PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

STELARA® Pre-filled Pen

Solution for Injection

Active ingredient and its quantity:
Each pre-filled pen contains:
ustekinumab 45 mg/0.5 ml
ustekinumab 90 mg/1 ml

Inactive and allergenic ingredients in the preparation – see section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Plaque psoriasis
Stelara is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA (psoralen in combination with UV).

Psoriatic arthritis (PsA)
Stelara, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients, when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Crohn's disease
Stelara is indicated for the treatment of adult patients with moderately to severely active Crohn's disease, who had an inadequate response to, lost response to or were intolerant to either conventional therapy or TNFα antagonists or have medical contraindications to such therapies.

Ulcerative colitis
Stelara is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who had an inadequate response to, lost response to or are intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

Therapeutic group: Interleukin inhibitors

Stelara contains the active ingredient ustekinumab, which is a monoclonal antibody.

Monoclonal antibodies are proteins that recognize 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.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine that are listed in section 6 "Further Information".
- You are suffering from an active infection which your doctor thinks is important.

If you are unsure if the above applies to you, consult the doctor or pharmacist before you start using Stelara.

Special warnings regarding use of the medicine

Talk to the doctor before you start using Stelara. The doctor will check how well you are before each treatment. Before each treatment, tell the doctor about any illness you have. Also, tell the doctor if you have recently been near anyone who might have tuberculosis. The doctor will examine you and do a test for tuberculosis before starting Stelara treatment. If the doctor thinks you are at risk of tuberculosis, he may give you medicinal treatment.

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 illnesses during the course of treatment with Stelara. See "Serious side effects" in section 4 "Side effects" for a full list of these side effects.

Before treatment with Stelara, tell the doctor:

- **If you ever had an allergic reaction to Stelara.** If you are not sure, ask the doctor.
- **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 medical product contains latex rubber, which may cause severe allergic reaction in people who are sensitive to latex. See "Serious side effects" in section 4 "Side effects" 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, consult the doctor 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 and 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 stroke

Heart attack and stroke have been observed in a study in patients with psoriasis treated with Stelara.

Your doctor will regularly check your risk factors for heart diseases and stroke in order to ensure that they are appropriately treated. Seek medical attention right away if you develop chest pain, weakness or an abnormal sensation on one side of your body, facial droop or speech or vision abnormalities.

Children and adolescents

The Stelara pre-filled pen is not intended for treatment in children and adolescents under 18 years of age with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis 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.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines, nutritional supplements and vaccines, tell the doctor or pharmacist. In particular, 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 six months after birth if you received Stelara during the pregnancy, unless your baby's doctor recommends otherwise.

Pregnancy and breastfeeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- A higher risk of birth defects has not been seen in babies exposed to Stelara in the womb. However, there is limited experience with Stelara in pregnant women. It is therefore preferable to avoid the use of Stelara in pregnancy.
- 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.
- 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 healthcare professionals if you received Stelara during 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 six 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. Tell the doctor if you are breastfeeding or are planning to breastfeed. You and your doctor should decide if you should breastfeed or use Stelara. Do not do both together.

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

3. HOW SHOULD THE MEDICINE BE USED?

Stelara is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Stelara is intended.
Always use the medicine in accordance with the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain regarding the medicine dosage and treatment regimen.
Talk to your doctor about when you will have your injections and follow-up appointments.
The dosage, frequency, duration of treatment and treatment method will be determined by the doctor only.
The usual dosage is generally:

Adults over 18 years of age:

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 will be given to you by the attending 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. The doctor will decide when you should receive the next injection.

Do not exceed the recommended dosage.

How Stelara is given:
- Stelara is given as an injection under the skin (subcutaneous). 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 use” at the end of this leaflet.

Consult a doctor if you have questions about how to self-inject the medicine.

If you accidentally take a higher dosage:
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 forgot to take the medicine:
If you forget a dose of Stelara, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.
Adhere to the treatment regimen recommended by the doctor.

If you stop taking the medicine:
It is not dangerous to stop using Stelara. However, if you stop, your symptoms may come back. Consult the doctor if you are interested in discontinuing the treatment.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Stelara may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Serious side effects
Some patients may suffer from serious side effects that require urgent treatment.
Allergic reaction – may require urgent treatment. Inform the doctor immediately or proceed to an emergency room to receive urgent medical treatment if you notice any of the following signs.

Serious allergic reaction (anaphylaxis) is rare in patients treated with Stelara (may occur in up to 1 in 1,000 users). Signs include:
- Difficulty breathing or swallowing
- Low blood pressure that may cause dizziness or light-headedness
- Swelling of the face, lips, mouth or throat

Common signs of an allergic reaction include skin rash and hives (which can occur in up to 1 in 100 users).

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 – may need urgent treatment. Inform the doctor straight away if you

notice any of the following signs:

- Infections of the nose or throat and common cold are common (can occur in up to 1 in 10 users)
- Infections of the chest are uncommon (can occur in up to 1 in 100 users)
- Inflammation of the tissue under the skin (cellulitis) is uncommon (can occur in up to 1 in 100 users)
- Shingles (a type of painful rash with blisters) are uncommon (can occur in up to 1 in 100 users)

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 eyes have been reported in patients receiving treatment with ustekinumab.

While using Stelara, monitor for symptoms of infection. The symptoms 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 painful rash with blisters
- Burning when passing water
- Diarrhea
- Visual disturbances or vision loss
- Headache, neck stiffness, light sensitivity, nausea or confusion

Inform the doctor immediately 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. Inform the doctor if you have an infection that will not go away or keeps coming back. The doctor may decide that you should not use Stelara until the infection goes away. Also tell the doctor if you have open cuts or sores on your skin, since they might get infected.

Shedding of skin – increase in redness and shedding of the skin over large areas of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. Inform the doctor immediately if you notice any of these symptoms.

Additional side effects:

Common side effects – effects that may occur in up to 1 in 10 users:

- Diarrhea
- 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 – effects that may occur in up to 1 in 100 users:

- 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 paralysis, Bell's palsy) – this effect 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 – effects that may occur in up to 1 in 1,000 users:

- Redness and shedding of skin over large areas 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 – effects that may occur in up to 1 in 10,000 users:

- Blistering of the skin that may be red, itchy and painful (bullous pemphigoid).
- Skin lupus or lupus-like syndrome (red, raised and scaly rash on areas of the skin exposed to the sun, possibly with joint pains).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult a doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Storage conditions:

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Store refrigerated (2°C-8°C), do not freeze.
- Store in the original package to protect from light.

- If needed, individual Stelara pre-filled pen 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 was first removed from the refrigerator in the designated space on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a pre-filled pen has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator.
  Discard the 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 pen. Prolonged vigorous shaking may damage the medicine.

Do not use the medicine:
- After the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- If the liquid has become discolored, cloudy or foreign particles (other than those described in section 6) can be seen floating in it. See section 6 “What the medicine looks like and the contents of the package”.
- If you know or think that the medicine 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 medicine remaining in the pre-filled pen should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Sucrose, L-histidine, polysorbate 80, water for injection.

What the medicine looks like and the contents of the package:
Clear to slightly opalescent (pearl-like shine) and colorless to light yellow solution for injection. The solution may contain a few small, translucent or white particles of protein. Each box contains one single-dose pre-filled pen (0.5 ml or 1 ml).

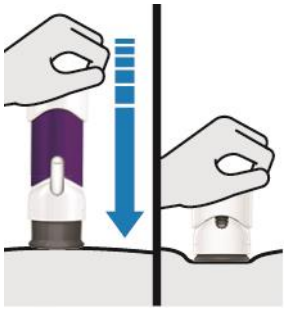
Manufacturer: Cilag AG, Hochstrasse 201, CH-8200 Schaffhausen, Switzerland.

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
177-10-38054-00

Approved in September 2024

Instructions for use of Stelara (ustekinumab) injection for subcutaneous use, pre-filled pen



These “Instructions for Use” contain information on how to inject Stelara.

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

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

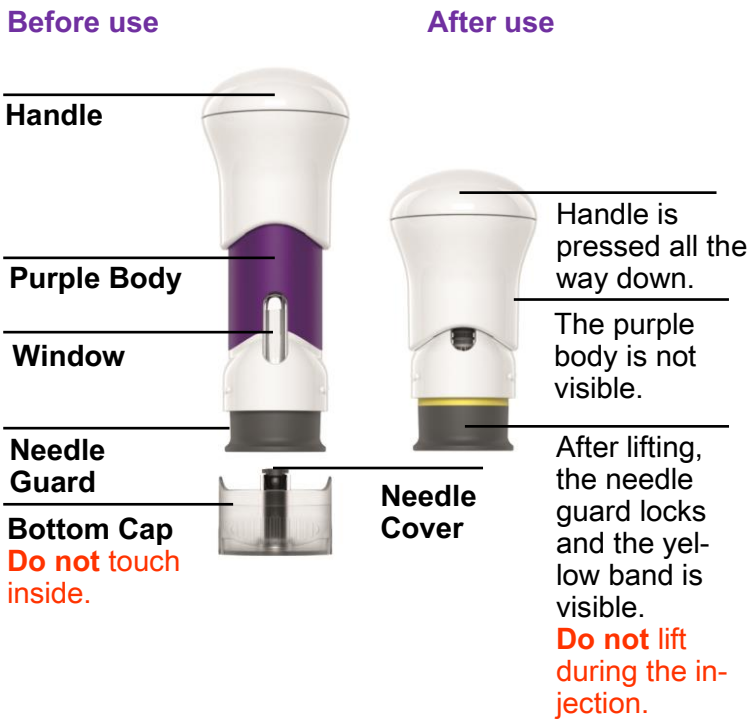
To reduce the risk of accidental needle sticks, each pre-filled pen has a needle guard that automatically covers the needle and locks after the injection is given and the injector is lifted. Do not lift the pre-filled pen during the injection until the injection is complete.

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 leaflet carefully before starting the injection and discuss any question you have with the doctor or nurse.

Storage conditions:
Store refrigerated at 2° - 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 out of the reach of children.
Do not shake the pre-filled pen. Shaking may damage the medicine. If the pre-filled pen has been shaken, do not use it and get a new pre-filled pen.

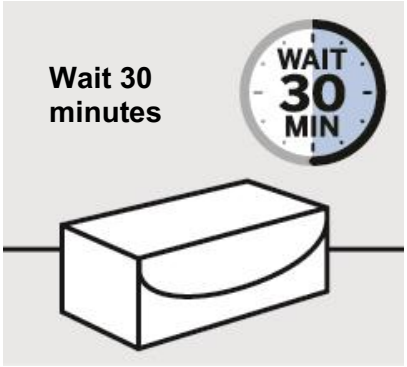
Keep the pre-filled pen in the original carton to protect from light and physical damage.

Pre-filled pen parts



Gather the following supplies.
Provided in the carton:
Pre-filled pen
Not provided in the carton:
Alcohol swabs
Cotton balls or gauze pads
Adhesive bandages
Sharps container (see step 3)

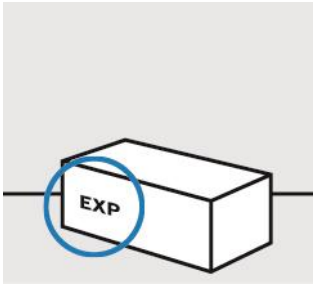
1. Preparing to Inject Stelara



Take the carton

If refrigerated, remove the carton of Stelara pre-filled pen 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.**

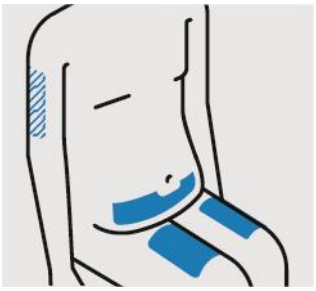


Expiry

Check the expiration date (EXP) and the seal on the carton.

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 the doctor or pharmacist about a new pre-filled pen.



Choose an injection site

Select from the following areas for the injection:

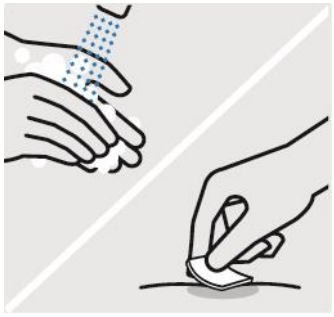
- Front of thighs
- Lower stomach area, except for a 5-centimeter area around your navel

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.

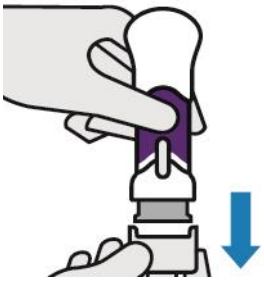
Clean injection site

Wipe your selected 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.

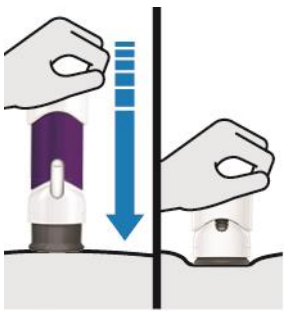
Inspect liquid in viewing window

Choose a well-lit, clean and 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 **colorless to light yellow** and may contain **a few small, translucent or white particles of protein** and **one or more air bubbles**. This is normal.
Do not inject if the liquid is frozen, cloudy, discolored, or has large particles. Call the doctor or pharmacist about a new pre-filled pen.

2. Injecting Stelara



Pull off the bottom cap.
Keep your 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 was dropped after removing the cap. Call the doctor or pharmacist about a new pre-filled pen.



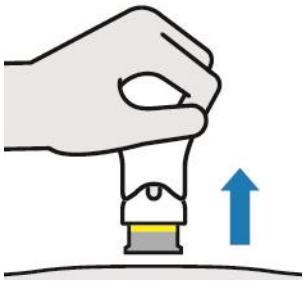
Place straight on the skin. Push handle all the way down until purple body is not visible.

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 the injection is complete.
The injection is complete when:

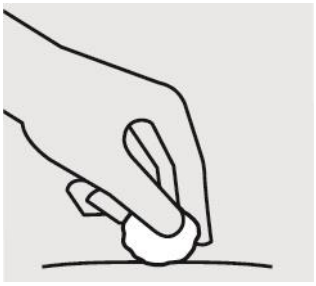
- **The purple body is not visible.**
- You cannot press the handle down anymore.
- You may hear a click.



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

3. After the 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 the 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 the bleeding stops.

Do not rub the injection site.

If needed, cover the injection site with a bandage.

If you received 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.**