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STELARA®

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STELARA®

Package leaflet: Information for the user

STELARA® 45 mg
solution for injection in pre-filled pen

ustekinumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This leaflet has been written for the person taking the medicine.
- 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.

What is in this leaflet

1 What Stelara is and what it is used for

What Stelara is
Stelara contains the active substance 'ustekinumab', a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

Stelara belongs to a group of medicines called 'immunosuppressants'. These medicines work by weakening part of the immune system.

What Stelara is used for
Stelara administered using the pre-filled pen is used to treat the following inflammatory diseases:
- Plaque psoriasis - in adults
- Psoriatic arthritis - in adults
- Moderate to severe Crohn's disease - in adults
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis
Plaque psoriasis is a skin condition that causes inflammation affecting the skin and nails. Stelara will reduce the inflammation and other signs of the disease.

Stelara administered using the pre-filled pen is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, or where these treatments did not work.

Psoriatic arthritis
Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given Stelara to:
- Reduce the signs and symptoms of your disease.
- Improve your physical function.
- Slow down the damage to your joints.

Crohn's disease
Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Stelara to reduce the signs and symptoms of your disease.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Stelara to reduce the signs and symptoms of your disease.

2 What you need to know before you use Stelara

Do not use Stelara
- **If you are allergic to ustekinumab** or any of the other ingredients of this medicine (listed in section 6).
- **If you have an active infection** which your doctor thinks is important.

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

Warnings and precautions
Talk to your doctor or pharmacist before using Stelara. Your doctor will check how well you are before each treatment. Make sure you tell your doctor about any illness you have before each treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have Stelara. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for serious side effects
Stelara can cause serious side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking Stelara. See 'Serious side effects' in section 4 for a full list of these side effects.

Before you use Stelara tell your doctor:
- **If you ever had an allergic reaction to Stelara**. Ask your doctor if you are not sure.
- **If you have ever had any type of cancer** – this is because immunosuppressants like Stelara weaken part of the immune system. This may increase the risk of cancer.
- **If you have been treated for psoriasis with other biologic medicines (a medicine produced from a biological source and usually given by injection)** – the risk of cancer may be higher.
- **If you have or have had a recent infection.**
- **If you have any new or changing lesions** within psoriasis areas or on normal skin.
- **If you have ever had an allergic reaction to latex or Stelara injection** – the container of this medicinal product contains latex rubber, which may cause severe allergic reactions in people who are sensitive to latex. See 'Look out for serious side effects' in section 4 for the signs of an allergic reaction.
- **If you are having any other treatment for psoriasis and/or psoriatic arthritis** – such as another immunosuppressant or phototherapy (when your body is treated with a type of ultraviolet (UV) light). These treatments may also weaken part of the immune system. Using these therapies together with Stelara has not been studied. However it is possible it may increase the chance of diseases related to a weaker immune system.
- **If you are having or have ever had injections to treat allergies** – it is not known if Stelara may affect these.
- **If you are 65 years of age or over** – you may be more likely to get infections.

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

Some patients have experienced lupus-like reactions including skin lupus or lupus-like syndrome during treatment with ustekinumab. Talk to your doctor right away if you experience a red, raised, scaly rash sometimes with a darker border, in areas of the skin that are exposed to the sun or with joint pains.

Heart attack and strokes
Heart attack and strokes have been observed in a study in patients with psoriasis treated with Stelara. Your doctor will regularly check your risk factors for heart disease and stroke in order to ensure that they are appropriately treated. Seek medical attention right away if you develop chest pain, weakness or abnormal sensation on one side of your body, facial droop, or speech or visual abnormalities.

Children and adolescents
The Stelara pre-filled pen is not recommended for use in children and adolescents under 18 years of age with psoriasis because it has not been studied in this age group. The pre-filled syringe or vial should be used instead for children 6 years of age and older and adolescents with psoriasis.

Stelara is not recommended for use in children and adolescents under 18 years of age with psoriatic arthritis, Crohn's disease, or ulcerative colitis because it has not been studied in this age group.

Other medicines, vaccines and Stelara
Tell your doctor or pharmacist:
- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Stelara.
- If you received Stelara while pregnant, tell your baby's doctor about your Stelara treatment before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis). Live vaccines are not recommended for your baby in the first twelve months after birth if you received Stelara during the pregnancy unless your baby's doctor recommends otherwise.

Pregnancy and breast-feeding
- It is preferable to avoid the use of Stelara in pregnancy. The effects of Stelara in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Stelara and for at least 15 weeks after the last Stelara treatment.
- Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- Stelara can pass across the placenta to the unborn baby. If you received Stelara during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals if you received Stelara during your pregnancy before the baby receives any vaccine. Live vaccines such as the BCG vaccine (used to prevent tuberculosis) are not recommended for your baby in the first twelve months after birth if you received Stelara during the pregnancy unless your baby's doctor recommends otherwise.
- Ustekinumab may pass into breast milk in very small amounts. Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you should breast-feed or use Stelara - do not do both.

Driving and using machines
Stelara has no or negligible influence on the ability to drive and use machines.

3 How to use Stelara

Stelara is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Stelara is intended.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Talk to your doctor about when you will have your injections and follow-up appointments.

How much Stelara is given
Your doctor will decide how much Stelara you need to use and for how long.

Adults aged 18 years or older
Psoriasis or Psoriatic Arthritis
- The recommended starting dose is 45 mg Stelara. Patients who weigh more than 100 kilograms (kg) may start on a dose of 90 mg instead of 45 mg.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the starting dose.

Crohn's disease or Ulcerative Colitis
- During treatment, the first dose of approximately 6 mg/kg Stelara will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg Stelara after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg Stelara may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

How Stelara is given
- Stelara is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject Stelara.
- However, you and your doctor may decide that you may inject Stelara yourself. In this case you will get training on how to inject Stelara yourself.
- For instructions on how to inject Stelara, see 'Instructions for administration' at the end of this leaflet.

Talk to your doctor if you have any questions about giving yourself an injection.

If you use more Stelara than you should
If you have used or been given too much Stelara, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to use Stelara
If you forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop using Stelara
It is not dangerous to stop using Stelara. However, if you stop, your symptoms may come back.

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

4 Possible side effects

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

Serious side effects
Some patients may have serious side effects that may need urgent treatment.

Allergic reactions – these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs.
- Serious allergic reactions ('anaphylaxis') are rare in people taking Stelara (may affect up to 1 in 1,000 people). Signs include:
  - difficulty breathing or swallowing
  - low blood pressure, which can cause dizziness or light-headedness
  - swelling of the face, lips, mouth or throat.
- Common signs of an allergic reaction include skin rash and hives (these may affect up to 1 in 100 people).

In rare cases, allergic lung reactions and lung inflammation have been reported in patients who receive ustekinumab. Tell your doctor right away if you develop symptoms such as cough, shortness of breath, and fever.

If you have a serious allergic reaction, your doctor may decide that you should not use Stelara again.

Infections – these may need urgent treatment. Tell your doctor straight away if you notice any of the following signs.
- Infections of the nose or throat and common cold are common (may affect up to 1 in 10 people)
- Infections of the chest are uncommon (may affect up to 1 in 100 people)
- Inflammation of tissue under the skin ('cellulitis') is uncommon (may affect up to 1 in 100 people)
- Shingles (a type of painful rash with blisters) are uncommon (may affect up to 1 in 100 people)

Stelara may make you less able to fight infections. Some infections could become serious and may include infections caused by viruses, fungi, bacteria (including tuberculosis), or parasites, including infections that mainly occur in people with a weakened immune system (opportunistic infections). Opportunistic infections of the brain (encephalitis, meningitis), lungs, and eye have been reported in patients receiving treatment with ustekinumab.

You must look out for signs of infection while you are using Stelara. These include:
- fever, flu-like symptoms, night sweats, weight loss
- feeling tired or short of breath; cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
- burning when passing water
- diarrhoea
- visual disturbance or vision loss
- headache, neck stiffness, light sensitivity, nausea or confusion.

Tell your doctor straight away if you notice any of these signs of infection. These may be signs of infections such as chest infections, or skin infections or shingles or opportunistic infections that could have serious complications. Tell your doctor if you have any kind of infection that will not go away or keeps coming back. Your doctor may decide that you should not use Stelara until the infection goes away. Also tell your doctor if you have any open cuts or sores as they might get infected.

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should tell your doctor straight away if you notice any of these signs.

Other side effects

Common side effects (may affect up to 1 in 10 people)**:**
- Diarrhoea
- Nausea
- Vomiting
- Feeling tired
- Feeling dizzy
- Headache
- Itching ('pruritus')
- Back, muscle or joint pain
- Sore throat
- Redness and pain where the injection is given
- Sinus infection

Uncommon side effects (may affect up to 1 in 100 people)**:**
- Tooth infections
- Vaginal yeast infection
- Depression
- Blocked or stuffy nose
- Bleeding, bruising, hardness, swelling and itching where the injection is given
- Feeling weak
- Drooping eyelid and sagging muscles on one side of the face ('facial palsy' or 'Bell's palsy'), which is usually temporary
- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Peeling of the skin (skin exfoliation)
- Acne

Rare side effects (may affect up to 1 in 1,000 people)**:**
- Redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis). Similar symptoms sometimes develop as a natural change in the type of psoriasis symptoms (erythrodermic psoriasis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis)

Very rare side effects (may affect up to 1 in 10,000 people)**:**
- Blistering of the skin that may be red, itchy, and painful (Bullous pemphigoid).
- Skin lupus or lupus-like syndrome (red, raised scaly rash on areas of the skin exposed to the sun possibly with joint pains).

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 at: www.mhra.gov.uk/yellowcardor 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 Stelara

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2°C–8°C). Do not freeze.
- Keep the pre-filled pen in the outer carton in order to protect from light.
- If needed, individual Stelara pre-filled pens may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton in order to protect from light. Record the date when the pre-filled pen is first removed from the refrigerator and the discard date in the space provided on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a syringe or pre-filled pen has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. Discard the syringe or pre-filled pen if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake Stelara pre-filled pens. Prolonged vigorous shaking may damage the medicine.

Do not use this medicine:
- After the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.
- If the liquid is discoloured, cloudy or you can see other foreign particles floating in it (see section 6 'What Stelara looks like and contents of the pack').
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).
- If the product has been shaken vigorously.

Stelara is for single use only. Any unused product remaining in the syringe or pre-filled pen should be thrown away. 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 Stelara contains
- The active substance is ustekinumab. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injections.

What Stelara looks like and contents of the pack
Stelara is a clear to slightly opalescent (having a pearl-like shine), colourless to light yellow solution for injection. The solution may contain a few small translucent or white particles of protein. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled pen. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL of solution for injection.

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HP12 4EG
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Manufacturer
Janssen Biologics B.V.
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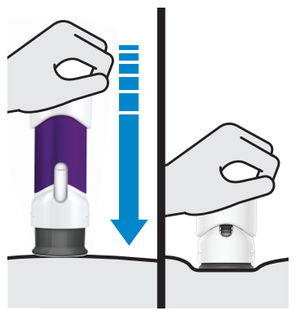
2333 CB Leiden
The Netherlands

For information in large print, tape, CD or Braille, telephone 0800 7318450

This leaflet was last revised in August 2024.

Instructions for use
Stelara® (ustekinumab)
injection, for subcutaneous use
Pre-filled pen



This “Instructions for Use” contains information on how to inject Stelara.

Important

Stelara comes in a single-dose pre-filled pen containing one 45 mg dose or one 90 mg dose.

During injection, push handle all the way down until purple body is not visible to inject the full dose. DO NOT LIFT PRE-FILLED PEN during injection! If you do, the pre-filled pen will lock and you will not get the full dose.

If your doctor decides that you or a caregiver may be able to give your injections of Stelara at home, you should receive training on the right way to prepare and inject Stelara using the pre-filled pen. **Do not try to inject yourself until you have been trained by your doctor.**

Each pre-filled pen can only be used one time. Throw it away (see Step 3) after use even if there is medicine left in it.

Do not reuse the pre-filled pen.

Read these Instructions for Use before using the Stelara pre-filled pen and each time you get a new pre-filled pen. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

If you cannot give yourself the injection:
- ask your doctor or nurse to help you, or
- ask someone who has been trained by a doctor or nurse to give your injections.

To reduce the risk of accidental needle sticks, each pre-filled pen has a needle guard that automatically covers the needle and locks after you have given your injection and the injector is lifted. Do not lift the pre-filled pen during the injection until the injection is complete.

The needle cover inside the bottom cap of the pre-filled pen contains latex. **Do not handle the needle cover if you are allergic to latex.**
Please also read the Package Leaflet carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

Storage information

Store in refrigerator at 2° to 8°C. If needed, store at room temperature up to 30°C for up to 30 days in the original carton. **Do not return to refrigerator** once stored at room temperature.

Do not freeze the pre-filled pen.

Keep the pre-filled pen and all medicines out of reach of children.

Do not shake the pre-filled pen. Shaking may damage the Stelara medicine. If the pre-filled pen has been shaken, do not use it. Get a new pre-filled pen.

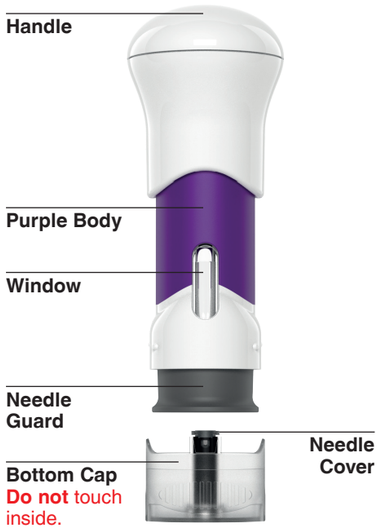
Keep the pre-filled pen in the original carton to protect from light and physical damage.

Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

Pre-filled pen injector parts

Before use

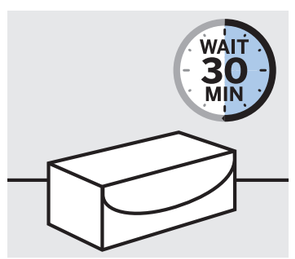


After use

Gather the following supplies.
Provided in the carton:
- **Pre-filled pen injector**

Not provided in the carton:
- **Alcohol swabs**
- **Cotton balls or gauze pads**
- **Adhesive bandages**
- **Sharps container** (See Step 3)

1. Preparing to Inject Stelara

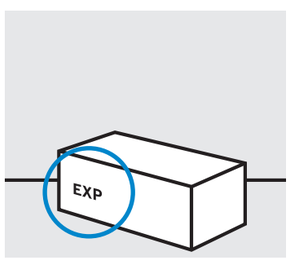


Gather carton(s)

If refrigerated, remove the pre-filled pen carton(s) from the refrigerator and place on a flat surface.
Leave at **room temperature for at least 30 minutes** before use.
Do not warm any other way.

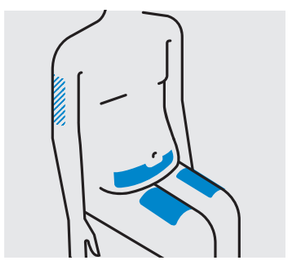
If your dose is 45 mg, you will receive one 45 mg pre-filled pen.
If your dose is 90 mg, you will receive one 90 mg or two 45 mg pre-filled pens.
If you receive two 45 mg pre-filled pens, follow Steps 1-3 for both injections.

Choose a different injection site for the second injection.



Check the expiration date (‘EXP’) and seals on the carton(s)

Do not use the pre-filled pen if the seals on the carton are broken or if the expiration date has passed.
Do not use the pre-filled pen if it has been kept at room temperature for longer than 30 days or if it has been stored above 30°C.
Call your doctor or pharmacist for a new pre-filled pen.



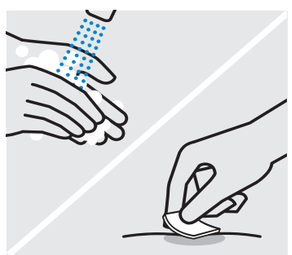
Choose injection site

Select from the following areas for your injection:
- Front of thighs
- Lower stomach area (lower abdomen), except for a 5-centimetre area right around your navel (belly-button)

If someone else is giving you the injection, they may also use:
- Back of upper arms

Do not inject into skin that is tender, bruised, red, or hard.

Use a different injection site for each injection.



Wash hands

Wash your hands well with soap and warm water.

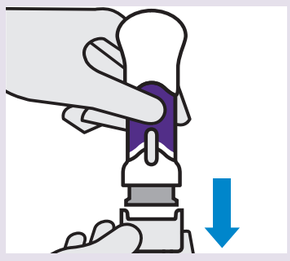
Clean injection site

Wipe your chosen injection site with an alcohol swab and allow it to dry.
Do not touch, fan, or blow on the injection site after you have cleaned it.

Inspect liquid in window

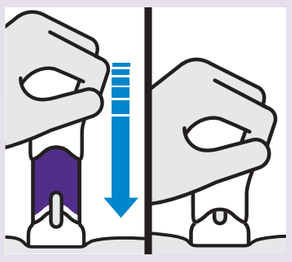
Choose a well-lit, clean, flat work surface.
Take the pre-filled pen out of the carton and check for damage.
Check the liquid in the viewing window.
It should be **clear to slightly opalescent** and **colourless to light yellow** and may contain **tiny white or clear particles** and **one or more air bubbles.** This is normal.
Do not inject if the liquid is frozen, cloudy, discoloured, or has large particles.
Call your doctor or pharmacist for a new pre-filled pen.

2. Injecting Stelara



Pull off bottom cap

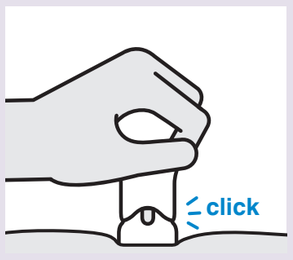
Keep hands away from the needle guard after the cap is removed. It is normal to see a few drops of liquid.
Inject Stelara within 5 minutes of removing the cap.
Do not put the cap back on. This could damage the needle.
Do not use a pre-filled pen if it is dropped after removing the cap.
Call your doctor or pharmacist for a new pre-filled pen.



Place straight on skin. Push handle all the way down until purple body is not visible.

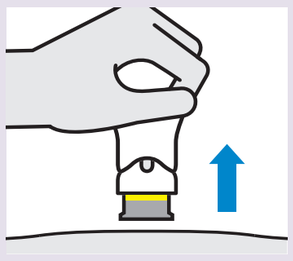
DO NOT LIFT PRE-FILLED PEN during injection!
If you do, the needle guard will lock, showing a yellow band, and you will not get the full dose.

You may hear a click when the injection begins. Keep pushing.
If you feel resistance, keep pushing. This is normal.
The medication injects as you push. Do this at a speed that is comfortable for you.



Confirm your injection is complete

Your injection is complete when:
- **The purple body is not visible.**
- You cannot press the handle down anymore.
- You may hear a click.



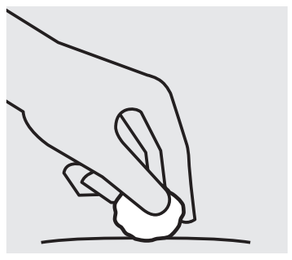
Lift straight up

The yellow band indicates that the needle guard is locked into place.

3. After your injection

Dispose of the pre-filled pen

Put the used pre-filled pen in a sharps disposal container right away after use.
Do not throw away (dispose of) the pre-filled pens in the household trash.
Do not recycle your used sharps disposal container.



Check injection site

There may be a small amount of blood or liquid at the injection site. This is normal.
Press a cotton ball or gauze pad to the injection site until any bleeding stops.
Do not rub the injection site.
If needed, cover the injection site with a bandage.

If you receive two 45 mg pre-filled pens for a 90 mg dose, repeat Steps 1-3 with the second pre-filled pen. **Choose a different injection site for the second injection.**