequently.
- Shower or bathe daily and use an unscented lotion to prevent your skin from becoming dry and cracked.
- Cook meat and eggs all the way through to kill any germs.
- Carefully wash raw fruits and vegetables.
- Protect your skin from direct contact with pet bodily waste (urine or feces) by wearing vinyl or household cleaning gloves when cleaning up after your pet. Wash your hands immediately afterwards.
- Use gloves for gardening.
- Clean your teeth and gums with a soft toothbrush, and if your doctor or nurse recommends one, use a mouthwash to prevent mouth sores.
- Try and keep all your household surfaces clean.
- If you get a cut or scrape, cover it with a clean bandage until it heals.
- To prevent cuts when shaving, consider using an electric razor instead of a blade.

Things to avoid during chemotherapy:



- Crowds of people and people with colds or other infections
- Cuts or tears of the skin or nails
- Nicks or cuts when using sharp instruments - Handle sharp objects with caution and wear protective gloves when performing tasks that expose you to a risk of cuts or scrapes, such as gardening
- Squeezing or scratching pimples
- Taking medicines to reduce the symptoms of infection without your doctor's consent
- Situations in which you may bruise or break your skin
- Immunisations or vaccinations, unless recommended by your doctor
- Sharing food, drink cups, utensils or other personal items, such as toothbrushes.⁶

TREATMENT DIARY

Keeping track of your NEUPOGEN® injections can help you stay organized. It's important to follow the treatment schedule your doctor has prescribed for you. To help you remember, tick (✓) in this tracker the days you have taken NEUPOGEN®.

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FOR FURTHER INFORMATION PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT CAME WITH YOUR MEDICINE OR AVAILABLE AT www.medicines.ie/medicines/list/all/page-1/per-page-25?query=neupogen

Visit the patient website www.amgencare.ie for more information (for quick access, scan the below QR code with your phone's camera or QR reader app)



References:

1. American Cancer Society. Why People with Cancer are More Likely to Get Infections. [Available at: www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/low-blood-counts/infections/why-people-with-cancer-are-at-risk.html. Accessed: July 2020]
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3. American Cancer Society. Chemotherapy Side Effects. [Available at: www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/chemotherapy-side-effects.html. Accessed: July 2020]
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