

Package leaflet: Information for the user

Pelmeg 6 mg solution for injection in pre-filled syringe pegfilgrastim

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.

What is in this leaflet

1. What Pelmeg is and what it is used for
2. What you need to know before you use Pelmeg
3. How to use Pelmeg
4. Possible side effects
5. How to store Pelmeg
6. Contents of the pack and other information

1. What Pelmeg is and what it is used for

Pelmeg 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.

Pelmeg is used in adult patients 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 Pelmeg 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 Pelmeg

Do not use Pelmeg if

- you are allergic to pegfilgrastim, filgrastim, *E. coli* derived proteins, or any of the other ingredients of this medicine.

Warnings and precautions

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

- 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 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 tirednessThese could be symptoms of 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 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.
- Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body) 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 these symptoms.

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

Severe skin reactions (Stevens-Johnson syndrome) have been reported with the use of Pelmeg. Stop using Pelmeg 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 Pelmeg, 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 Pelmeg

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. Pelmeg 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.

If you become pregnant during Pelmeg treatment, please inform your doctor.

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

Driving and using machines

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

Pelmeg contains sorbitol (E 420) and sodium acetate

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 (23 mg) sodium per 6 mg dose, that is to say essentially 'sodium-free'.

3. How to use Pelmeg

Pelmeg is for use in adults aged 18 and over.

Always use Pelmeg 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) using a pre-filled syringe and it should be given at least 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

Do not shake Pelmeg vigorously as this may affect its activity.

Injecting Pelmeg yourself

Your doctor may decide that it would be more convenient for you to inject Pelmeg yourself. Your doctor or nurse will show you how to inject yourself. Do not try to inject yourself if you have not been trained.

For further instructions on how to inject yourself with Pelmeg, please read the section at the end of this leaflet.

If you use more Pelmeg than you should

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

If you forget to inject Pelmeg

If you have forgotten a dose of Pelmeg, you should contact your doctor to discuss when you should inject the next 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):

- 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.

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).

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

- Inflammation of the 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 Pelmeg 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 via the the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pelmeg

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).

You may take Pelmeg out of the refrigerator and keep it at room temperature (not above 30 °C) for no longer than 4 days. Once a syringe has been removed from the refrigerator and has reached room temperature (not above 30 °C) it must either be used within 4 days or disposed of.

Do not freeze. Pelmeg may be used if it is accidentally frozen for two periods of less than 72 hours each.

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 Pelmeg 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 (E 420), polysorbate 20 and water for injections. See section 2.

What Pelmeg looks like and contents of the pack

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

Each pack contains 1 pre-filled glass syringe with an attached stainless steel needle and needle cap. The syringe is provided with an automatic needle guard.

Marketing Authorisation Holder

Mundipharma Biologics S.L.
Calle García Ximénez, nº3-1º
31002 Pamplona (Navarra)
Spain

Manufacturer

PharmaKorell GmbH
Marie-Curie-Strasse 8
D-79539 Lörrach
Germany

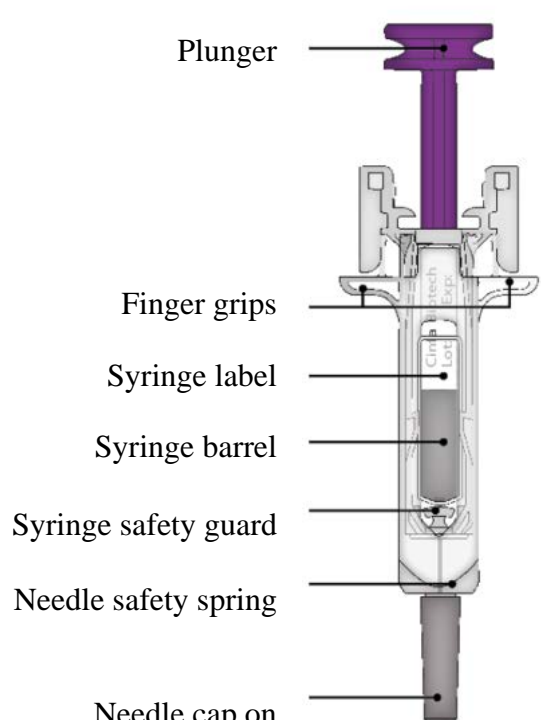
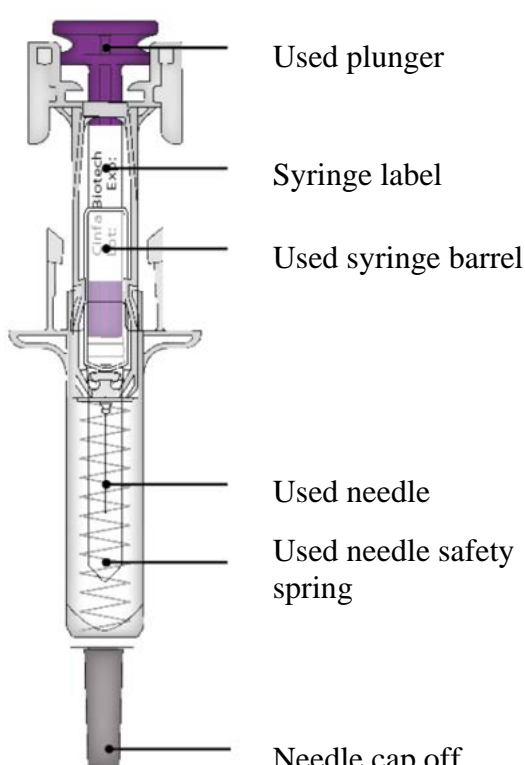
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
 NAPP Pharmaceuticals Limited
 Tel: +44(0) 1223 424444

This leaflet was last revised in 11/2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

Instructions for use	
Guide to parts	
Before use	After use
<p>Before use</p> 	<p>After use</p> 

Important

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

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Pelmeg is given as an injection into the tissue just under the skin (subcutaneous injection).
- ✗ **Do not** remove the needle cap from the pre-filled syringe until you are ready to inject.
- ✗ **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.
- ✗ **Do not** attempt to activate the pre-filled syringe prior to injection.
- ✗ **Do not** attempt to remove the clear pre-filled syringe safety guard from the pre-filled syringe
- ✗ **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.

Step 1: Prepare

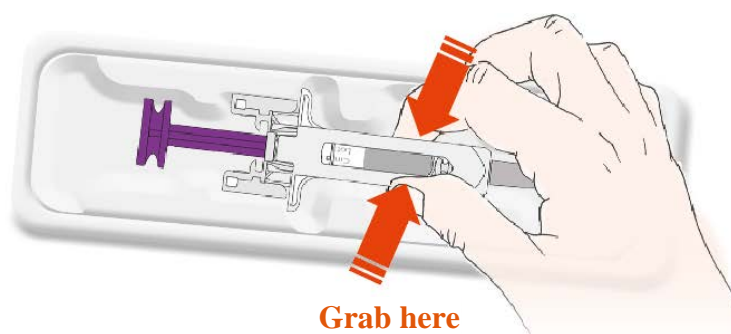
- A Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container (not included).

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.

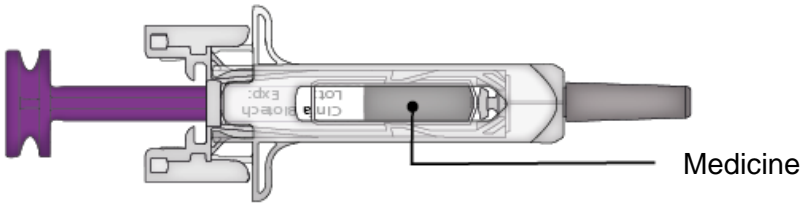
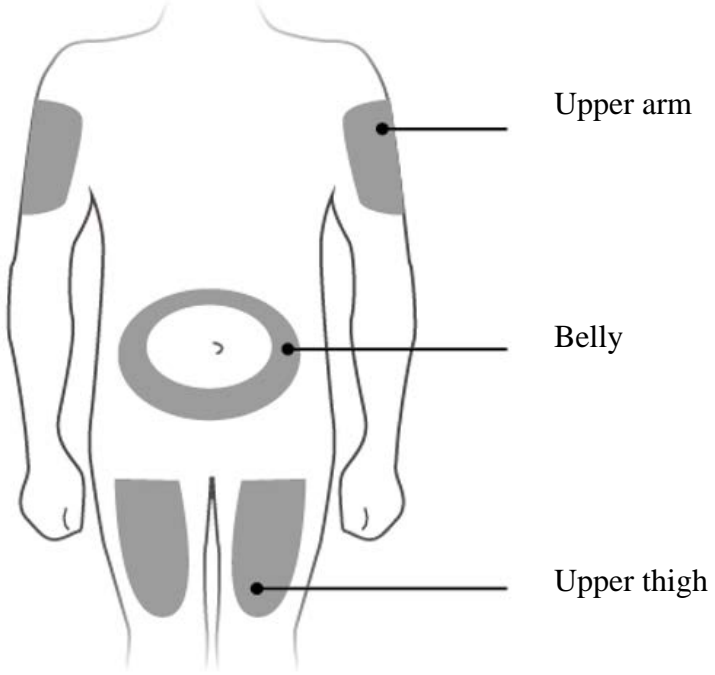

- ✗ **Do not** try to warm the syringe by using a heat source such as hot water or microwave.
- ✗ **Do not** leave the pre-filled syringe exposed to direct sunlight.
- ✗ **Do not** shake the pre-filled syringe.
- ✗ **Keep pre-filled syringes out of the sight and reach of children.**

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



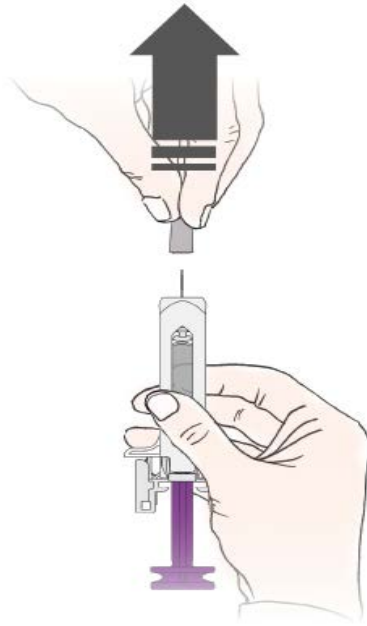
For safety reasons:

- ✗ **Do not** grasp the plunger.
- ✗ **Do not** grasp the needle cap.

C	Inspect the medicine and pre-filled syringe.
	
<p>✘ Do not use the pre-filled syringe if:</p> <ul style="list-style-type: none"> • 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 needle cap is missing or not securely attached. • The expiry date printed on the label has passed the last day of the month shown. <p>In all cases, call your doctor or healthcare provider.</p>	
Step 2: Get ready	
A	Wash your hands thoroughly. Prepare and clean your injection site.
	
<p>You can use:</p> <ul style="list-style-type: none"> • 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). <p>Clean the injection site with an alcohol wipe. Let your skin dry.</p> <p>✘ Do not touch the injection site before injecting.</p> <p> Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.</p>	

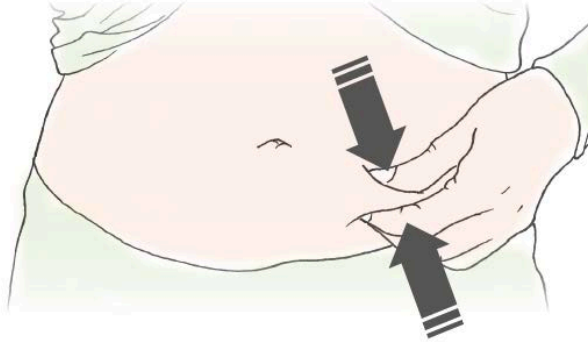
B

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



C

Pinch your injection site to create a firm surface.



Its important to keep the skin pinched when injecting.

Step 3: Inject

A

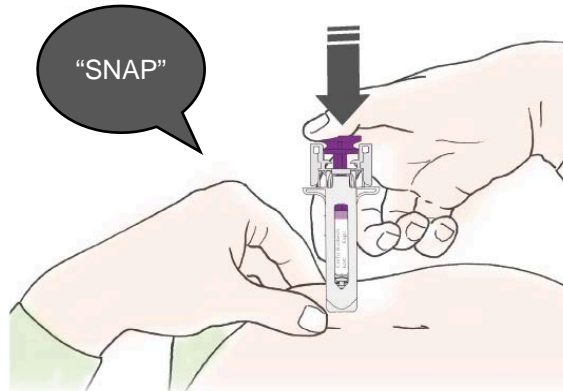
Hold the pinch. INSERT the needle into skin.



✘

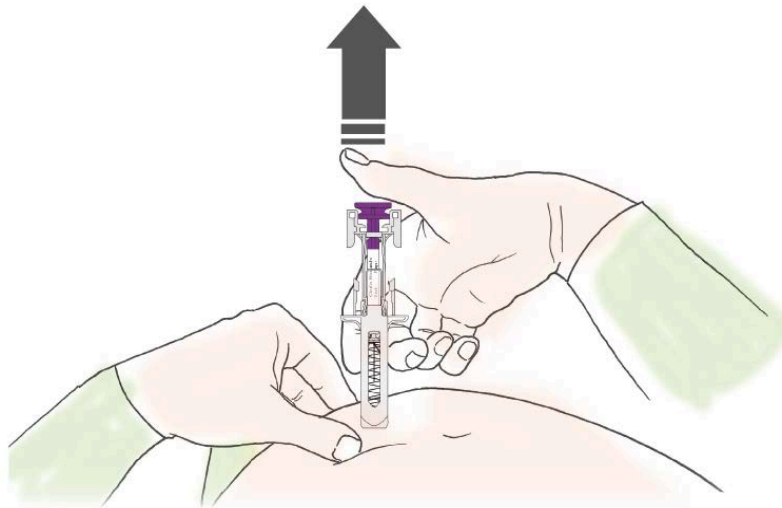
Do not touch the cleaned area of the skin.

B PUSH the plunger with slow and constant pressure until you feel or hear a “snap”. Push all the way down through the snap.



It is important to push down through the “snap” to deliver your full dose.

C RELEASE your thumb. Then LIFT the syringe off skin.



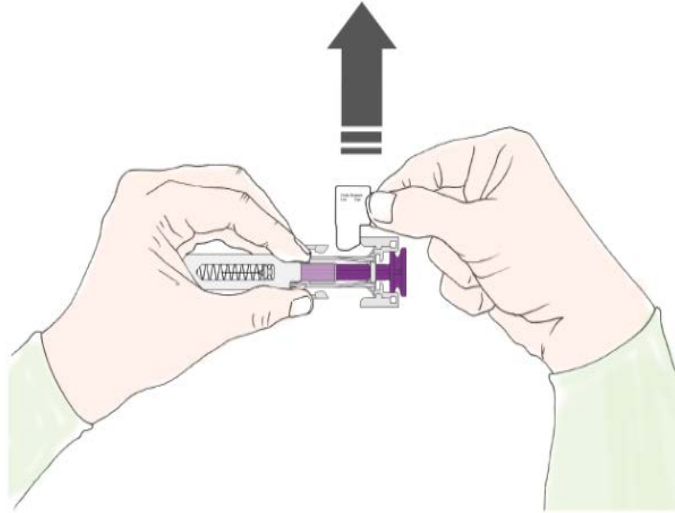
After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.

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

Healthcare professionals only

The trade name and the batch number of the administered product should be clearly recorded in the patient file.

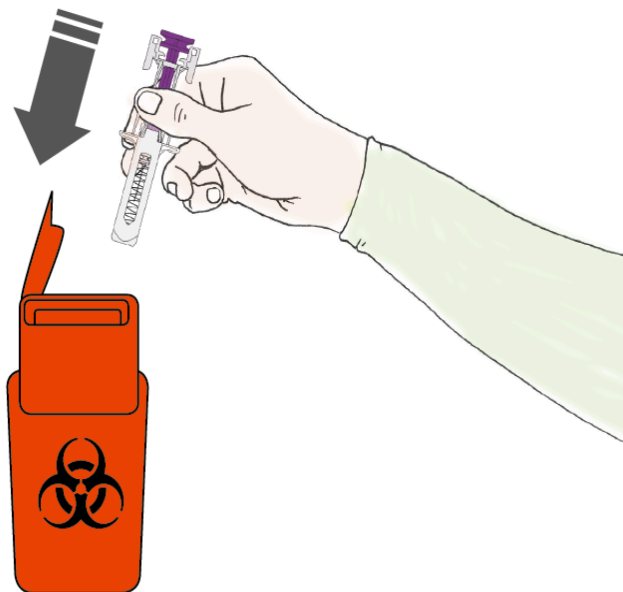
Remove and save the pre-filled syringe label



Turn the plunger to move the label into a position where you can remove the syringe label

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.

- ✗ **Do not** reuse the pre-filled syringe.
- ✗ **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. **Do not** rub the injection site. Apply a plaster if needed.