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Patient Information Leaflet (PIL)

SCHEDULING STATUS

Schedule 4

STELARA® 45 mg solution for injection (vials, pre-filled syringes and pre-filled pen)

STELARA® 90 mg solution for injection (pre-filled syringes and pre-filled pen)

Ustekinumab

Contains sugar (sucrose).

STELARA 45 mg subcutaneous dose contains 38 mg of sucrose.

STELARA 90 mg subcutaneous dose contains 76 mg of sucrose.

Read all of this leaflet carefully before you start using STELARA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- STELARA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What STELARA is and what it is used for
2. What you need to know before you use STELARA
3. How to use STELARA
4. Possible side effects
5. How to store STELARA

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6. Contents of the pack and other information

1. What STELARA is and what it is used for

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 is used to treat the following inflammatory diseases:

- Plaque psoriasis - in adults and children aged 6 years and older
- Psoriatic arthritis - in adults
- Moderate to severe Crohn's disease - in adults
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis

STELARA is intended for the treatment of moderate to severe plaque psoriasis in adults and children aged 6 years and older. Plaque psoriasis is an inflammatory disease of the skin and nails.

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 don't respond well enough to these medicines, you may be given STELARA.

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 hypersensitive (allergic)** to ustekinumab or any of the other ingredients in STELARA (listed in section 6).
- if you have **tuberculosis (TB**).

Warnings and precautions

Tell your doctor or health care provider before being given an injection:

Talk to your doctor or pharmacist before using STELARA. Your doctor will check how well you are before treatment. Make sure you tell your doctor about any illness you have

before 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.

Take special care with STELARA:

Tell your doctor about all of your medical conditions before each treatment, including if you:

- **Ever had an allergic reaction to STELARA**. Ask your doctor if you are not sure.
- **Have any kind of infection** even if it is very minor, or have any signs of an infection. This could include fever, tiredness, cough, flu-like symptoms, diarrhoea, dental problems and burning on urination. Also, tell your doctor if you have any open cuts or sores, have an infection that won't go away or a history of an infection that keeps coming back. This is important because STELARA may lower your ability to fight infections. Some infections could become serious and lead to hospitalisation;
- **Have or have had any type of cancer**. Medicines such as STELARA that decrease the activity of the immune system, may increase the risk of cancer.
- **Have any new or changing lesions** within psoriasis areas or on normal skin.
- **Have recently received or are scheduled to receive a vaccine**. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause

serious problems.

- **Are having or have ever had injections to treat allergies** – it is not known if STELARA may affect these.

  If you ever had an allergic reaction to or STELARA injection

  The needle cover of the pre-filled syringe and the needle cover inside the bottom cap of pre-filled pen contain latex rubber, which may cause severe allergic reactions in people who are sensitive to latex.

- **If you are having any other treatment therapies** – such as immunosuppressive medicine (a medicine that inhibits the actions of your immune system) or phototherapy (when your body is treated with specific Ultra Violet light) while using STELARA. STELARA has an effect on your immune system and the combination of these therapies may increase the risk of diseases related to a weakened immune system. However, the combination of these therapies has not been investigated.

- **Are pregnant, planning to become pregnant, or breastfeeding.**
  Ask your doctor for advice before taking this medicine. STELARA should be used during pregnancy, if needed. STELARA may pass into your breast milk in very small amounts. Women who are breastfeeding should talk to their doctor about whether or not to use STELARA.

Your doctor will assess your health before treatment. Tell your doctor about all of your medical conditions.

Children and adolescents

STELARA is not recommended for children with psoriasis under 6 years of age, or for use in children 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

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist:

- 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 used STELARA while pregnant, tell your baby's doctor about your STELARA use before the baby receives any vaccine, including live vaccines, such as BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any live vaccines.

STELARA with food and drink

STELARA can be used with or without food or drink.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using STELARA.

Driving and using machines

It is not known if STELARA will affect the ability to drive or use machines.

It is not always possible to predict to what extent STELARA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the

above activities until they are aware of the measure to which STELARA affects them.

STELARA contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using STELARA. STELARA contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How STELARA will be given

STELARA is intended for the 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.

Your doctor will tell you how long treatment with STELARA will last. Do not stop treatment early because your symptoms may return. If you have the impression that the effect of STELARA is too strong or too weak for you, tell your doctor or pharmacist.

How much STELARA is given

Your doctor will decide how much STELARA you need to receive and for how long.

Adults aged 18 years or older

Psoriasis and 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.

Children and adolescents aged 6 years or older

Psoriasis

- The doctor will work out the right dose for you, including the amount (volume) of STELARA to be injected to give the right dose. The right dose will depend on your body weight at the time each dose is given.
- A 45 mg vial is available for children who need to receive less than the full 45 mg dose.
- If you weigh less than 60 kg, the recommended dose is 0,75 mg of STELARA per kg body weight.
- If you weigh 60 kg to 100 kg, the recommended dose is 45 mg STELARA.
- If you weigh more than 100 kg, the recommended dose is 90 mg STELARA.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks.

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

STELARA can cause side effects.

Not all side effects reported for STELARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving STELARA, please contact your health care provider for advice.

If you experience any of the following side effects, tell your doctor immediately or

go to the casualty department at your nearest hospital:

• ***Infections (including tuberculosis)*** - signs of infection include: fever, tiredness, (persistent) cough, shortness of breath, flu-like symptoms, night sweats, diarrhoea, wounds, dental problems and burning on urination.

• ***Allergic reaction*** - signs of serious allergic reactions (anaphylaxis) include: skin rash; hives; swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing; low blood pressure, which can cause dizziness or light-headedness; swelling of the hands, feet or ankles. In rare cases, symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction to STELARA.

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

These are all serious side effects. You may need urgent medical attention.

Other side effects that have been observed with STELARA are included below.

Tell your doctor if you experience any of these side effects

Frequently reported side effects:

- Diarrhoea
- Tiredness
- Dizziness
- Headache
- Itching
- Back or muscle pain
- Sore throat
- Redness and pain where the injection is given
- Nausea
- Joint pain

- Vomiting
- Sinus infection.

Less frequently reported side effects:

- Depression
- Blocked or stuffy nose
- Inflammation of tissue under the skin ('cellulitis'), showing as warmth, swelling, redness, and pain of the skin
- Pain, swelling, itching, hardness, bleeding, bruising and irritation at the injection site
- Shingles (a type of painful rash with blisters)
- Pustular psoriasis (a change in psoriasis where redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever)
- An increase in redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis)
- Peeling of the skin (skin exfoliation)
- Fungal infection (thrush) of the vulva and vagina
- Acne
- Loss of strength, weakness, or lack of energy (asthenia)
- Dental infections
- Inflammation of small blood vessels, which can lead to skin rash with small red or purple bumps, fever or joint pain (vasculitis).
- Drooping eyelid and sagging muscles on one side of the face ('facial palsy' or 'Bell's palsy'), which is usually temporary

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of STELARA.

5. How to store STELARA

Store all medicine out of reach of children.

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

Do not use STELARA if you know, or think, that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

Keep the product in the original outer carton in order to protect the solution from light.

Do not shake STELARA vials, pre-filled syringes or pre-filled pens. Prolonged vigorous shaking may damage the product. Do not use the product if it has been shaken vigorously.

Do not use STELARA 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.

Do not use STELARA if the seal is broken.

The solution is clear to slightly opalescent, colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for solutions containing protein. Do not use STELARA if the liquid is discoloured, cloudy or you can see other foreign particles floating in it.

Do not mix STELARA with other liquids for injection.

STELARA is for single use only. Any unused product remaining in the vial, pre-filled syringe or pre-filled pen should be thrown away.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What STELARA contains

- The active substance is ustekinumab. Each vial or pre-filled syringe contains 45 mg ustekinumab in 0,5 mL or 90 mg ustekinumab in 1,0 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride
- monohydrate, polysorbate 80, sucrose and water for injection.
- Contains sugar (sucrose).
- STELARA 45 mg subcutaneous dose contains 38 mg of sucrose.
- STELARA 90 mg subcutaneous dose contains 76 mg of sucrose.

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 2 mL vial.

Alternatively, it is supplied as a carton containing 1 single-dose, glass 1 mL pre-filled syringe or pre-filled pen.

Each vial, pre-filled syringe or pre-filled pen contains 45 mg ustekinumab in 0,5 mL or 90 mg ustekinumab in 1 mL of solution for injection.

Holder of Certificate of Registration

Johnson&Johnson



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This leaflet was last revised in

Date of registration of STELARA 45 mg and 90 mg: 27 July 2012

Date of revision of text: 15 May 2026

Registration numbers

STELARA 45 mg: 43/30.1/0727

STELARA 90 mg: 43/30.1/0728

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.

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FURTHER INFORMATION

INSTRUCTIONS FOR ADMINISTRATION

At the start of your therapy, STELARA may be injected by medical or nursing staff. However, your doctor may decide that you may inject STELARA yourself. In this case, you will receive training on how to inject STELARA.

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

STELARA is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING STELARA FROM A VIAL:

Do not shake STELARA vials. Prolonged vigorous shaking may damage the product.

Do not use the product if it has been shaken vigorously.

1. Check vials and assemble materials:

Take the vial out of the refrigerator. Let the vial stand for about half an hour.

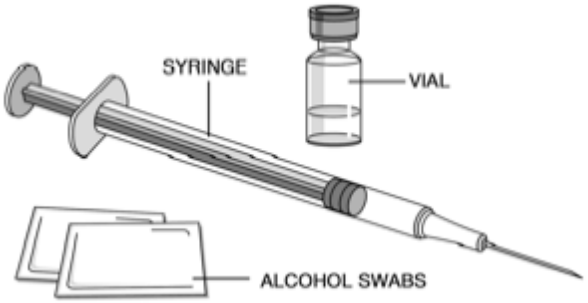
This will let the liquid come to a comfortable temperature for injection (room temperature).

If your dose is 45 mg you will receive one 45 mg vial of STELARA. If your dose is 90 mg, you will receive either one 90 mg vial of STELARA or two 45 mg vials of STELARA and you will need to give yourself two injections. Choose two different sites for these injections (for example one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other. Use a new needle and syringe for each injection.

- Check the vial(s), to make sure that it is the right product (i.e. number of vials and strength is correct), has not passed its expiration date.
- Make sure the vial is not damaged, and the seal is not broken, and the liquid is clear to slightly opalescent and colourless to slightly yellow. DO NOT use if it is frozen, discoloured, cloudy or contains large particulates.

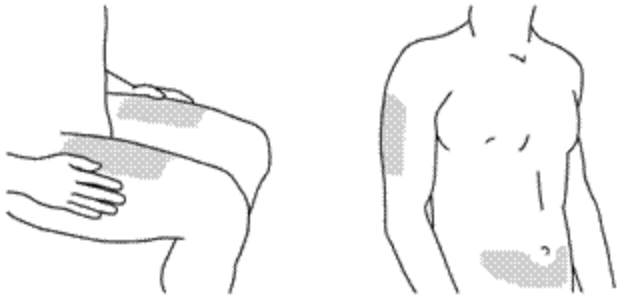
Thoroughly wash your hands with soap and warm water.

• Assemble and lay out on a clean surface everything you need such as a syringe, needle and antiseptic swabs



2. Choosing and preparing the injection site:

• Choose an injection site. STELARA is given by injection under the skin (subcutaneously). Good sites for the injection are the upper thigh or around the belly (abdomen) at least 5 centimeters away from the navel. Avoid, if possible, areas of skin that already show symptoms of psoriasis. If someone will assist in giving you the injection, then he/she may also choose the upper arms or buttocks as injection site.

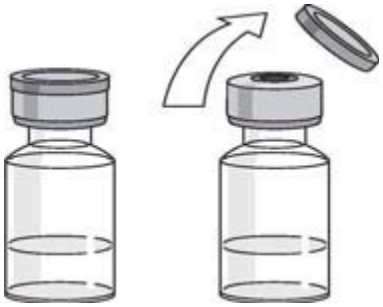


*Areas in gray are recommended injection sites.

• Preparing injection site. Wipe the injection site with an alcohol swab. **DO NOT** touch this area again before giving the injection.

3. Preparing the dose:

• Remove the cap from the top of the vial but do not remove the stopper.



• Clean the stopper with an antiseptic swab.

• Remove the needle cover. Do not touch the needle or allow the needle to touch anything.

• Put the vial on a flat surface and push the syringe needle through the rubber stopper.

• Turn the vial and the syringe upside down. Pull on the syringe plunger to fill the syringe with the amount of liquid prescribed by your doctor (0,5 mL - 1,0 mL). It is important that the needle is always in the liquid in order to prevent air bubbles forming in the syringe.



• Remove the needle from the vial. Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



4. Injecting the dose:

• Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

• Push the syringe needle into the pinched skin.

• Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.



• When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

• Dispose of your used syringe in a safe container and dispose of your vial. See section 5 " How to store STELARA".

5. After the injection:

- Press an antiseptic wipe over the injection site for a few seconds after the injection.
- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- Do not rub the skin at the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

6. Disposal:

- Used syringes and needles should be placed in a puncture-resistant container, like a sharps container. Never re-use needles and syringes, for your safety and health, and for the safety of others. Dispose of your sharps container according to your local regulations

Empty vials, antiseptic wipes, and other supplies can be disposed of in your garbage.

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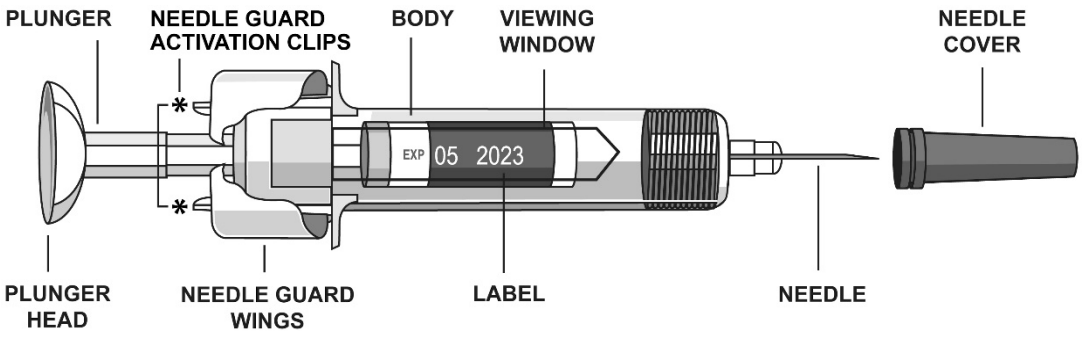
INSTRUCTIONS FOR INJECTING STELARA USING A PRE-FILLED SYRINGE

At the start of treatment, your health care provider will assist you with your first injection. However, you and your doctor may decide that you may inject STELARA yourself. If this happens, you will get training on how to inject STELARA. Talk to your doctor if you have any questions about giving yourself an injection.

- Do not mix STELARA with other liquids for injection
- Do not shake STELARA pre-filled syringes. This is because strong shaking may damage the medicine. Do not use the medicine if it has been shaken strongly.

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

1. Preparing for pre-filled syringe use

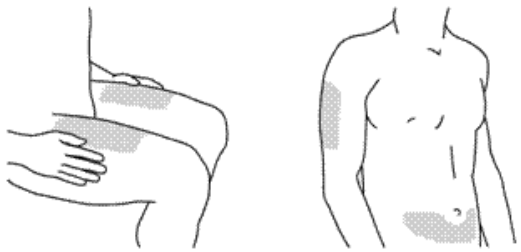


- Take the pre-filled syringe(s) out of the refrigerator. Let the pre-filled syringe stand outside the box for about half an hour. This will let the liquid come to a comfortable temperature for injection (room temperature). Do not remove the syringe's needle cover while allowing it to reach room temperature.
- Check the package to make sure that it is the right dose (i.e. that the number of pre-filled syringes and strength is correct).
    - If your dose is 45 mg you will get one 45 mg pre-filled syringe of STELARA
    - If your dose is 90 mg you will get two 45 mg pre-filled syringes of STELARA or one 90 mg pre-filled syringe of STELARA and you will need to give yourself two injections. Choose two different sites for these

injections (e.g. one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other.

- Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, don't use it.
- Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.
- Hold the pre-filled syringe with the covered needle pointing upward.
- Do not hold by the plunger head, plunger, needle guard wings, or needle cover.
- Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear to slightly opalescent and colourless to slightly yellow. **DO NOT** use if it is frozen, discoloured, cloudy or contains large particles and contact your healthcare provider for assistance.
- **DO NOT** remove the needle cover from the pre-filled syringe until instructed to do so.
- **DO NOT** pull back on the plunger head at any time.
- **DO NOT** touch the needle guard activation clips (as indicated by asterisks * in Figure above) to prevent pre-maturely covering the needle with the needle guard.

2. Choosing and preparing the injection site



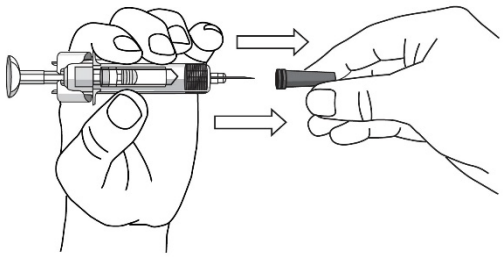
*Areas in gray are recommended injection sites.

- STELARA is given by injection under the skin (subcutaneously).

- Good sites are the top of the thigh and around the tummy (abdomen) but about 5 cm away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms as well.
- Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3. Remove the needle cover

- The needle cover should **not** be removed until you are ready to inject the dose
- Pick up the pre-filled syringe, hold the body of the syringe with one hand
- Pull the needle cover straight off and throw it away. Do not touch the plunger while you do this

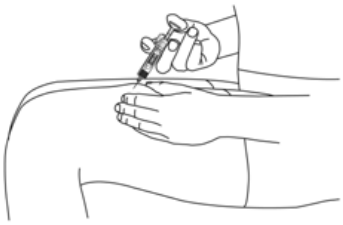


- You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal and do not need to be removed. Do not touch the needle or allow it to touch any surface. **Note:** The needle cover should **NOT** be removed until you are ready to inject the dose.
- Do not use pre-filled syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your health care provider for assistance. Inject the dose promptly after removing the needle cover.

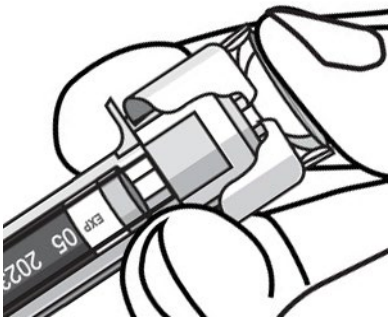
4. Injecting the dose

- Hold the pre-filled syringe with one hand between the middle and index fingers and place the thumb on top of the plunger head and use the other hand to gently pinch the cleaned skin between your thumb and index finger. Do not squeeze it tightly.
- Do not pull back on the plunger at any time.

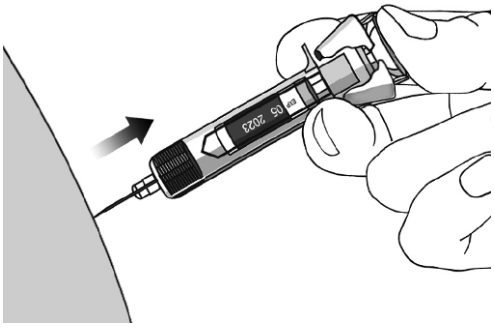
In a single and swift motion, insert the needle through the skin as far as it will go.



- Inject all of the medication by pushing in the plunger until the plunger head is completely between the needle guard wings.



- When the plunger is pushed as far as it will go, continue to keep the pressure on the plunger head, take out the needle and let go of the skin.



- Slowly take your thumb off the plunger head to allow the empty syringe to move up until the entire needle is covered by the needle guard, as shown below.

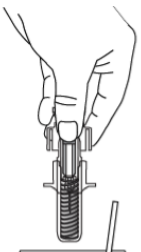


5. After the injection

- Press an antiseptic wipe over the injection site for a few seconds after the injection.
- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- Do not rub the skin at the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

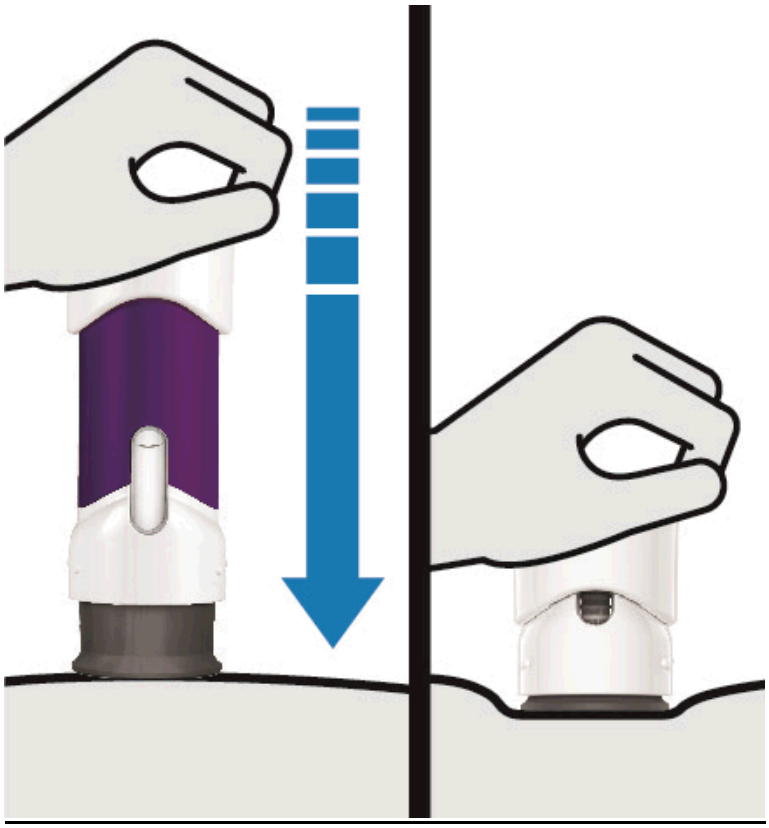
6. Disposal:

- Used syringes should be placed in a puncture-resistant container, like a sharps container (see below). Never re-use a syringe, for your safety and health and for the safety of others. Dispose of your sharps container according to your local regulations
- Antiseptic wipes and other supplies can be disposed of in your garbage.



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INSTRUCTIONS FOR INJECTING STELARA USING A PRE-FILLED PEN



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 healthcare provider (doctor, nurse, or pharmacist) 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 healthcare provider.

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 your pre-filled pen.

Read this Instructions for Use before you start using your STELARA pre-filled pen and each time you get a new prefilled pen. There may be new information. This leaflet does not take the place of talking with your healthcare provider 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.

Storage information

Store in refrigerator at 2° to 8°C. If needed, store at room temperature up to 86°F 30°C for up to 30 days in the original carton. Do not return to refrigerator once stored at room temperature.

Do not freeze your pre-filled pen.

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

Do not shake your pre-filled pen. Shaking may damage your STELARA medicine.

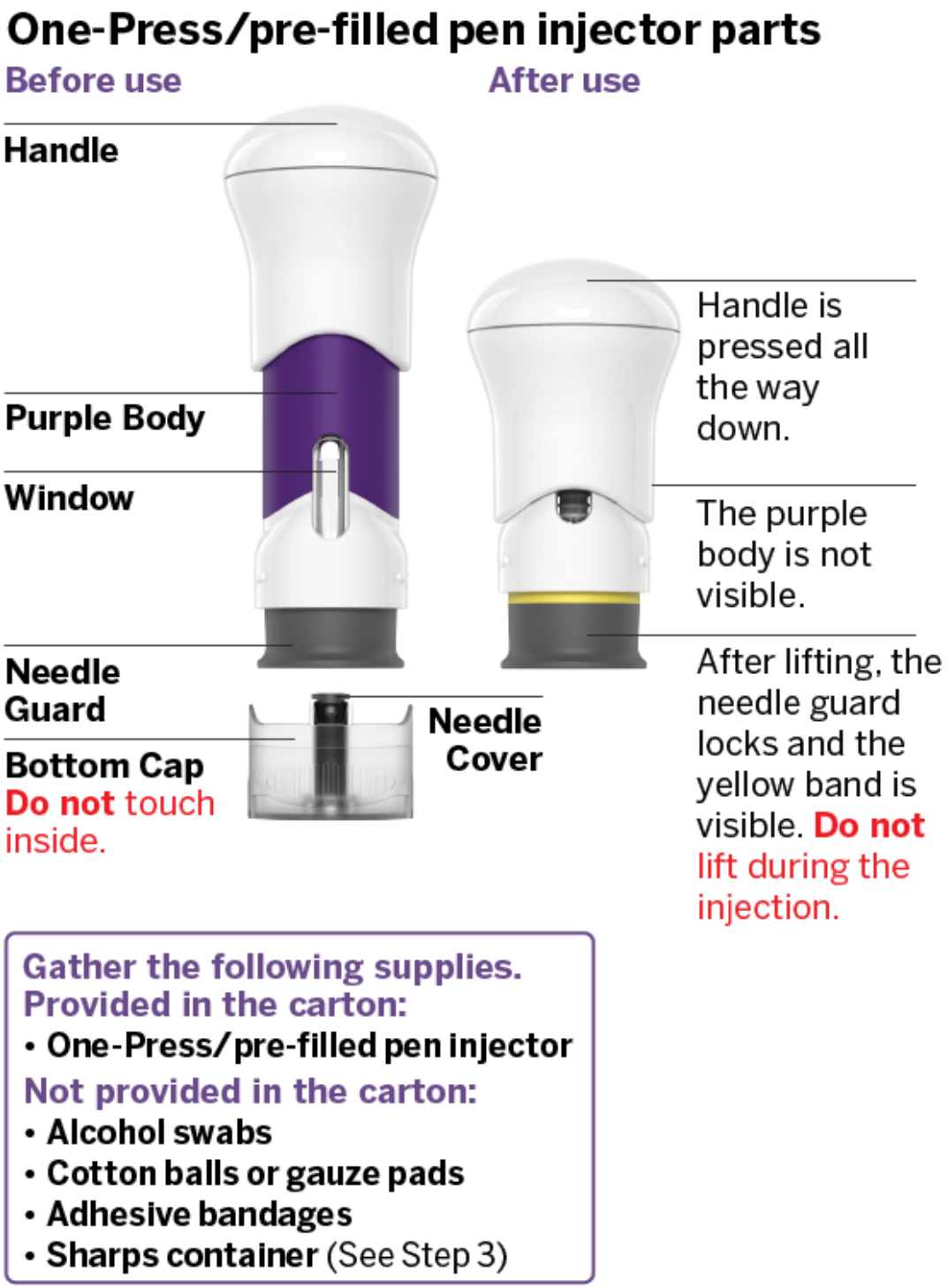
If your pre-filled pen has been shaken, do not use it. Get a new pre-filled pen.

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

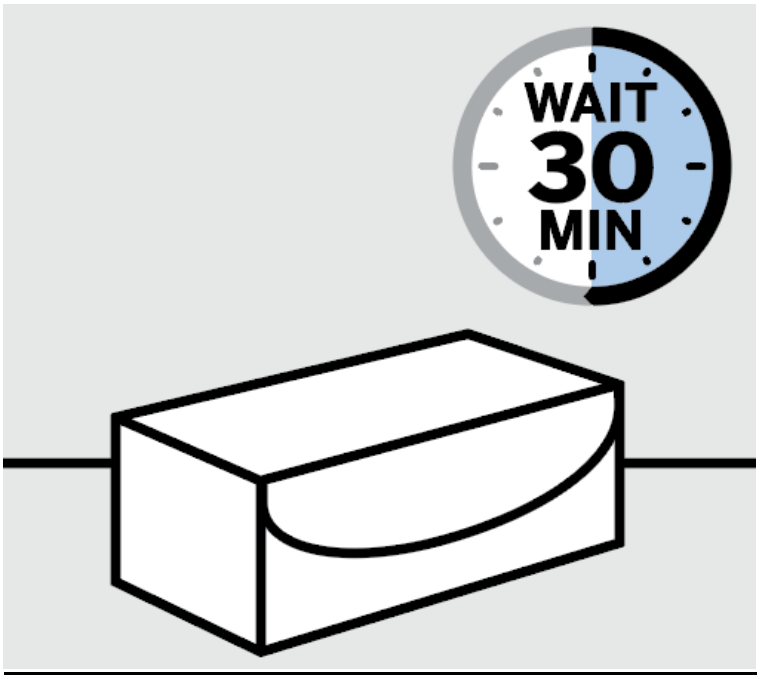
Need help?

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

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1.Preparing to Inject STELARA



Gather carton(s)

If refrigerated, remove your 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.

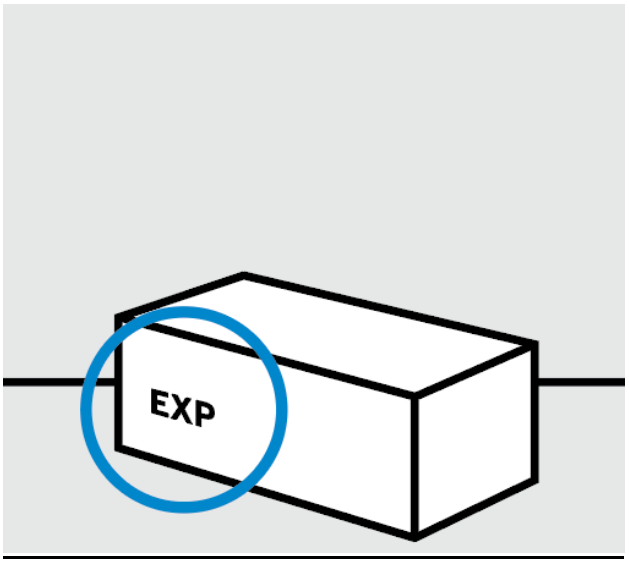
Do not warm any other way.

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.

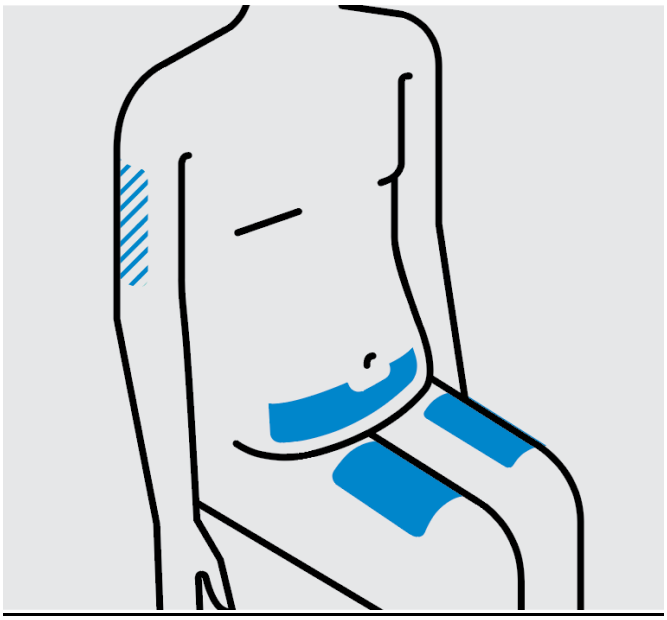
Choose a different injection site for the second injection.



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

Do not use your pre-filled pen if the seals on the carton are broken or if the expiration date has passed.

Do not use your 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 healthcare provider or pharmacist for a new pre-filled pen.



Choose injection site

Select from the following areas for your injection:

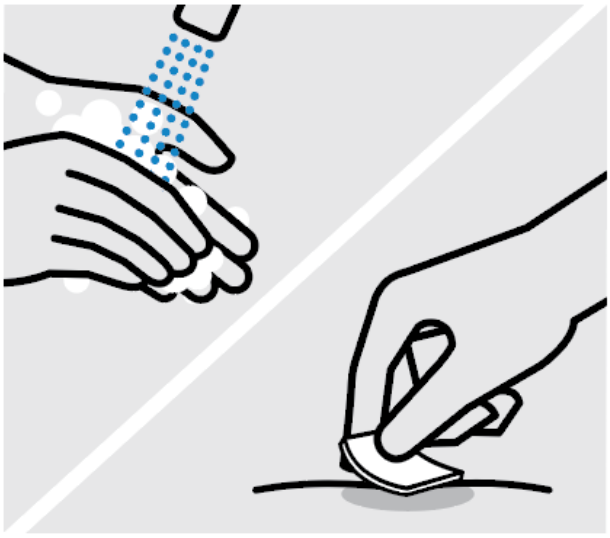
- **Front of thighs**
- **Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)**

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.



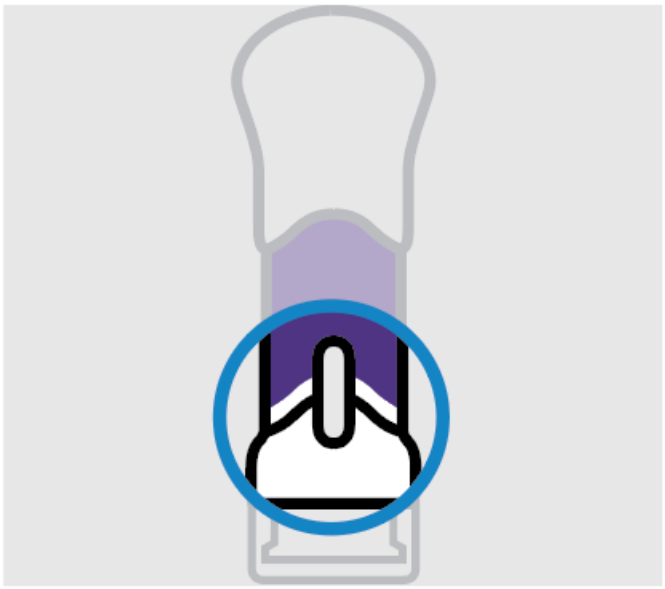
Wash hands

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

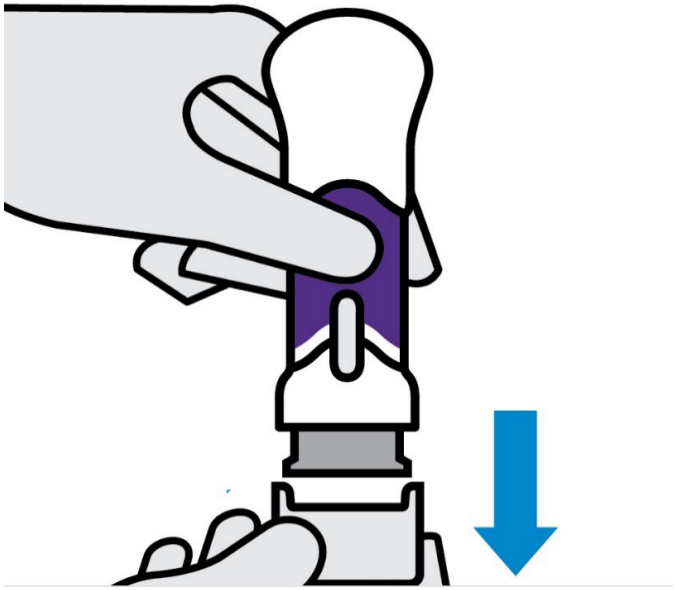
Choose a well-lit, clean, flat work surface.

Take your pre-filled pen out of the carton and check for damage.

Check the liquid in the viewing window. It should be clear and colorless to slightly 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, discolored, or has large particles. Call your healthcare provider or pharmacist for a new pre-filled pen.

2.Injecting STELARA



Pull off bottom cap

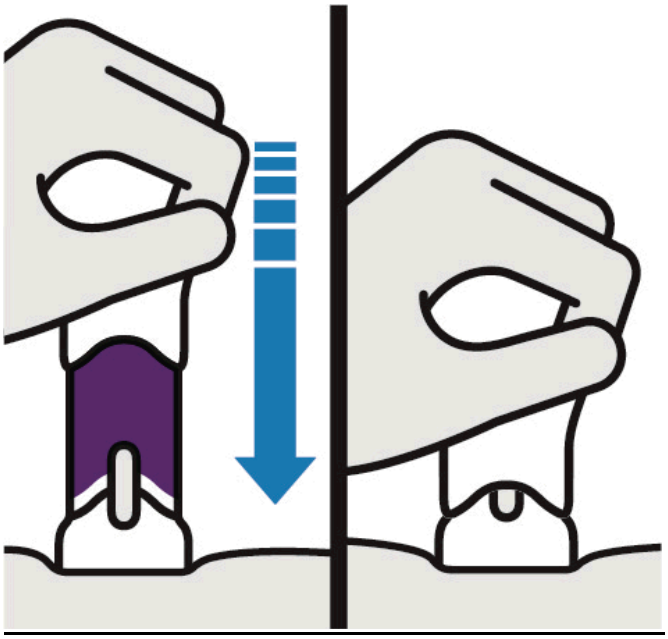
Keep hands away from the needle guard after the cap is removed. It is normal to see a few drops of liquid.

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 healthcare provider or pharmacist for a new pre-filled pen.

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

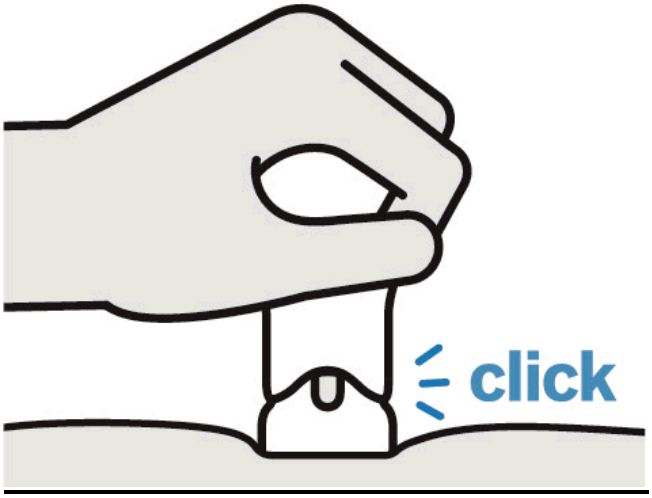
DO NOT LIFT PRE-FILLED PEN during injection!

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.

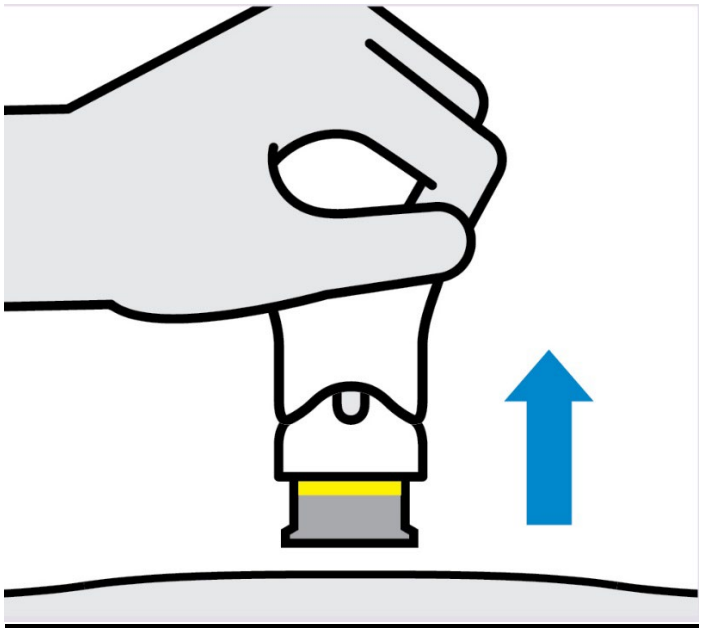
The medication injects as you push. Do this at a speed that is comfortable for you.



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



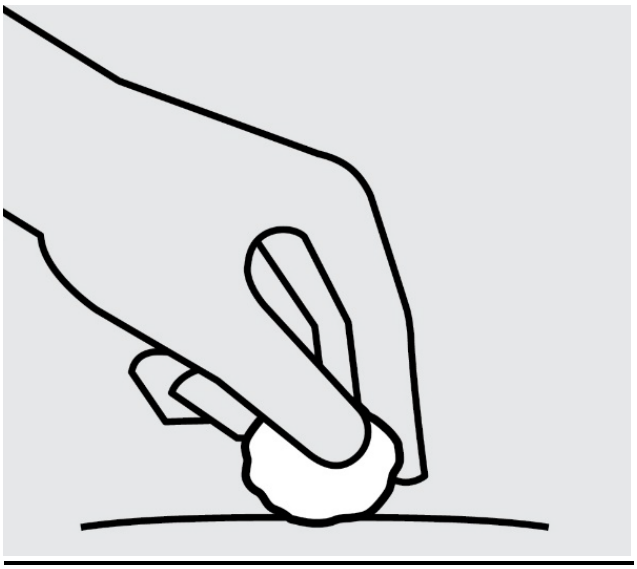
Dispose of your pre-filled pen

Put your used pre-filled pen in a sharps disposal container right away after use.

Do not throw away (dispose of) your injectors/pre-filled pens in your household trash.

Do not recycle your used sharps disposal container.

For more information, see "Disposing of STELARA pre-filled pen".



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 your second pre-filled pen. Choose a different injection site for the second injection.

Disposing of STELARA pre-filled pen

If you do not have a sharps disposal container, you may use a household container that is:

- **made of heavy-duty plastic.**
- **can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out.**
- **upright and stable during use.**

- **leak-resistant.**
- **and properly labeled to warn of hazardous waste inside the container.**

When your sharps disposal container is almost full, follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how to throw away syringes and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in your community, go to your regulatory agency's website or consult your pharmacist.