

Package leaflet: Information for the user

EVENTITY 105 mg solution for injection in pre-filled pen romosozumab

▼ 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You will be given a patient alert card, which contains important safety information you need to be aware of before and during your treatment with EVENTITY.

What is in this leaflet

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

1. What EVENTITY is and what it is used for

What EVENTITY is

EVENTITY contains the active substance romosozumab, a medicine that helps to make the bones stronger, and reduce the risk of broken bones.

What EVENTITY is used for

EVENTITY is used to treat severe osteoporosis in women after the menopause who are at high risk of broken bone (fracture).

Osteoporosis is a disease that causes your bones to become thin and fragile. Many patients with osteoporosis have no symptoms, but they may be at increased risk of fractures.

How EVENTITY works

EVENTITY is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognize and attach to specific proteins in the body. EVENTITY attaches to a protein called sclerostin. By attaching to and blocking the activity of sclerostin, EVENTITY:

- helps to form new bone, and
- slows down the loss of existing bone.

This makes the bones stronger, and lowers the risk of fractures.

2. What you need to know before you use EVENITY

Do not use EVENITY if

- you are allergic to romosozumab or any of the other ingredients of this medicine (listed in section 6);
- you have low levels of calcium in the blood (hypocalcaemia). Your doctor will be able to tell you if your levels are too low;
- you have a history of heart attack or stroke.

Do not use EVENITY if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using EVENITY.

Warnings and precautions

Talk to your doctor or pharmacist and discuss your medical history before using EVENITY.

Heart attack and stroke

Heart attack and stroke have been reported in people receiving EVENITY.

Seek medical attention straight away if you get:

- chest pain, shortness of breath;
- headache, numbness, or weakness in your face, arms, or legs, difficulty talking, changes in vision, loss of balance.

Your doctor will carefully evaluate the risk of cardiovascular problems before he/she lets you start treatment with EVENITY. Tell your doctor if you know that you have an increased risk of cardiovascular problems such as established cardiovascular disease, high blood pressure, high blood fat levels, diabetes, smoking or kidney problems.

Low levels of calcium in the blood

EVENITY may cause low levels of calcium in your blood.

Tell your doctor if you notice:

- spasms, twitches, or cramps in your muscles;
- numbness or tingling in your fingers, toes or around your mouth.

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood before you start your treatment and while you take EVENITY. Take calcium and vitamin D as your doctor tells you to.

Tell your doctor if you have or have ever had severe kidney problems, kidney failure or have needed dialysis as this may increase your risk of getting low blood calcium if you do not take calcium supplements.

Serious allergic reactions

Serious allergic reactions can happen to people who use EVENITY.

Seek medical attention straight away if you get:

- swelling of the face, mouth, throat, hands, feet, ankles, lower legs (angioedema), or hives;
- acute skin eruption showing multiple round, red/pink spots with a blistering or crusting centre (erythema multiforme);
- difficulty in swallowing or breathing.

Problems with your mouth, teeth or jaw

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1,000 people) in patients receiving EVENITY. ONJ can also occur after stopping treatment. It is important to try to prevent ONJ developing, as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, there are some precautions you should take.

Before receiving EVENITY, tell your doctor or nurse if you:

- have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction;
- do not receive routine dental care or have not had a dental check-up for a long time;
- are a smoker (as this may increase the risk of dental problems);
- have previously been treated with a bisphosphonate (used to treat or prevent bone disorders, such as osteoporosis);
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone);
- have cancer.

Your doctor may ask you to undergo a dental examination before you start treatment with EVENITY.

While being treated, you should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures, you should make sure these fit properly. If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with EVENITY.

Contact your doctor and dentist immediately if you get any problems with your mouth or teeth such as:

- loose teeth;
- pain or swelling;
- mouth sores that do not heal;
- discharge.

Unusual thigh bone fractures

People who have used EVENITY rarely developed unusual fractures of the thigh bone caused by little or no trauma. These fracture types are often preceded by warning signs of thigh or groin pain for several weeks before the fracture occurs. It is not known whether EVENITY caused these unusual fractures. Tell your doctor or pharmacist if you get any new or unusual pains in your hip, groin or thigh.

Children and adolescents

The use of romosozumab in children and adolescents has not been studied and it is not approved for use in paediatric patients (age <18 years).

Other medicines and EVENITY

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

Pregnancy and breast-feeding

EVENITY is only intended to treat women after menopause.

EVENITY should not be used by women of child-bearing potential, or when pregnant or breast-feeding. It is not known whether EVENITY may harm an unborn or breast-fed child.

Contact your doctor if you have any questions.

Driving and using machines

EVENITY is expected to have no effect or very little effect on the ability to drive and use machines.

EVENITY contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use EVENITY

EVENITY will be initiated and supervised by specialist physicians experienced in the management of osteoporosis. Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The injection should only be given by a person who has been properly trained.

How much to use

- The recommended dose of EVENITY is 210 mg.
- Since one pre-filled pen contains 105 mg of the active substance romosozumab in 1.17 ml of solution (90mg/ml), 2 pre-filled pens must be used for each dose. The second injection must be given immediately after the first one but at a different injection site.
- Do this once every month for 12 months.

How to use

- EVENITY has to be injected under the skin (sub-cutaneous injection).
- EVENITY should be injected in either the stomach area (abdomen) or thigh. The outer area of your upper arm can also be used as an injection site, but only if someone else is giving you the injection.
- If the same injection area is planned to be used for the second injection, a different injection spot should be used.
- EVENITY should not be injected into areas where the skin is tender, bruised, red, or hard.

It is important that you read the **Instructions for Use** for detailed information on how to use the EVENITY pre-filled pen.

Ask your doctor or pharmacist if you have any further questions on the use of the medicine.

If you use more EVENITY than you should

If, by mistake, you have used more EVENITY than you should, contact your doctor or pharmacist.

If you forget to use or cannot take EVENITY at your usual time

If you miss a dose of EVENITY, contact your doctor as soon as possible to schedule another dose. Thereafter, the next dose should be given not earlier than one month after the date of the last dose.

If you stop taking EVENITY

If you are considering stopping EVENITY treatment, please discuss this with your doctor. Your doctor will advise you on how long you should be treated with EVENITY.

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

Discuss with your doctor the need to switch to another osteoporosis treatment after the end of your treatment with EVENITY.

4. Possible side effects

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

Seek medical attention straight away if you get any of the following possible symptoms of **heart attack** or **stroke** (uncommon: may affect up to 1 in 100 people):

- chest pain, shortness of breath;
- headache, numbness, or weakness in your face, arms, or legs, difficulty talking, changes in vision, loss of balance.

Seek medical attention straight away if you get the following symptoms of a **serious allergic reaction** (rare: may affect up to 1 in 1,000 people):

- swelling of the face, mouth, throat, hands, feet, ankles, lower legs (angioedema), or hives;
- acute skin eruption showing multiple round, red/pink spots with a blistering or crusting centre (erythema multiforme);
- difficulty in swallowing or breathing.

Tell your doctor if you notice the following symptoms of **low levels of calcium** in the blood (hypocalcaemia) (uncommon: may affect up to 1 in 100 people):

- spasms, twitches, or cramps in your muscles;
- numbness or tingling in your fingers, toes or around your mouth.

See also section 2 “What you need to know before you use EVENITY”.

Other side effects may include:

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

- Common cold;
- Joint pain.

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

- Rash, inflammation of the skin;
- Headache;
- Sinusitis;
- Neck pain;
- Muscle spasms;
- Redness or pain around the site where the injection was given.

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

- Hives (urticaria);
- Cataract.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: 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 EVENITY

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 label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Once you take the carton containing the pre-filled pens out of the refrigerator for use, you should not put it back into the refrigerator but you can keep it at room temperature (up to 25°C) for up to 30 days. If not used within this period the product should be discarded.

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

Visually check the solution. Do not use it if the solution is discoloured, cloudy, or contains flakes or particles.

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 protect the environment.

6. Contents of the pack and other information

What EVENITY contains

- The active substance is romosozumab. Each pre-filled pen contains 105 mg of romosozumab in 1.17 ml of solution (90mg/ml).
- The other ingredients are calcium acetate, glacial acetic acid, sodium hydroxide (for pH adjustment), sucrose, polysorbate 20 and water for injections. See section 2 “EVENITY contains sodium”

What EVENITY looks like and contents of the pack

EVENITY is a clear to opalescent, colourless to light yellow solution for injection provided in a single use disposable pre-filled pen. The syringe inside the pen is made of plastic with a stainless steel needle.

Pack size of 2 pre-filled pens.

Multipack containing 6 (3 packs of 2) pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom.

Manufacturer

Amgen Europe B.V.,

Minervum 7061,

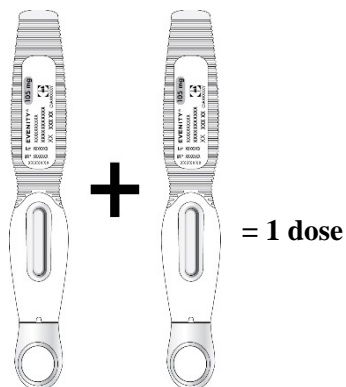
4817 ZK Breda, Netherlands

This leaflet was last revised in September 2021

Please turn over for the Instructions for Use.

INSTRUCTIONS FOR USE FOR THE EVENITY INJECTION BY MEANS OF A PRE-FILLED PEN

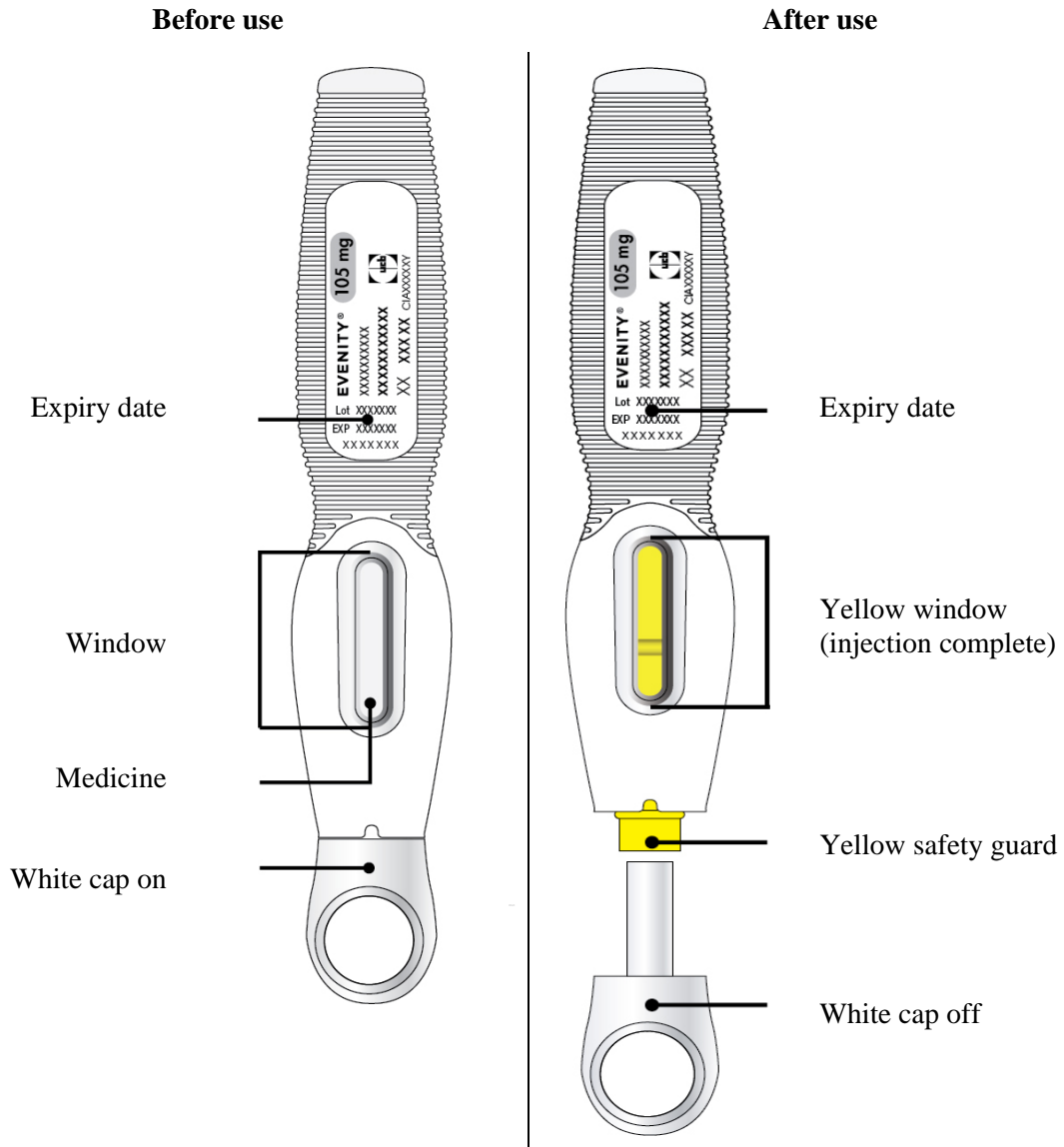
Inject two pre-filled pens one immediately after the other to get a full dose



The following instructions explain how to use the pre-filled pen to inject EVENITY.

- **Please read these instructions carefully and follow them step by step.**
- If you have any questions or you feel unsure about the injection procedure, please contact a doctor or pharmacist.
- It is important to make sure that the injection is only administered by an individual that has been properly trained.
- The pre-filled pen is also referred to as “the medicine”.

Guide to parts: pre-filled pen

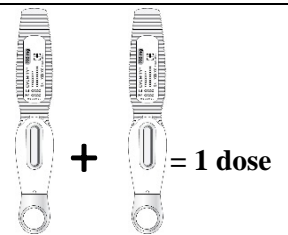


STOP



Read this before the medicine is injected.

Your healthcare provider has prescribed a dose of 210 mg every month: **To receive your full dose, two 105 mg pre-filled pens should be injected, one immediately after the other.**

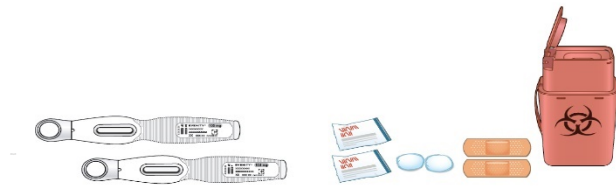


Step 1: Prepare

- A**
- Take the carton containing the two pre-filled pens out of the refrigerator.
 - Your pre-filled pens should be left outside the refrigerator to reach room temperature (up to 25°C) **for at least 30 minutes** before injection (do not warm in any other way). This will make the injection more comfortable.
 - Open the carton and gather all materials you need for the injection (as listed in Step B).
 - Wash your hands thoroughly.
 - Lift the pre-filled pens straight up out of the carton – do not remove the white caps from the pre-filled pens yet.
 - Do not shake the pre-filled pens.
 - Check the medicine through the viewing window. The medicine should be a clear to opalescent, colourless to light yellow solution.
 - Do not use the pre-filled pens if the solution is discoloured, cloudy, or contains flakes or particles.
 - You may see air bubbles. Injecting the solution subcutaneously (under the skin) which contains air bubbles is harmless.
 - Do not use the pre-filled pens if:
 - it has been dropped;
 - the white cap is missing or not securely attached;
 - the seal is missing or broken or if any other part appears cracked or broken.
- In such case, use a new pen and contact your doctor as soon as possible.

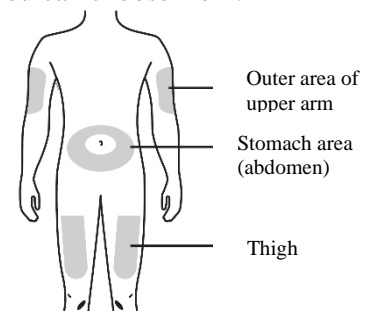
- B** On a clean, well-lit work surface, place:

- two pre-filled pens;
- two alcohol wipes;
- two cotton balls or gauze pads;
- two adhesives bandages;
- special disposal container.

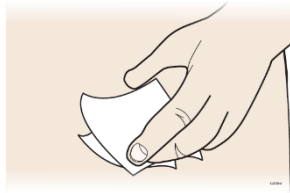


- C** Prepare and clean the skin where you are going to inject the medicine. You can choose from:

- the thighs;
- the stomach area (abdomen), but not the 5 cm area around the belly button;
- the outer area of the upper arm (if someone else is giving you the injection).



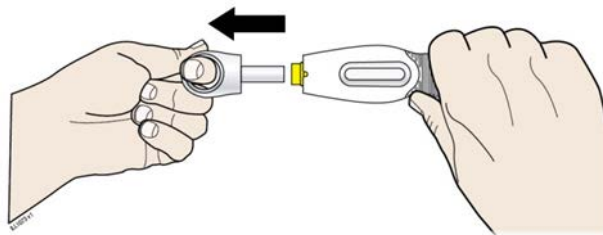
- The second injection should be given on a different site than the one used for the first injection. If you wish to use the same injection site, make sure it is not the exact same injection spot.
- Do not inject into areas where the skin is tender, bruised, red, hard, has scars, or stretch marks, or has raised thick, red, or scaly skin patches or lesions.
- Clean the area you are going to inject with an alcohol wipe. Let the skin dry before the injection.



- Do not touch this area again before injecting.

Step 2: Get ready

- D**
- Pull the white cap straight off just before the injection.
 - Once the cap is removed, the injection must be given within 5 minutes. There is no need to rush the injection - 5 minutes is enough time.

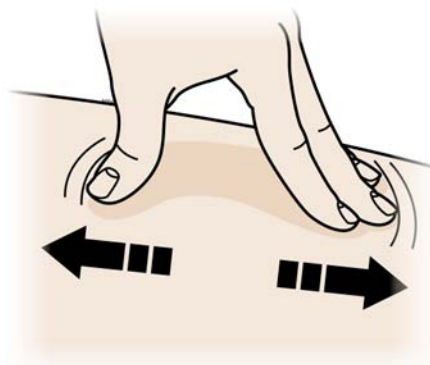


- Do not twist or bend the white cap.
- Discard the white cap in the special disposal container. Do not place the white cap back onto the pre-filled pen.
- Although hidden from view, the needle tip is now uncovered. Do not try to touch the needle as it could activate the pre-filled pen. It is normal to see a drop of liquid at the end of the needle (inside the yellow safety guard).

- E** Stretch or pinch the injection site to create a firm surface.

Stretch method

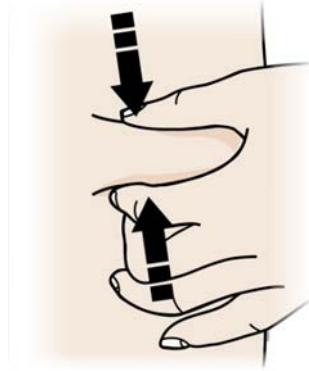
- Stretch the skin firmly by moving thumb and fingers in opposite directions, to create an area about 5 cm wide.



OR

Pinch method

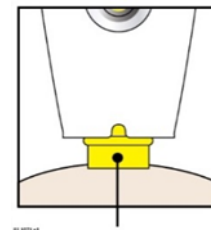
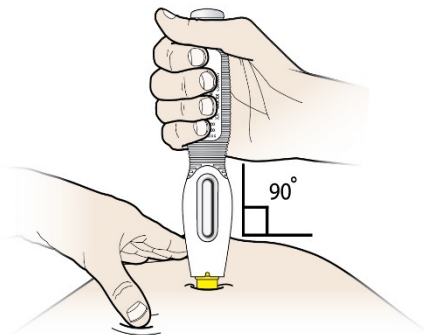
- Pinch the skin firmly between thumb and fingers, to create an area about 5 cm wide.



- **Important:** Keep the skin stretched or pinched while injecting.

Step 3: Inject

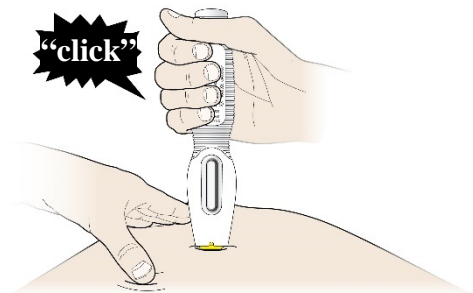
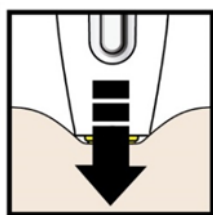
- F**
- **Important:** The pre-filled pen should not be pushed down until the actual injection is ready to be performed.
 - The stretch or pinch should be held. With the other hand, the pre-filled pen's yellow safety guard should be placed down on the area of the skin that previously has been cleaned (the "injection site") at a 90° degree angle.



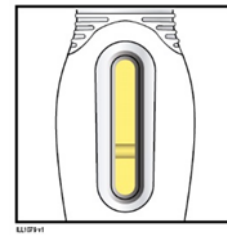
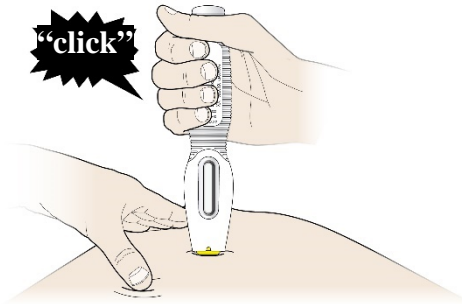
Yellow safety guard

- G**
- The pre-filled pen should be firmly pushed down onto the skin until the yellow safety guard stops moving. When you hear or feel a click, the injection will begin.
- H**
- **Keep pushing down on the skin.** The injection could take about 15 seconds.
 - When the injection is complete, the viewing window will turn fully yellow and you may also hear or feel a second click.

Push down



15 seconds



Window turns fully yellow when injection is complete.

- The used pre-filled pen may now be removed by carefully pulling it straight up from the skin.
- **Important:** When you remove the pre-filled pen, if the window has not turned fully yellow, or if it looks like the medicine is still injecting, this means the full dose has not been delivered. Your healthcare provider should be informed as soon as possible.
- After removing the pre-filled pen from the skin, the needle will be automatically covered. Do not try to touch the needle.

Step 4: Dispose

- I • Discard the entire used pre-filled pen and the white cap in a special container straight away after use.



- Do not throw away (dispose of) the pre-filled pen in the household waste.
- Do not re-use the pre-filled pen.
- **Important:** Always keep the special disposal container out of the sight and reach of children.

Step 5: Examine the injection site

- J If there is blood, use a cotton ball or a piece of gauze and apply light pressure over the injection site for a few seconds. Do not rub the injection site. The injection site can be covered with a small adhesive bandage, if necessary.

Step 6: Repeat for the second injection to get the full dose

- K** Repeat all steps starting from step C with the second pre-filled pen to inject the full dose. The second injection should be given on a different site than the one used for the first injection. If you wish to use the same injection site, make sure it is not the exact same injection spot.

