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

The medicine is dispensed with a doctor's prescription only

# STELARA® 45 mg Vial, Solution for Injection

# STELARA® Pre-filled Syringe, 45 mg, Solution for Injection

# STELARA® Pre-filled Syringe, 90 mg, Solution for Injection

**Active ingredient and its quantity:**

Each vial contains:

ustekinumab 45 mg/0.5 ml

Each 0.5 ml pre-filled syringe contains:

ustekinumab 45 mg

Each 1 ml pre-filled syringe contains:

ustekinumab 90 mg

Inactive and allergenic ingredients in the preparation – see section 6 "Further Information" and in section 2 "Important information about some of the ingredients of the medicine".

**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 adult patients (18 years or older) who have failed to, have a contraindication to, or who are intolerant to other systemic therapies including ciclosporin, methotrexate or Psoralen plus U.V (PUVA).

**Plaque psoriasis in children**

Stelara is indicated for the treatment of moderate to severe plaque psoriasis in children

and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

**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 have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist 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 have had an inadequate response with, lost response to, or were 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 infectious disease 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 your condition before each treatment. Tell the doctor about any illness you have before each treatment. 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. Look out for certain signs of illness during the course of treatment with Stelara. See “Serious side effects” in section 4 “Side effects” for a full list of these signs.

**Before treatment with Stelara tell the doctor if:**

- **you ever had an allergic reaction to Stelara.** If you are not sure, ask the doctor.
- **you have ever had any type of cancer** – since immunosuppressants like Stelara weaken part of the immune system. This may increase the risk of cancer.
- **you have been treated in the past with other biological medicines (a medicine produced from a biological source and which is usually given by injection) for psoriasis,** the risk of cancer may be higher.
- **you have or have recently had an infection.**
- **you have any changes in lesions or new lesions** within psoriasis areas or on normal skin.
- **you have ever had an allergic reaction to latex or to a Stelara injection:** The pre-filled syringe contains latex rubber, which may cause a serious allergic reaction in people who are sensitive to latex. See “Serious side effects” in section 4 “Side effects” for signs of an allergic reaction.
- **you are receiving any other treatment for psoriasis and/or psoriatic arthritis,** such as another immunosuppressant or phototherapy (treatment with a type of UV light). These treatments may also weaken part of the immune system. These treatments in combination with Stelara have not been studied. However, such treatment may increase the risk of diseases related to a weaker immune system.
- **you are receiving or have ever received injections to treat allergies** – it is not known if Stelara may affect these.
- **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 conditions apply 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 to ensure that they are being treated properly. Seek medical assistance immediately if you develop chest pain, weakness or an abnormal sensation on one side of your body, facial droop or speech or vision disturbances.

**Children and adolescents**

Stelara is not intended for treatment of psoriasis in children under 6 years of age and for psoriatic arthritis, Crohn's disease or ulcerative colitis in children under 18 years of age, since it was not tested in this age group.

**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 received a vaccination or are due to receive a vaccination. Do not receive certain vaccinations (that contain a live vaccine) during the course of treatment with 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, breastfeeding and fertility**

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask the attending doctor for advice before taking the 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, avoid becoming pregnant by using adequate contraception during treatment with 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 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 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. 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 does not affect or only negligibly affects the ability to drive and operate machinery.

**Important information about some of the ingredients of the medicine**

Stelara contains polysorbate 80.

Stelara contains 0.04 mg (Stelara 90 mg/1.0 ml) or 0.02 mg (Stelara 45 mg/0.5 ml) of polysorbate 80 (E433) in each dosage unit, which is equivalent to 0.04 mg/ml. Polysorbates may cause an allergic reaction. Tell your doctor if you have any known allergies.

## 3. HOW SHOULD THE MEDICINE BE USED?

Stelara is intended for use according to the instructions and under the 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.

Speak to the doctor about the injection administration schedules and check-up schedules.

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 initial 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 receiving the initial dose, you will be given the second dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the initial dose.

**Crohn's disease or ulcerative colitis**

- During treatment, the first dose of approximately 6 mg/kg will be given by the attending doctor by an intravenous infusion in your arm. After receiving the initial dose, you will receive the next dose of 90 mg Stelara by an injection under the skin (subcutaneously) after 8 weeks, then every 12 weeks thereafter.
- After receiving the first subcutaneous injection, some patients may receive 90 mg Stelara every 8 weeks. The doctor will decide when you should get the next injection.

**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 that contains this dose. The right dose depends on your body weight at the time it is given.
- The Stelara 45 mg vial can be used in children who need less than a full 45 mg dose.
- If you weigh less than 60 kg, the recommended dose is 0.75 mg Stelara per kg body weight.

- If you weigh between 60-100 kg, the recommended dose is 45 mg Stelara.
- If you weigh more than 100 kg, the recommended dose is 90 mg Stelara.
- After receiving the first dose, the second dose will be given 4 weeks later, and then every 12 weeks.

**Do not exceed the recommended dose.**

**How Stelara is given:**

- Stelara is given as an injection under the skin (subcutaneously). At the beginning of treatment, a nurse or healthcare professional can inject the medicine.
- However, if you decide with your doctor that you can inject Stelara on your own, you will have to undergo training on how to inject the medicine yourself.
- For instructions on how to inject Stelara, see “Instructions for use” at the end of the leaflet.

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

**If you accidentally take a higher dosage:**

Contact the doctor or pharmacist immediately. Bring the outer package of the medicine with you, even if it is empty.

**If you forget to take the medicine:**

Contact the doctor or pharmacist if you have forgotten to inject a dose of Stelara. Do not inject two doses to compensate for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

**If you stop taking the medicine:**

It is not dangerous to stop treatment with Stelara. However, if you stop, symptoms of the disease may come back. Consult the doctor if you are interested in discontinuing treatment.

**Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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 when reading 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.

**An 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:**

Severe allergic reaction (anaphylaxis) is rare in patients treated with Stelara (may

occur in up to 1 in 1,000 users). Signs include:

- Difficulty in 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, a pulmonary allergic reaction and lung inflammation have been reported in patients being treated with Stelara. Tell the doctor immediately if symptoms such as cough, shortness of breath and fever start to develop.**

If you experience a severe allergic reaction, the doctor may decide that you can no longer use Stelara.

**Infections – these may require urgent treatment. Inform the doctor immediately 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 weaken the body's ability to fight infections. Certain infections may worsen 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 shortness of breath, persistent cough
- Hot, red and painful skin or painful rash with blisters
- A burning sensation when urinating
- Diarrhea
- Visual disturbance or vision loss
- Headache, neck stiffness, light sensitivity, nausea or confusion

Inform the doctor immediately if you notice any symptoms of infection. These can be symptoms of infections such as infection of the chest, skin infection, shingles or opportunistic infections, which may have serious complications. Inform the doctor if you have an infection that does not go away or keeps coming back. The doctor may decide that you should not use Stelara until the infection goes away. In addition, tell

the doctor if you have open cuts or sores on your skin, since they may become infected.

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

**Additional side effects:**

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

- Diarrhea
- Nausea
- Vomiting
- Tiredness
- Dizziness
- Headache
- Itching
- Back pain, muscle or joint pain
- Sore throat
- Reddening and pain at the injection site
- Sinus infection

**Uncommon side effects – effects that may occur in up to 1 in 100 users:**

- Tooth infections
- Vaginal yeast infection
- Depression
- Blocked nose or nasal congestion
- Bleeding, bruising, hardening of the skin, swelling and itching/stinging at the injection site
- Weakness
- Drooping eyelid and muscle weakness on one side of the face (facial paralysis, Bell's palsy) – this effect is usually temporary
- A change in psoriasis with reddening and new small yellow- or white-colored blisters on the skin, sometimes accompanied by fever (pustular psoriasis)
- 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 with the 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?

- 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.

**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 can be seen floating in it (see section 6 "Further information").
- If you know or think that the medicine may have been exposed to extreme temperatures (such as mistakenly frozen or heated).
- If the preparation was vigorously shaken.
- If the vial cap is broken.

**Storage conditions:**

- Store refrigerated (2ºC-8ºC), do not freeze. For single use only.
- Store in the original package to protect from light.
- If needed, individual Stelara pre-filled syringes 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 syringe was first removed from the refrigerator in the designated space on the outer carton. The date of discard into a designated container must not be later than the expiry date printed on the carton. If the syringe has been stored at room temperature (up to 30°C), do not return it to the refrigerator.

  Discard the syringe into a designated container if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.

- Do not shake Stelara. Prolonged and vigorous shaking may damage the medicine.

Stelara is intended for single use only. Any unused product remaining in the syringe or the vial 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. 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 (having a pearl-like shine) and colorless to slightly yellow liquid for injection. The liquid may contain a few small, partly clear or white particles of protein.

Each box contains one pre-filled syringe/one vial.

Package sizes:

1 vial containing 45 mg/0.5 ml ustekinumab

1 pre-filled syringe containing 45 mg/0.5 ml ustekinumab

1 pre-filled syringe containing 90 mg/1 ml ustekinumab

**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:**

Stelara 45 mg Vial: 142 36 32021

Stelara Pre-filled Syringe: 146 81 33291

Revised in March 2025.

**<u>Instructions for use of the pre-filled Stelara syringe (hereinafter “syringe”)</u>:**

At the beginning of treatment, you will be assisted by the medical staff for the first injection. However, if you decide with your doctor that you can self-inject Stelara, you will undergo training on how to inject the medicine yourself. Consult a doctor if you have questions regarding self-injection.

- Do not mix Stelara with other liquids for injection.
- Do not shake the Stelara syringe. Vigorous and prolonged shaking may damage the medicine. If the medicine was shaken vigorously, do not use it.

Stelara syringe does not contain preservatives, and therefore, do not use any unused solution remaining in the syringe after the injection. Stelara syringe is a sterile, single-use product.

Figure 1 shows what the syringe looks like.

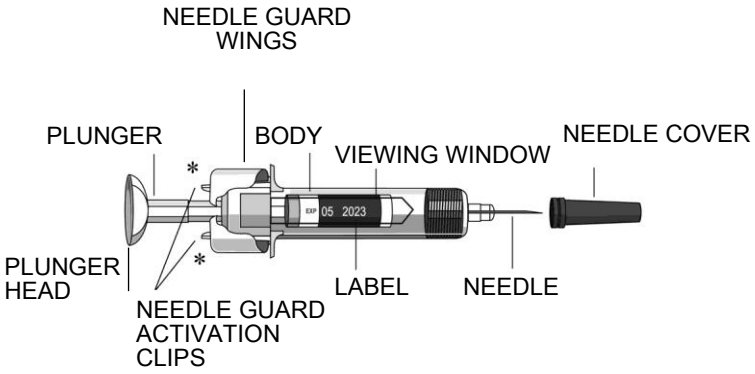



**Figure 1**

**1. Check the number of syringes and prepare the necessary materials:**

Preparing the syringe for use

- Take the syringe out of the refrigerator. Let the syringe stand outside of the box for about half an hour, so that the liquid in it will reach a comfortable temperature for injection (room temperature). Do not remove the syringe's needle cover while allowing it to reach room temperature.
- Hold the pre-filled syringe by the body of the syringe, with the covered needle pointing upward.
- Do not touch the plunger head, plunger, needle guard wings or needle cover.
- Do not pull back on the plunger at any time.
- Do not remove the needle cover from the syringe until instructed to do so.
- Do not touch the needle guard activation clips (marked by asterisks in Figure 1) to prevent prematurely covering the needle with the needle guard.

Check the syringe to make sure that:

- The number of syringes and their strengths are correct:
  - If you have to inject 45 mg, use one 45 mg Stelara syringe.
  - If you have to inject 90 mg, you may use one 90 mg pre-filled Stelara syringe or use two 45 mg Stelara syringes. In the second case, you will have to inject yourself with two injections. Choose 2 different areas on the body (e.g., one injection in the right thigh and the other in the left thigh) and inject one injection after the other.
- It is the right medicine.
- It has not passed its expiry date.
- The syringe is not damaged.
- The solution in the syringe is clear to slightly opalescent (having a pearl-like shine) and colorless to light yellow and may contain a few small translucent or white particles of protein, which is not unusual for proteinaceous solutions.
- The solution in the syringe is not discolored or cloudy and does not contain any foreign particles.

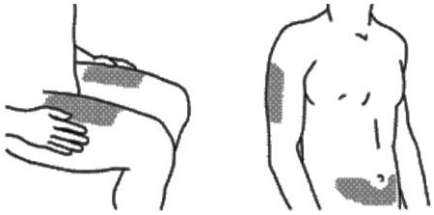
- The solution in the syringe is not frozen.

Prepare all the necessary supplies in advance and lay out on a clean surface. This includes an antiseptic wipe, a cotton ball or gauze pad, and a sharps container.

**2. Choose and prepare the intended injection site:**

Choose an injection site (Figure 2):

- Stelara is given as a subcutaneous injection.
- Good sites for injection are the upper part of the thigh and around the belly, at a distance of at least five cm from the navel.
- Avoid, as much as possible, injecting into skin affected with psoriasis.
- If a healthcare professional or a caregiver is giving you the injection, he/she may also choose the upper part of the arm.



Areas highlighted in gray are recommended injection sites

**Figure 2**

**Prepare the injection site:**

- Wash your hands very well with soap and warm water.
- Wipe the injection site on the skin with an antiseptic wipe.
- **Do not** touch this area again before giving the injection.

**3. Remove the needle cover (Figure 3):**

- 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.

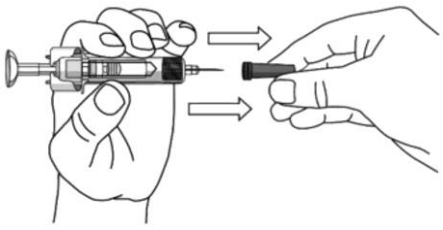


**Figure 3**

- You may notice an air bubble in the syringe or a drop of liquid at the end of the needle. These are both normal and do not need to be removed.
- Do not touch the needle or allow it to touch any surface.

- Do not use the syringe if it is dropped without the needle cover in place. If this happens, contact your doctor or pharmacist.
- Inject the dose promptly after removing the needle cover.

**4. Inject the dose:**

- Hold the syringe with one hand, between the index and middle fingers, and place the thumb on top of the plunger head. Use the other hand to gently pinch the cleaned skin between your thumb and index finger. Do not squeeze the skin tightly.
- Do not pull back on the plunger at any time.
- In one quick motion, insert the needle into the skin fold, as far as it will go (Figure 4).

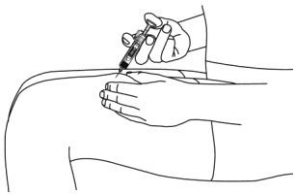


**Figure 4**

- Inject all of the medication by pushing in the plunger until the plunger head is completely between the needle guard wings (Figure 5).

**Figure 5**

- When the plunger is pushed as far as it will go, continue pressing on the plunger head, take out the needle and let go of the skin (Figure 6).

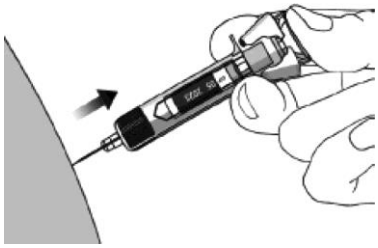


**Figure 6**

- 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 (Figure 7).

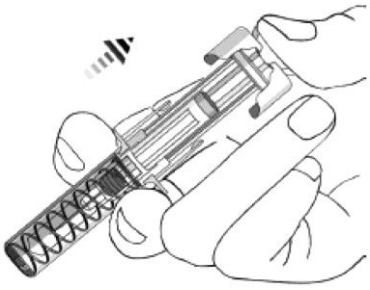


**Figure 7**

**5. After the injection:**

- Place an antiseptic wipe over the injection site and press for a few seconds.
- You may notice a small amount of blood or liquid at the injection site; this is normal.
- You can place a cotton ball or gauze pad over the injection site and hold it there for ten seconds.
- Do not rub the injection site. If necessary, place an adhesive bandage over the area.

**6. Disposal:**

Used syringes and needles should be disposed of in a sharps container. For your safety and health and for the safety of others, it is **absolutely forbidden** to re-use needles and syringes.

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

Dispose of the empty syringe into a sharps container (Figure 8).


**Figure 8**

**<u>Instructions for use for injecting Stelara from a vial</u>:**

At the beginning of treatment, you will be assisted by the medical staff for the first injection. However, if you and your doctor decide that you can self-inject Stelara, you will undergo training on how to inject the medicine yourself. If you have questions about self-injecting, consult a doctor.

- Do not mix Stelara with other liquids for injection.

- Do not shake the Stelara vial. Vigorous shaking may damage the medicine. If the medicine was vigorously shaken, do not use it.

Stelara vial does not contain preservatives, and therefore, do not use any unused solution remaining in the vial after the injection. Stelara vial is a sterile, single-use product.

**1. Check the number of vials and prepare the necessary materials:**

**Take the vial out of the refrigerator.** Allow the vial to stand at room temperature for approximately half an hour so that the liquid inside can reach a temperature comfortable for injection (room temperature).

Check the vial(s) to make sure that:

- The number of vials and their strengths are correct:
  - If you have to inject 45 mg or less, use one 45 mg Stelara vial.
  - If you have to inject 90 mg, use two 45 mg Stelara vials. You will have to inject yourself with two injections. Choose two different areas on the body (e.g., one injection in the right thigh and the other in the left thigh) and inject one injection after the other. Use a new needle and syringe for each injection.
- It is the right medicine.
- It has not passed its expiry date.
- The vial is not damaged and the cap is not broken.
- The solution in the vial is clear to slightly opalescent (having a pearl-like shine) and colorless to light yellow and may contain a few small translucent or white particles of protein, which is not unusual for proteinaceous solutions.
- The solution is not discolored or cloudy and does not contain foreign particles.
- The solution is not frozen.

Children weighing less than 60 kg need a dose smaller than 45 mg. Make sure that you know the correct amount (volume) that you must draw up from the vial and the type of syringe that is needed. If you do not know the appropriate amount and the type of syringe that is required, refer to a nurse, doctor or pharmacist.

Prepare all the necessary supplies in advance and lay out on a clean surface. This includes a 1 ml syringe, a needle, antiseptic wipes, a cotton ball or gauze pad and a sharps container (Figure 1).

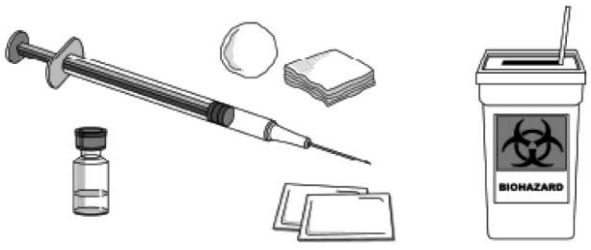
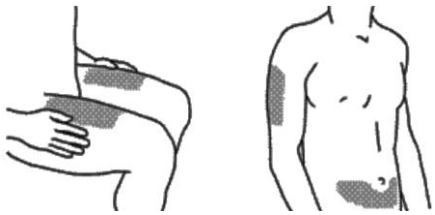



**Figure 1**

**2. Choosing and preparing the intended injection site:**

Choose the intended injection site (Figure 2):

- Stelara is given as a subcutaneous injection.
- Good sites for injection are the upper part of the thigh and around the belly, at a distance of at least five cm from the navel.
- Avoid, as much as possible, injecting into skin affected with psoriasis.
- If a healthcare professional or a caregiver is giving you the injection, he/she may also choose the upper part of the arm.



Areas highlighted in gray are recommended injection sites

**Figure 2**

**Prepare the intended injection site:**

- Wash your hands very well with soap and warm water.
- Wipe the injection site on the skin with an antiseptic wipe.
- **Do not** touch this area again before giving the injection.

**3. Preparing the dose for injection:**

- Remove the vial cap (Figure 3).

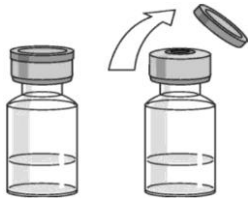


**Figure 3**

- Do not remove the rubber stopper.
- Clean the rubber stopper with an antiseptic wipe.
- Put the vial on a flat surface.
- Hold the syringe and remove the syringe needle cover.
- Do not touch the needle or allow it to touch anything.
- Insert the syringe needle into the vial through the rubber stopper.
- Turn the vial and the syringe inserted into it upside down so that the top of the vial is facing downwards.
- Pull on the syringe plunger and fill the syringe with the amount of liquid the doctor prescribed for you.
- Be sure that the needle is always in the liquid in the vial in order to prevent air bubbles from forming in the syringe (Figure 4).

**Figure 4**

- Remove the needle from the vial.
- Hold the syringe with the needle pointing upwards and check if there are any air bubbles inside.
- If there are air bubbles, tap the syringe body lightly until all the air bubbles go to the top (Figure 5).

**Figure 5**

- Press the plunger of the syringe until all of the air (but not the liquid) has been released.
- Do not lay the syringe down and do not allow the needle to touch anything.

**4. Injecting the medicine:**

- Gently pinch the cleaned skin between your thumb and index finger. Do not pinch the skin tightly.
- Insert the syringe needle into the skin fold that was formed.
- While gently keeping the skin pinched, push the syringe plunger with your thumb, slowly and evenly, as far as it will go, to inject the entire contents of the syringe.
- After you have pushed the syringe plunger to the end, take out the needle and release the skin fold.

**5. After the injection:**

- Place an antiseptic wipe over the injection site and press for a few seconds.
- You may notice a small amount of blood or liquid at the injection site; this is normal.
- You can place a cotton ball or gauze pad over the injection site and hold for ten

seconds.

- Do not rub the injection site. If necessary, you may cover the injection site with an adhesive bandage.

**6. Disposal:**

Used syringes and needles should be disposed of in a sharps container. For your safety and health and for the safety of others, it is **absolutely forbidden** to re-use needles and syringes.

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

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