





## YOUR GUIDE TO NEULASTA® (PEGFILGRASTIM)



#### 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.

## WELCOME TO NEULASTA® (PEGFILGRASTIM)

Your doctor, nurse, or healthcare provider has given you this booklet because you are being treated with a medication called Neulasta®.

This booklet contains information about:

- What is Neutropenia?
- Signs of Infection
- Steps to help reduce the risk of infection
- How Neulasta® works
- How to use Neulasta®
- How to store Neulasta®
- How to administer Neulasta® with a pre-filled syringe with automatic needle guard
- What to know before and while you use Neulasta®
- Possible side effects

Please read both this patient booklet and the Patient Information Leaflet (PIL) that comes with your Neulasta® pack, also available at www.medicines.ie/medicines/neulasta-pre-filled-syringe-34724/patient-info

- Visit the patient website www.amgencare.ie to see more information about Neulasta® and neutropenia.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms of illness are the same as yours.

Remember, you should always ask your doctor or nurse any specific questions about your condition or treatment.

3



## WHAT IS NEUTROPENIA?

You are receiving chemotherapy to treat cancer. Chemotherapy works by destroying the fast-growing cancer cells in your body. At the same time, chemotherapy can damage healthy cells in your body, such as blood cells.

Your blood is made up of many different types of components, which are formed in the bone marrow. One of the main components is the white blood cells, which are a vital part of your body's immune system.<sup>3</sup>

Normally, the most common type of white blood cell is the neutrophil. This is a very important defense against most types of infection. Each neutrophil lives less than a day, so your bone marrow must constantly make new neutrophils to maintain protection against infection.<sup>3</sup>

Unfortunately, chemotherapy tends to stop your bone marrow making new neutrophils, which makes your immune system much weaker and less able to fight off any infection.<sup>4,5</sup> Neutropenia is the term used when the number of neutrophils in your blood drops below the number that most people have in their blood i.e. low neutrophils. Low neutrophils are a common side effect of chemotherapy.<sup>5</sup> Some people may even develop a fever that is often caused by an infection which is known as febrile neutropenia.<sup>2</sup>

People receiving chemotherapy may experience neutropenia, which is the biggest risk factor for getting a serious infection.<sup>5</sup>

## 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 <sup>6</sup> , report them to your doctor immediately:											
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

#### Once you begin chemotherapy, follow these steps and precautions which can help you avoid getting an infection<sup>6</sup>:

- 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.



#### X 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



## **HOW DOES NEULASTA® WORK?**

Neulasta® can be used to reduce the duration of neutropenia and the occurrence of febrile neutropenia after treatment with chemotherapy to help prevent infections<sup>2</sup>:

Before chemotherapy:



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

With chemotherapy:

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

After Neulasta®:



Neulasta® can help stimulate the production of neutrophils, shortening the time and depth of a low white blood cell count after chemotherapy. This can help your body fight infection.2

Neulasta® contains the active substance pegfilgrastim which is very similar to a protein found in your body (granulocytecolony stimulating factor). It helps your bone marrow to make more neutrophils to replace those that have been lost through chemotherapy. By helping increase the number of neutrophils in your blood and bringing your neutrophil levels closer to normal, Neulasta® will help protect you against infection.2





## HOW TO USE NEULASTA®2

Always take Neulasta® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. The usual dose is one 6 mg subcutaneous injection (injection under your skin) and it should be given at least 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

If you use more Neulasta® than you should contact your doctor, pharmacist or nurse.

If you have forgotten your dose of Neulasta® and you are self injecting, you should contact your doctor to discuss when you should inject the next dose.

## HOW TO STORE NEULASTA®2



Keep this medicine out of the sight and



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

Keep the container in the outer

carton in order to protect from light.



take Neulasta out of the temperature (not above



Do not freeze. Neulasta mav be used if it is accidentally frozen for a single period of less than 24 hours.



Do not use this medicine if you notice it is cloudy or there are particles in it.



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



Store in a refrigerator [2°C - 8°C]. You may refrigerator and keep it at room temperature (not above 30°C) for no longer than 3 days. Once a syringe has been removed from the refrigerator and has reached room 30°C) it must either be used within 3 days or disposed of.

## HOW TO USE THE NEULASTA® PRE-FILLED SYRINGE WITH AUTOMATIC NEEDLE GUARD (ANG)2

A step by step video demonstration showing how to administer your Neulasta® ANG pre-filled syringe is available at www.amgencare.ie

The ANG pre-filled syringe is used like a standard syringe. After delivering the full injection, a needle guard is automatically activated as you release pressure from the plunger, safely covering the injection needle.

Important: Before you use a Neulasta® pre-filled syringe with automatic needle guard, read this important information:

#### Guide to parts

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Neulasta® is given as an injection into the tissue iust under the skin (subcutaneous injection).
- Tell your doctor if you have an allergy to latex. The needle cap on the pre-filled syringe contains a derivative of latex and may cause severe allergic reactions.
- Before use Svringe label Used syringe barrel Used needle Syringe barrel Syringe safety guard Used needle safety Needle safety spring Grev needle cap on -Grev needle cap off
- **X** Do not remove the grey needle cap from the pre-filled syringe until you are ready to
- X Do not use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.
- X Do not attempt to activate the pre-filled syringe prior to injection.
- X Do not attempt to remove the clear pre-filled syringe safety guard from the pre-filled syringe.
- X Do not attempt to remove the peelable label on the pre-filled syringe barrel before administering your injection.

Call your doctor or healthcare provider if you have any questions.

(continued on next page)

#### Step 1: Prepare

A Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container (not included).

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting. Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

**X** Do not try to warm the syringe by using a heat source such as hot water or microwave.

X Do not leave the pre-filled syringe exposed to direct sunlight.

X Do not shake the pre-filled syringe.

Keep the pre-filled syringe out of the sight and reach of children.



B Open the tray, peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.

For safety reasons:

X Do not grasp the plunger.

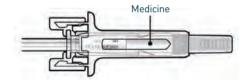
X Do not grasp the grey needle cap.

C Inspect the medicine and pre-filled syringe.

X Do not use the pre-filled syringe if:

- The medicine is cloudy or there are particles in it. It must be a clear and colourless liquid
- Any part appears cracked or broken.
- The grey needle cap is missing or not securely attached.
- The expiry date printed on the label has passed the last day of the month shown.

In all cases, call your doctor or healthcare provider.



#### Step 2: Get ready

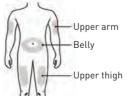
A Wash your hands thoroughly. Prepare and clean your injection site.

#### You can use:

- ✓ Upper part of your thigh.
- ✓ Belly, except for a 5 cm (2-inch) area right around your belly button.
- ✓ Outer area of upper arm (only if someone else is giving you the injection).

Clean the injection site with an alcohol wipe. Let your skin dry.

X Do not touch the injection site before injecting.





Do not inject into areas where the skin is tender. bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

#### Step 2: Get ready (continued)

B Carefully pull the grey needle cap straight out and away from your body.



C Pinch your injection site to create a firm surface.



It is important to keep the skin pinched when injecting.

#### Step 3: Inject

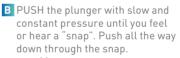
A Hold the pinch while you give the injection.

INSERT the needle into skin.

X Do not touch the cleaned area of the skin.



C RELEASE your thumb. Then LIFT the syringe off skin. After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.





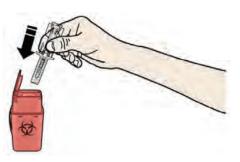
It is important to push down through the "snap" to deliver vour full dose.



X Do not put the grey needle cap back on used pre-filled syringes.

#### Step 4: Finish

A Discard the used pre-filled syringe and other supplies in a sharps disposal container.



Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Keep the syringe and sharps disposal container out of sight and reach of children.

- X Do not reuse the pre-filled syringe.
- X Do not recycle pre-filled syringes or throw them into household waste.
- B Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site.

**X** Do not rub the injection site.

Apply a plaster if needed.

# WHAT YOU NEED TO KNOW BEFORE AND WHILE YOU ARE TAKING NEULASTA®2

#### Please tell your doctor immediately if you:

- Experience an allergic reaction including weakness, drop in blood pressure, difficulty breathing, swelling of the face (anaphylaxis), redness and flushing, skin rash and areas of the skin that itch.
- Have an allergy to latex. The needle cap on the pre-filled syringe contains a derivative of latex and may cause severe allergic reactions.
- Experience a cough, fever and difficulty breathing. This can be a sign of Acute Respiratory Distress Syndrome (ARDS).
- 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.
- Get left upper abdominal pain or pain at the tip of your shoulder. This may be a sign of a problem with your spleen (splenomegaly).
- Have recently had a serious lung infection (pneumonia), fluid in the lungs (pulmonary oedema), inflammation of the lungs (interstitial lung disease) or an abnormal chest x-ray (lung infiltration).
- Are aware of any altered blood cell counts (e.g. increase in white blood cells or anaemia) or decreased blood platelet counts, which reduces the ability of your blood to clot (thrombocytopenia). Your doctor may want to monitor you more closely.
- Have sickle cell anaemia. Your doctor may monitor your condition more closely.
- If you are a patient with breast cancer or lung cancer, Neulasta® in combination with chemotherapy and/or radiation therapy
  may increase your risk of a precancerous blood condition called myelodysplastic syndrome (MDS) or a blood cancer called acute
  myeloid leukaemia (AML). Symptoms may include tiredness, fever, and easy bruising or bleeding.

#### Please tell your doctor immediately if you (continued):

- Have 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 these could be signs of a severe allergic reaction.
- If you have symptoms of inflammation of aorta (the large blood vessel which transports blood from the heart to the body), this has been reported rarely in cancer patients and healthy donors. The symptoms can include fever, abdominal pain, malaise, back pain and increased inflammatory markers.
- Notice reddish target-like or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes which can be preceded by fever and flu-like symptoms. Severe skin reactions (Stevens-Johnson syndrome) have been reported with the use of Neulasta®. Stop using Neulasta® and seek medical attention immediately if you experience those symptoms.

## **POSSIBLE 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 Neulasta®. Please tell your doctor immediately if you have any of the following or combination of the following side effects:

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

- Bone pain. Your doctor will tell you what you can take to ease the bone pain.
- Nausea and headaches.

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

- Pain at the site of injection.
- General aches and pains in the joints and muscles.
- Some changes may occur in your blood, but these will be detected by routine blood tests. Your white blood cell count may become high for a short period of time. Your platelet count may become low which might result in bruising.

THIS IS NOT A FULL LIST OF POSSIBLE SIDE EFFECTS, WARNINGS AND PRECAUTIONS. Please refer to the patient information leaflet found in your Neulasta® pack or available on www.medicines.ie/medicines/neulasta-pre-filled-syringe-34724/patient-info for a complete list of possible uncommon side effects (may affect up to 1 in 100 people) and rare side effects (may affect up to 1 in 1000 people). If you have any questions or concerns about side effects, please talk to your doctor, nurse or pharmacist.

(continued on next page.)

## TREATMENT DIARY

Keeping track of your Neulasta® 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 Neulasta®.

January	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
February	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29		
March	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
April	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
May	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
June	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
July	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
August	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
September	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
October	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
November	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
December	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

14 15

# PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT CAME WITH YOUR MEDICINE, OR AVAILABLE AT www.medicines.ie/medicines/neulasta-pre-filled-syringe-34724/patient-info

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. NHS. Chemotherapy [Available at: www.nhs.uk/conditions/chemotherapy/. Accessed December 2020] 2. Neulasta® [pegfilgrastim] Patient Information Leaflet. [Available at: www.medicines.ie/medicines/neulasta-pre-filled-syringe-34724/patient-info] 3. American Society of Hematology. Blood basics. [Available at: www.hematology.org/education/patients/blood-basics. Accessed December 2020] 4. American Cancer Society. Chemotherapy Side Effects. [Available at: www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy-side-effects.html. Accessed December 2020] 5. American Cancer Society. Low White Blood Cell Counts (Neutropenia). [Available at: www.cancer.org/treatment/treatments-and-side-effects/low-blood-counts/neutropenia.html. Accessed December 2020] 6. National Center for Chronic Disease Prevention and Health Promotion. What you need to know neutropenia and risk for infection. [Available at: www.preventcancerinfections.org/content/materials-patients-and-caregivers. Accessed: December 2020]

