Package leaflet: Information for the user

Neulasta 6 mg solution for injection with on-body injector
pegfilgrastim

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Whilst wearing the Neulasta on-body injector it is important that you keep the Patient Alert Card provided by your doctor, pharmacist or nurse with you. It contains important advice on how to monitor your device for medication errors including under dose leading to lack of effect, and when to seek immediate medical attention.

What is in this leaflet

1. What Neulasta is and what it is used for

Neulasta contains the active substance pegfilgrastim. Pegfilgrastim is a protein produced by biotechnology in bacteria called *E. coli*. It belongs to a group of proteins called cytokines, and is very similar to a natural protein (granulocyte-colony stimulating factor) produced by your own body.

Neulasta is used to reduce the duration of neutropenia (low white blood cell count) and the occurrence of febrile neutropenia (low white blood cell count with a fever) which can be caused by the use of cytotoxic chemotherapy (medicines that destroy rapidly growing cells). White blood cells are important as they help your body fight infection. These cells are very sensitive to the effects of chemotherapy which can cause the number of these cells in your body to decrease. If white blood cells fall to a low level there may not be enough left in the body to fight bacteria and you may have an increased risk of infection.

Your doctor has given you Neulasta to encourage your bone marrow (part of the bone which makes blood cells) to produce more white blood cells that help your body fight infection.

2. What you need to know before you use Neulasta

Do not use Neulasta

- if you are allergic to pegfilgrastim, filgrastim, or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Neulasta:

- 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.
- 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.
- if you have an allergy to acrylic adhesives. The on-body injector uses acrylic adhesive and may result in an allergic reaction.
- if you experience a cough, fever and difficulty breathing. 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 could be symptoms of a condition called "Capillary Leak Syndrome" which causes blood to leak from the small blood vessels into your body. See section 4.
- if you 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).
- if you 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).
- if you 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.
- if you 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.
- if you 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. Tell your doctor if you experience those symptoms.

Your doctor will check your blood and urine regularly as Neulasta can harm the tiny filters inside your kidneys (glomerulonephritis).

Severe skin reactions (Stevens-Johnson syndrome) have been reported with the use of Neulasta. Stop using Neulasta and seek medical attention immediately if you notice any of the symptoms described in section 4.

You should talk to your doctor about your risks of developing cancers of the blood. If you develop or are likely to develop cancers of the blood, you should not use Neulasta, unless instructed by your doctor.

Loss of response to pegfilgrastim

If you experience a loss of response or failure to maintain a response with pegfilgrastim treatment, your doctor will investigate the reasons why including whether you have developed antibodies which neutralise pegfilgrastim's activity.

Other medicines and Neulasta

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Neulasta has not been tested in pregnant women. It is important to tell your doctor if you:
- are pregnant;
- think you may be pregnant; or
- are planning to have a baby.

Unless your doctor directs you otherwise, you must stop breast-feeding if you use Neulasta.

Driving and using machines

Neulasta has no or negligible effect on the ability to drive or use machines.

Neulasta contains sorbitol (E420) and sodium

This medicine contains 30 mg sorbitol in each pre-filled syringe which is equivalent to 50 mg/mL. This medicine contains less than 1 mmol sodium (23 mg) per 6 mg dose, that is to say essentially 'sodium-free'.

3. How to use Neulasta

Neulasta is for use in adults aged 18 and over.

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.

Using Neulasta with the on-body injector

Your doctor may decide that it would be more convenient for you to use Neulasta with the on-body injector. For further information on use with the on-body injector, please read the instructions for use at the end of this leaflet.

Check the instructions at the end of this leaflet and contact your healthcare provider if:
- during the monitoring of your on-body injector you are concerned that it is leaking; or
- after the injection is complete you are concerned that you may not have received the full dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please tell your doctor immediately 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 an uncommon (may affect up to 1 in 100 people) condition called "Capillary Leak Syndrome" which causes blood to leak from the small blood vessels into your body and needs urgent medical attention.

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):

- rash, itchy red raised bumps (contact dermatitis/local skin reactions) have been seen with the on-body injector.
- pain at the site of injection.
- application site reactions which may include redness, bleeding, bruising, pain and discomfort have been seen with the on-body injector.
- 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.

Uncommon side effects (may affect up to 1 in 100 people):

- allergic-type reactions, including redness and flushing, skin rash, and raised areas of the skin that itch.
- serious allergic reactions, including anaphylaxis (weakness, drop in blood pressure, difficulty breathing, swelling of the face).
- increased spleen size.
- spleen rupture. Some cases of splenic rupture were fatal. It is important that you contact your doctor immediately if you experience pain in the upper left side of the abdomen or left shoulder pain since this may relate to a problem with your spleen.
- breathing problems. If you have a cough, fever and difficulty breathing please tell your doctor.
- Sweet's syndrome (plum-coloured, raised, painful lesions on the limbs and sometimes the face and neck with fever) has occurred but other factors may play a role.
- cutaneous vasculitis (inflammation of the blood vessels in the skin).
- damage to the tiny filters inside your kidneys (glomerulonephritis).
- redness at the site of injection.
- coughing up blood (haemoptysis).
- blood disorders (myelodysplastic syndrome [MDS] or acute myeloid leukaemia [AML]).

Rare side effects (may affect up to 1 in 1,000 people):

- inflammation of aorta (the large blood vessel which transports blood from the heart to the body), see section 2.
- bleeding from the lung (pulmonary haemorrhage).
- Stevens-Johnson syndrome, which can appear as reddish target-like or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Neulasta if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

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 this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Neulasta

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

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.

Store in a refrigerator (2°C – 8°C).

The syringe for use with the on-body injector must either be used within 36 hours after it has reached room temperature (not above 30°C) or disposed of.

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

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

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.

6. Contents of the pack and other information

What Neulasta contains

- The active substance is pegfilgrastim. Each pre-filled syringe contains 6 mg of pegfilgrastim in 0.6 mL of solution.
- The other ingredients are sodium acetate, sorbitol (E420), polysorbate 20 and water for injections. See section 2.

What Neulasta looks like and contents of the pack

Neulasta is a clear, colourless solution for injection in a pre-filled syringe (6 mg/0.6 mL).

Each pack contains 1 glass pre-filled syringe with an attached stainless steel needle and needle cap.

One pre-filled syringe with blister wrapping and with an on-body injector.

Marketing Authorisation Holder
Amgen Limited
216 Cambridge Science Park
Milton Road
Cambridge

CB4 0WA
United Kingdom

Manufacturer
Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

Manufacturer
Amgen Technology (Ireland) Unlimited Company
Pottery Road
Dun Laoghaire
Co Dublin
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Amgen Limited
Tel: +44 (0)1223 420305

This leaflet was last revised in August 2022.

On-body injector for Neulasta 6 mg solution for injection
Patient instructions for use

Important information

The on-body injector delivers your Neulasta dose with an under-the-skin (subcutaneous) injection. Your healthcare provider will fill the on-body injector with Neulasta and then apply it directly to your skin using an adhesive pad. The adhesive pad is water-resistant but you are advised to avoid submerging the on-body injector in water.

The on-body injector is worn for 27 hours after placement and is programmed to make sure you do not receive Neulasta any sooner than 24 hours after your chemotherapy. The on-body injector will use sounds and lights to let you know its status.

Allergies

- Serious allergic reactions can happen with Neulasta. Ask your caregiver to be nearby for the first use. Plan to be in a place where you or your caregiver can appropriately monitor the on-body injector for Neulasta during the approximately 45 minute Neulasta delivery and for an hour after the delivery.
- Tell your healthcare provider if you have had severe skin reactions to acrylic adhesives. If you have an allergic reaction during the delivery of Neulasta, remove the on-body injector by grabbing the edge of the adhesive pad and peeling off the on-body injector. Get emergency medical help right away.
- Tell your healthcare provider if you have an allergy to latex. A pre-filled syringe is used to fill the on-body injector. The grey needle cap of the pre-filled syringe contains dry natural rubber, which is derived from latex. Latex may be transferred to your skin.

Activity

- **Avoid** knocking or pulling the on-body injector. Consider wearing loose clothing and take care when changing clothes. There is a small cannula which sits just under your skin. If the on-body injector has been knocked or pulled, the cannula may become dislodged. If this happens, you may not receive your dose of Neulasta.
- Avoid activities and places that may interfere with monitoring during the dosing of Neulasta. For example **AVOID**, travelling, driving, or operating heavy machines during 26-29 hours following application of the on-body injector (this includes the 45-minute dose delivery period plus an hour post-delivery).
- The on-body injector can be worn in a shower. After showering, check the on-body injector to ensure it has not become dislodged.
- **Do not** use baths, hot tubs, whirlpool baths, or saunas while wearing the on-body injector. This may affect your medicine.
- Only expose the on-body injector to temperatures between 5°C - 40°C.
- **Do not** expose the on-body injector to direct sunlight. If it is exposed to direct sunlight for more than 1 hour, it may affect your medicine. Wear the on-body injector under your clothing.
- **Do not** expose the on-body injector to the following because the on-body injector may be damaged and you could be injured:
  - Diagnostic imaging (e.g. CT scan, MRI, ultrasound, x-ray).
  - Radiation treatment.
  - Oxygen rich environments, such as hyperbaric chambers (a transparent chamber with an increase in atmospheric pressure).

On-body injector becomes loose or falls off

- **Contact your healthcare provider immediately** if the on-body injector comes away from your skin at any time before your full dose has been delivered, **do not** reapply it. There is a small cannula which sits just under your skin. If the on-body injector has been knocked or pulled, the cannula may become dislodged. If this happens, you may not receive your dose of Neulasta.

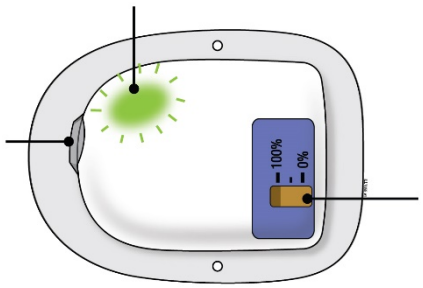
Electrical equipment

- **Keep the on-body injector at least 10 cm (4 inches) away from electrical equipment** such as mobile phones, cordless telephones, microwaves and other common appliances. Failure to keep the on-body injector at least this recommended distance may interfere with its operation and can lead to a missed or incomplete dose of Neulasta.

If you have any concerns or further questions on the use of this medicine, contact your healthcare provider.

Guide to parts for on-body injector for Neulasta

Green flashing status light

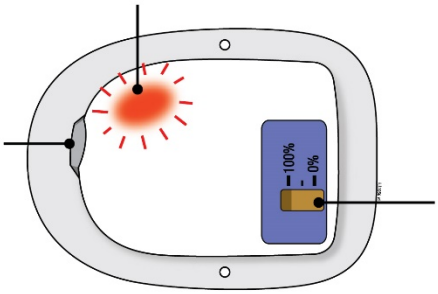


Cannula window

Fill indicator

The on-body injector is working properly.

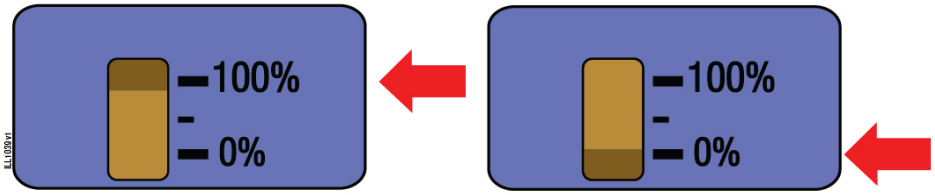
Red flashing status light



Cannula window

Fill indicator

Important: If at any time you hear beeping, check the status light. If it is flashing red, contact your healthcare provider immediately as you may need a replacement dose.



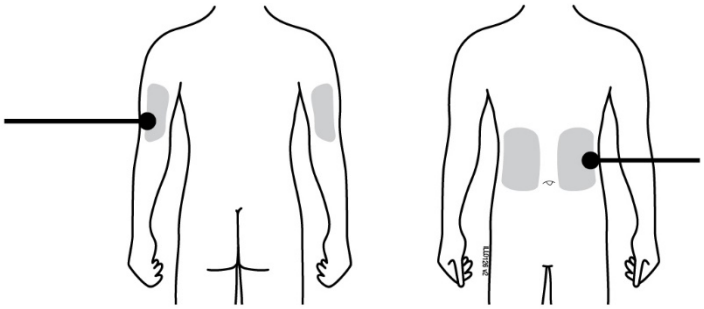
100% (full) 0% (empty)

Fill indicator

On-body injector placement

Important: Contact your healthcare provider immediately if you have severe pain or skin discomfort around your on-body injector.

Back of upper arm



Abdomen

Apply to intact, non-irritated skin on the stomach area abdomen or back of the arm. Use the arm only if a caregiver can help monitor the on-body injector's status.

Step 1: Monitor your on-body injector

A **For the next 27 hours, occasionally check the status light for at least 10 seconds. If the status light is flashing green, it is ok.**

If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor its status. **Do not** try to do this yourself, as you may accidently move it and dislodge the cannula from your skin leading to a missed or incomplete dose of Neulasta.

- Be careful not to bump or knock the on-body injector off your body.
- The on-body injector has a self-adhesive backing to attach it to the skin, **do not** use additional materials to hold it in place as this could dislodge the cannula leading to a missed or incomplete dose of Neulasta.
- If the on-body injector at any time comes away from your skin before your full dose delivery, **do not** reapply it. Call your healthcare provider immediately as you may need a replacement dose.
- Keep the on-body injector dry for the last 3 hours prior to the start of dose delivery. Avoid getting lotions, creams, oils or cleaning agents near the on-body injector, as these products may loosen the adhesive.
- **Do not** sleep on the on-body injector or apply pressure during wear, especially during dose delivery. This may affect the on-body injector's performance.

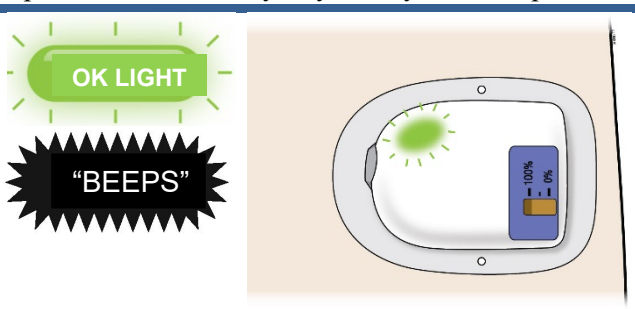
Important: If at any time you hear beeping, check the status light.
If it is flashing red, contact your healthcare provider immediately as you may need a replacement dose.

B **After about 27 hours, your on-body injector will produce a series of beeps to let you know your dose delivery is about to begin.**

Do not remove the on-body injector at this time.

- Dose delivery will start and take about 45 minutes to complete. The on-body injector will flash a fast green light.
- **Do not** remove the on-body injector before the dose delivery is complete. This may result in a missed or incomplete dose of Neulasta.

Important: If at any time you hear beeping, check the status light. If it is flashing red, contact your healthcare provider immediately as you may need a replacement dose.

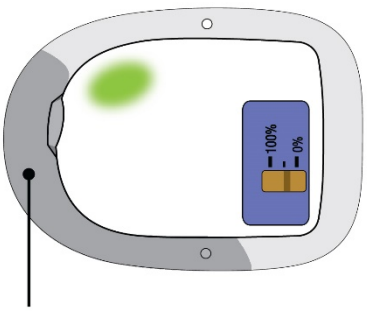


Do not remove the on-body injector before the dose delivery is complete.

Step 2: Monitor Dose Delivery

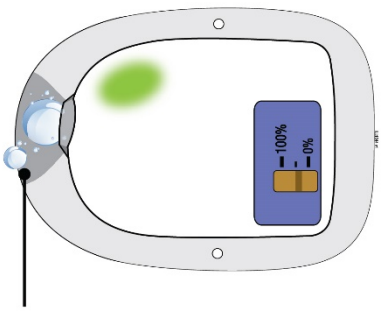
For the next 45 minutes, monitor your on-body injector frequently for leaks during dose delivery.
If it was placed on the back of your arm, a caregiver must be available to monitor your on-body injector.

Not working correctly



Noticeably wet (saturated) adhesive

Not working correctly



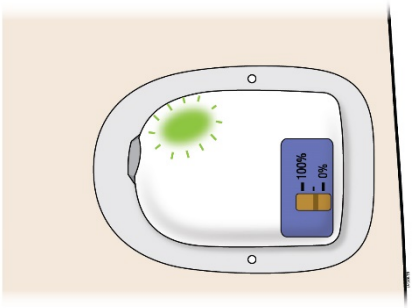
Dripping fluid from your on-body injector

If the adhesive becomes noticeably wet (saturated) with fluid, or you see dripping, contact your healthcare provider immediately as you may need a replacement dose.

A **Your dose delivery will take around 45 minutes to complete.**

- During this time, the on-body injector will flash a fast green light.
- You may hear a series of clicks. This is ok.
- When dose delivery is complete, a long beep will sound and the status light will be solid green.

45 minutes

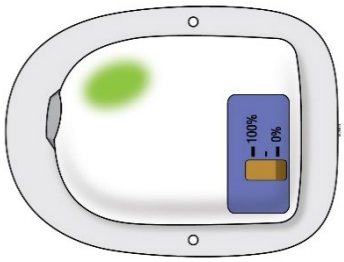


Important: If at any time you hear beeping, check the status light.
If it is flashing red, contact your healthcare provider immediately.

Step 3: Remove your on-body injector when dose delivery is complete

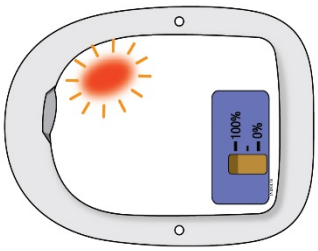
A **After the beep, check the colour of the status light.**

Correct



Check to see if the status light is SOLID GREEN or has switched off. This means the dose is complete. If the dose is complete, go to the next step.

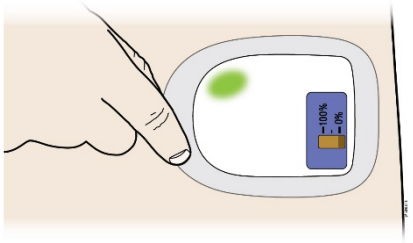
Not working correctly



If you see the status light is flashing red, your on-body injector is not functioning properly. Remember, **any time you see a status light flashing red, call your healthcare provider immediately, as you may need a replacement dose.**

B **Grab the edge of the adhesive pad. Slowly peel off the on-body injector.**

- **If medicine has leaked or the adhesive is noticeably wet (saturated), contact your healthcare provider immediately as you may not have received your full dose and you may need a replacement dose.**
- Remove any extra adhesive using soap and water.

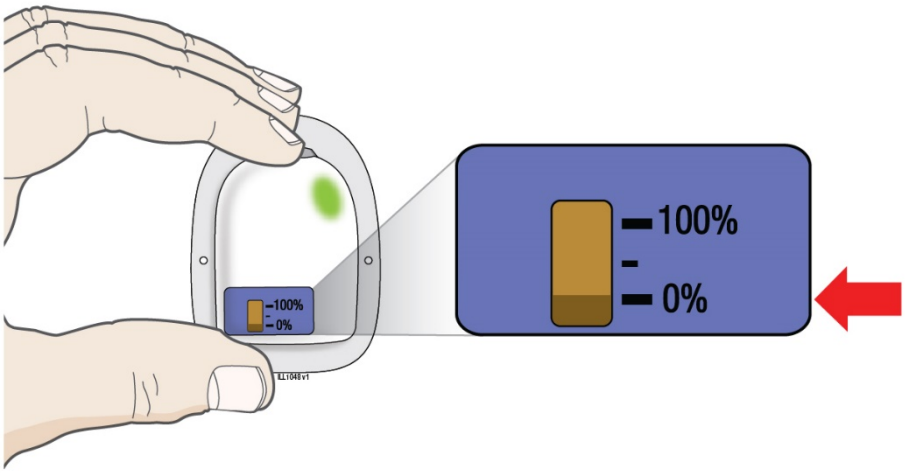


Important: Do not grasp the on-body injector itself to try to pull it off of your body.

Step 4: Finish

STOP **Check to see if your on-body injector is empty.**

- You should see a black line next to the 0% (empty) indicator to confirm you have received a full dose. If the on-body injector is not empty, contact your healthcare provider immediately as you may need a replacement dose.



- Check your status light again. Watch for at least 10 seconds. If the status light is solid green or it has switched off, it is ok.
- If you hear beeping, or when you check the status light and it is flashing red, contact your healthcare provider immediately.
- If there is blood, press a clean cotton ball or gauze pad on the application site. Apply a plaster if needed.
- Contact your healthcare provider immediately if you experience persistent or worsening redness or tenderness at the application site, as this can be a sign of infection.
- After your on-body injector removal, place the on-body injector in a sharps disposal container whether the needle is exposed or not. If the needle is exposed, contact your healthcare provider immediately.

A **Record the end status of your on-body injector.**

Mark the box of the description that represents your on-body injector after it has been used.

- ☐ Status light is solid green or the status light has switched off. This means that the delivery is complete.
- ☐ The on-body injector leaked, contact your healthcare provider immediately as you may need a replacement dose.
- ☐ Status light is red, contact your healthcare provider immediately as you may need a replacement dose.

B **Properly dispose of the on-body injector.**

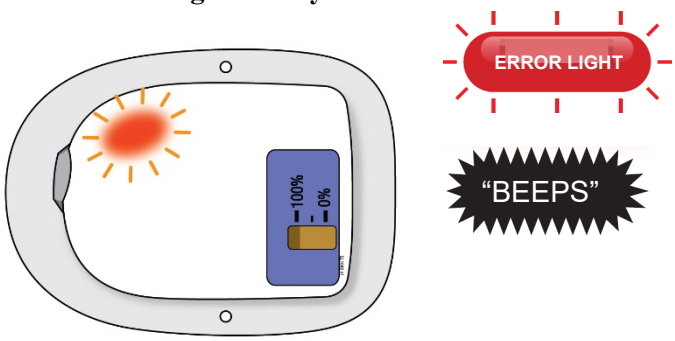
- The on-body injector contains batteries, electronics, and a needle. Dispose of it in a sharps disposal container as instructed by your healthcare provider or in accordance with local requirements.
- Keep children away from the used on-body injector.

Attention!

What to do if you hear beeping or when you look at the status light and it is flashing red.

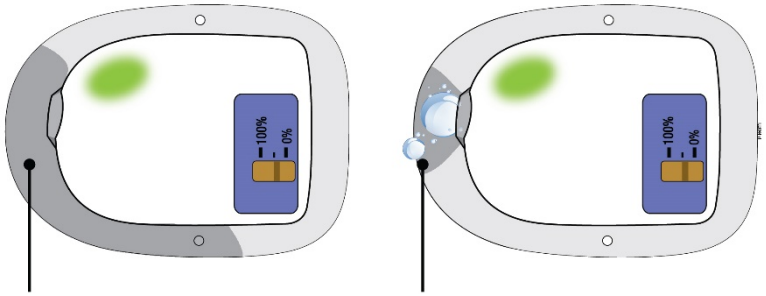
If the status light is flashing red, you may not have received your full dose and you may need a replacement dose. Contact your healthcare provider immediately.

Not working correctly



What to do if the on-body injector adhesive becomes noticeably wet (saturated) with fluid, or you see dripping.

Not working correctly **Not working correctly**



Noticeably wet (saturated) adhesive Dripping fluid from on-body injector

- If the adhesive becomes saturated with fluid, or you see dripping, your medicine may have leaked out.
- Even with a leak, the status light may remain green and the fill indicator may be at 0% (empty).
- Contact your healthcare provider immediately as you may not have received your full dose and may need a replacement dose.

Note: It is normal to see a few drops of fluid at the application site, but not normal to see a noticeably wet (saturated) adhesive.

What do I do if the on-body injector comes off before the full dose is delivered?

Contact your healthcare provider immediately if the on-body injector comes away from your skin at any time before your full dose has been delivered. There is a small cannula which sits just under your skin. If the on-body injector has been knocked or moved, this may become dislodged. If this happens, you may not receive your dose of Neulasta. Do not reapply it.

What if there is blood at my application site after the on-body injector has been removed?

If there is blood, press a clean cotton ball or gauze pad on the application site. Apply a plaster if needed.

What if my application site is red or tender after on-body injector removal?

Contact your healthcare provider immediately if you experience persistent or worsening redness or tenderness at the application site, as this can be a sign of infection.