

Package leaflet: Information for the user
Dyrupeg® 6 mg solution for injection in a 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 instructions on how to report side effects.

Read all of this leaflet carefully before you start using this medicinal product 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 signs 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 Dyrupeg is and what it is used for
 2. What you need to know before you use Dyrupeg
 3. How to use Dyrupeg
 4. Possible side effects
 5. How to store Dyrupeg
 6. Contents of the pack and other information

1. What Dyrupeg is and what it is used for

Dyrupeg 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.

Dyrupeg 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 (medicinal product that destroy rapidly growing cells), in adults aged 18 and over. 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 Dyrupeg to encourage your bone marrow (part of the bone that makes blood cells) to produce more white blood cells that help your body fight infection.

2. What you need to know before you use Dyrupeg

Do not use Dyrupeg

- if you are allergic to pegfilgrastim, filgrastim, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

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

- 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 a 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 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. Dyrupeg 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 severe allergic reaction.
- Inflammation of the aorta (the large blood vessel that 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 Dyrupeg can harm the tiny filters inside your kidneys (glomerulonephritis).

Severe skin reactions (Stevens-Johnson syndrome) have been reported with the use of pegfilgrastim. Stop using Dyrupeg 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 Dyrupeg 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 that neutralize pegfilgrastim’s activity.

Children and adolescents

Dyrupeg is not recommended for use in children and adolescents due to insufficient data on safety and effectiveness.

Other medicines and Dyrupeg

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Dyrupeg has not been tested in pregnant women. Therefore, your doctor may decide that you should not use this medicine. It is important to tell your doctor if you:

- are pregnant;
- think you may be pregnant; or
- are you planning to have a baby

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

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

Driving and using machines

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

Dyrupeg contains sorbitol (E420)

This medicine contains 30 mg sorbitol in each pre-filled syringe, which is equivalent to 50 mg/mL.

Dyrupeg contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per pre-filled syringe, that is to say, essentially ‘sodium-free.’

Dyrupeg contains polysorbate 20 (E432)

This medicine contains 0.02 mg of polysorbate 20 in each pre-filled syringe. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Dyrupeg

Always use Dyrupeg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. The recommended 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.

Injecting Dyrupeg yourself

Your doctor may decide that it would be more convenient for you to inject Dyrupeg 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 Dyrupeg, please read the section at the end of this leaflet.

Do not shake Dyrupeg vigorously, as this may affect its activity.

If you use more Dyrupeg than you should

If you use more Dyrupeg, then you should contact your doctor, pharmacist, or nurse.

If you forget to inject Dyrupeg

If you are injecting yourself and have forgotten a dose of Dyrupeg, you should contact your doctor to discuss when you should inject the next dose. If you have any further questions about the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

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

Please tell your doctor immediately if you have any of the following or a combination of the following side effects:

- Swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling, feeling fullness, and a general feeling of tiredness. These symptoms generally develop in a rapid fashion.

These could be symptoms of an uncommon condition (which may affect up to 1 in 100 people) 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.
- 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-colored, 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 the aorta (the large blood vessel that 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 Dyrupeg 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.

United Kingdom

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 Dyrupeg

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 refrigerator (2 °C – 8 °C).

You may take Dyrupeg out of the refrigerator and keep it at room temperature (not above 25 °C) for no longer than three days. Once a syringe has been removed from the refrigerator and has reached room temperature (not above 25 °C), it must be used within three days.

Do not freeze. Dyrupeg may be used if it is accidentally frozen for a single period of less than 72 hours.

Keep the pre-filled syringe in the outer carton in order to protect it from light.

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

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

6. Contents of the pack and other information

What Dyrupeg 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 (E432) and water for injections. See section 2, “Dyrupeg contains sorbitol (E420), polysorbate 20 (E432), and sodium.”

What Dyrupeg looks like and the contents of the pack

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

Each pack contains one glass pre-filled syringe with a rubber plunger stopper, a plunger rod, an attached stainless-steel needle, and a needle cap. The syringe is provided in a blister tray.

The syringes are provided with an automatic needle guard.

Marketing Authorization Holder

CuraTeQ Biologics s.r.o.

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19600, Prague, Czech Republic.

Manufacturer

APL Swift Services Malta Ltd.

HF26, Hal Far Industrial Estate,

Qasam Industrijali Hal Far,

Birzebbugia, BBG 3000, Malta.

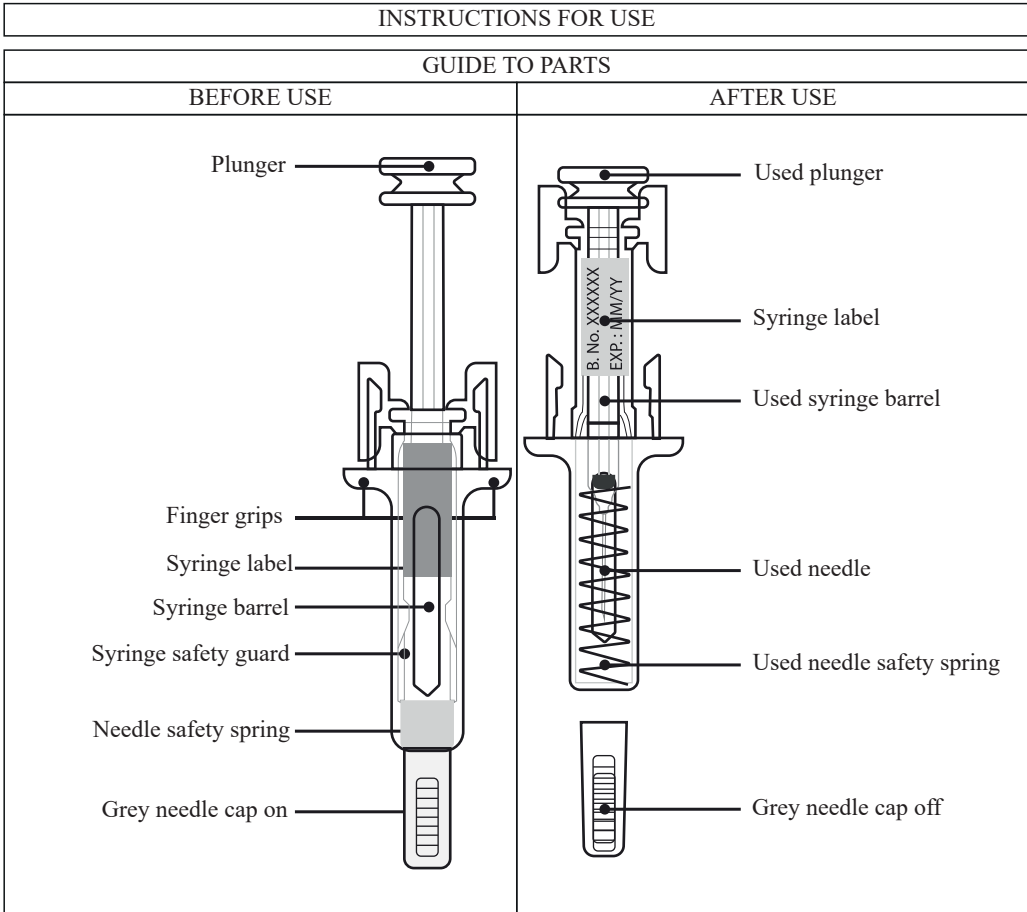
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Caution: Avoid contact with the plunger and needle during the preparation of the syringe. The safety device is normally activated by pressure from the plunger on the syringe.

IMPORTANT

Before you use a Dyrupeg pre-filled syringe with an 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.
- Dyrupeg 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.

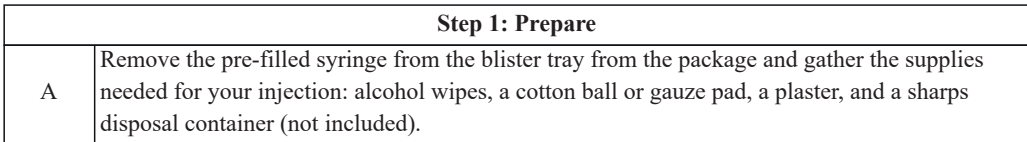
Do not use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.

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.



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.

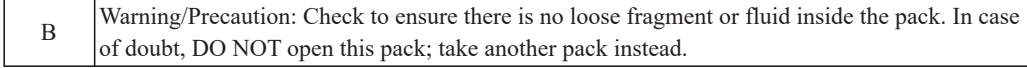
On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

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.

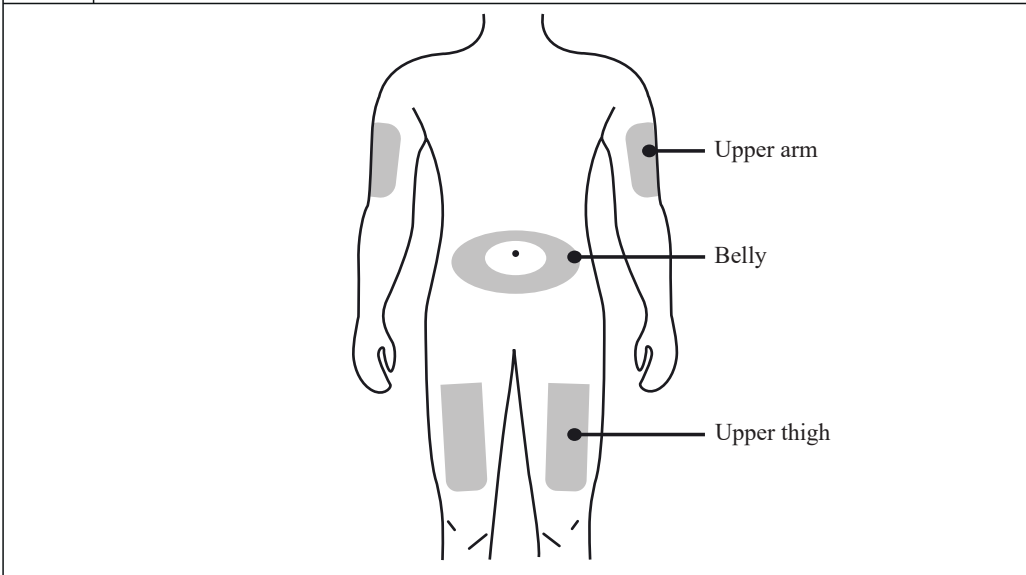
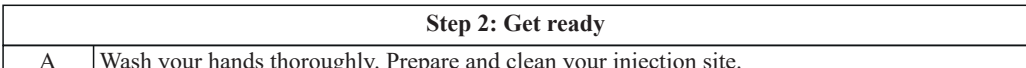
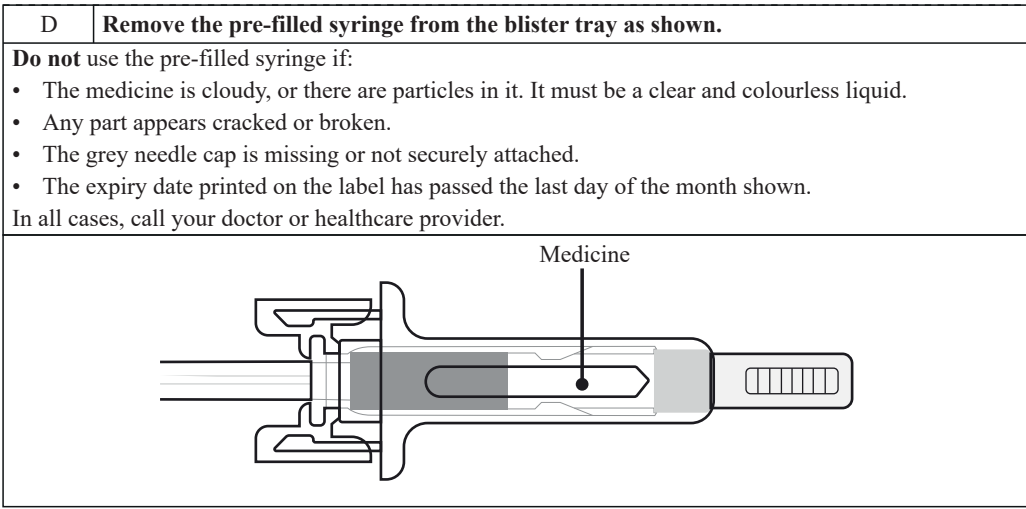
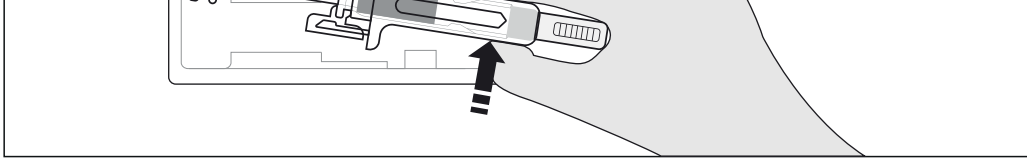
Do not shake the pre-filled syringe.

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



Warning/Precaution: Check to ensure there is no loose fragment or fluid inside the pack. In case of doubt, **DO NOT** open this pack; take another pack instead.

Warning/Precaution: **DO NOT** lift the product by the plunger or needle cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the blister tray.

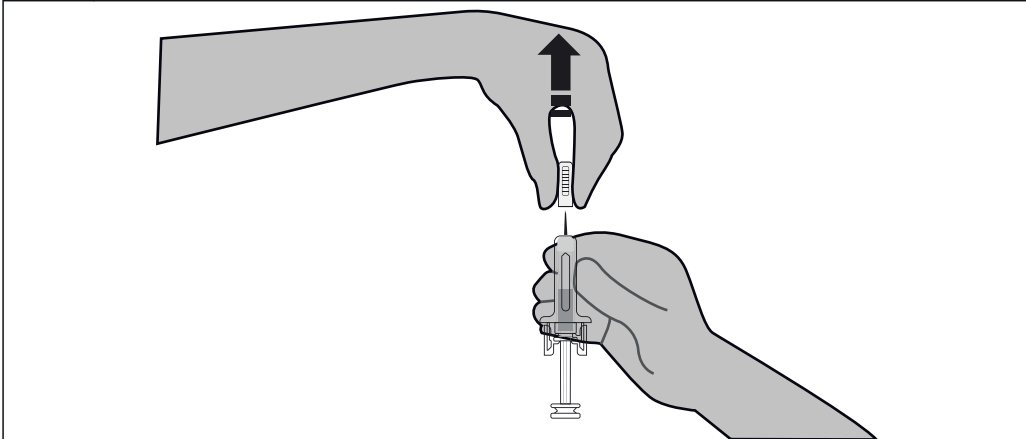


- You can use:
- Upper part of your thigh
 - Belly, except for a 5 cm (2-inch) area right around your belly button.
 - Outer area of the upper arm (only if someone else is giving you the injection).

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

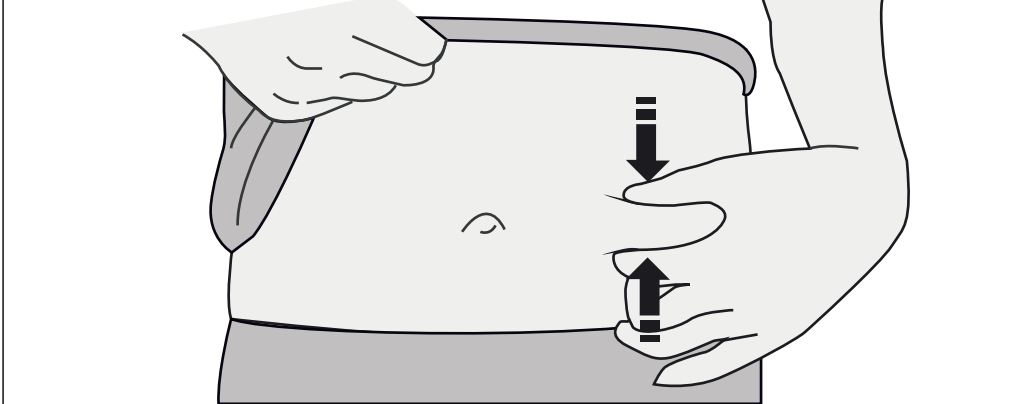
Do not touch the injection site before injecting.
Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

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

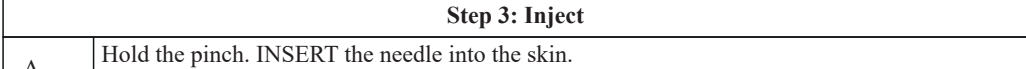


Warning/Precaution: **DO NOT** twist the needle cover or touch the needle or plunger. Pull the needle cover straight off as shown and handle the guard to avoid injuries or bending

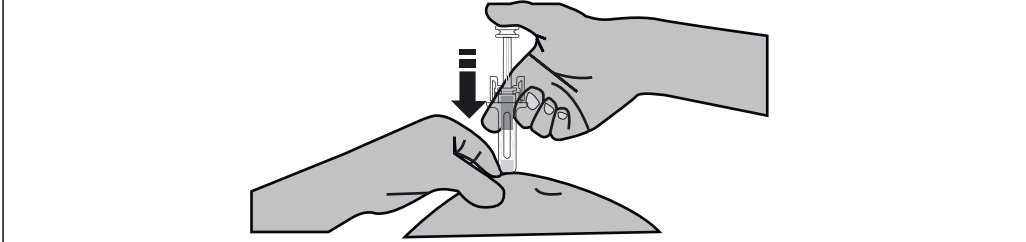
C Pinch your injection site to create a firm surface.



Warning/Precaution: It is important to keep the skin pinched when injecting

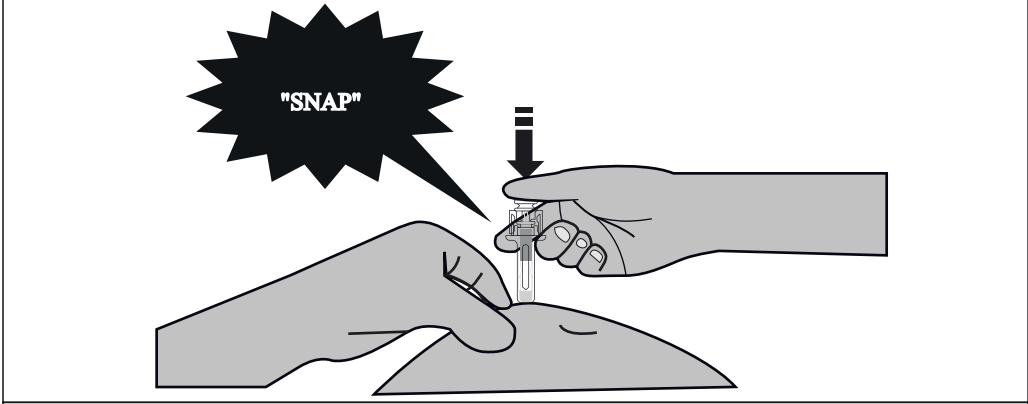


A Hold the pinch. INSERT the needle into the skin.



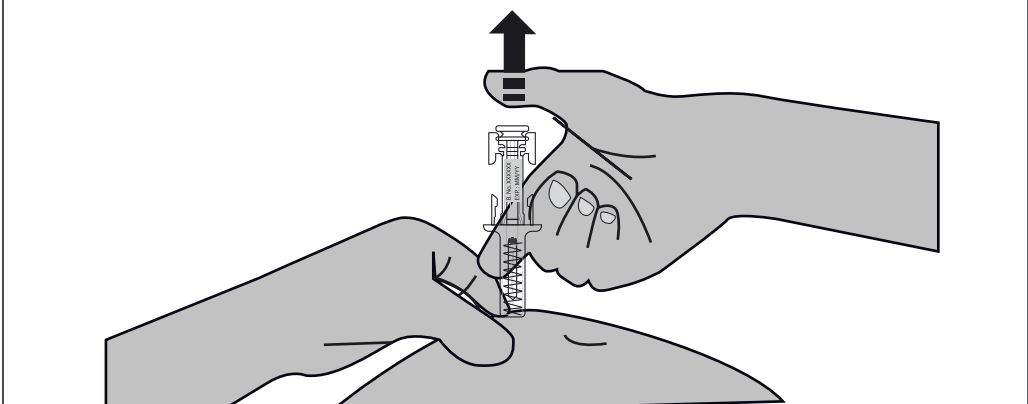
Warning/Precaution: **Do not** touch the cleaned area of the skin.

B PUSH the plunger with slow and constant pressure until you feel or hear a “snap.” Push all the way down through the snap. The entire dose has to be administered to trigger the guard.



Precaution: It is important to push down through the “snap” to deliver the complete dose

C RELEASE your thumb. Then, LIFT the syringe of the skin.



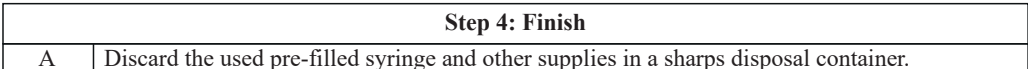
After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.

Warning/Precaution: **Do not** put the needle cap back on used pre-filled syringes.

If the guard is not activated or only partially activated, discard the product - without replacing the needle cover.

Healthcare professionals only

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



medicine should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicine that are no longer required. These measures will help to protect the environment. Keep the syringe and sharps disposal container out of sight and out of reach of children.

Warnings:

Do not reuse the pre-filled syringe.

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.