

Instructions for use

For healthcare professionals



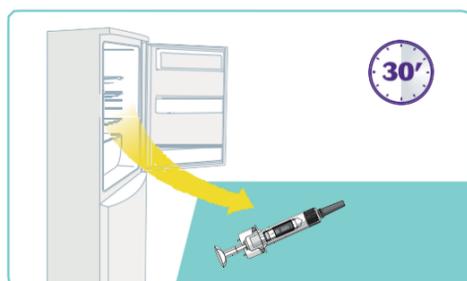
This material is intended for healthcare professionals managing patients with Crohn's disease who are being treated with Stelara® (ustekinumab). This guide has been developed to help your patients self-administer Stelara® injections using the Stelara® pre-filled syringe. Below are step-wise instructions showing how to prepare and inject Stelara® treatment. Please note that patients should not try to inject Stelara® by themselves until they have been shown the right way to self-administer the injections by a healthcare professional. This instruction for use is for you. Your patient should receive the patient's copy.

Please notify your patients that these instructions are not meant to replace the instructions for use that came with the Stelara® pre-filled syringe. Please advise the patients to thoroughly read the Instructions For Use and the Medication Guide enclosed in the carton before taking the medication and discuss with you any questions they may have.

Please inform your patients that a hypersensitivity reaction could occur when self-administering Stelara®. Tell your patient to immediately contact a physician if they notice any of the following serious side effects, as urgent medical treatment may be needed: signs of an allergic reaction, such as swelling of the face, lips, mouth or throat which may make it difficult to swallow or breathe; skin rash; hives; swelling of the hands, feet or ankles; signs of infection (including tuberculosis) such as fever, feeling tired or short of breath, persistent cough, flu-like symptoms, night sweats, diarrhoea, dental problems; a burning sensation when urinating; dizziness or light-headedness; warm, red and painful skin; or a painful skin rash with blisters.

Stelara® is not recommended for use in children and adolescents with Crohn's disease below the age of 18 due to a lack of data on safety and efficacy. When patients aged 65 and older received Stelara® in clinical studies, no overall differences in efficacy or safety were observed, compared with younger patients. However, because there is a higher incidence of infections in the elderly population in general, caution should be used in treating the elderly. Specific studies have not been conducted in patients with hepatic and renal impairment, and no dose recommendations can be made.

1 Allow the product to warm to room temperature



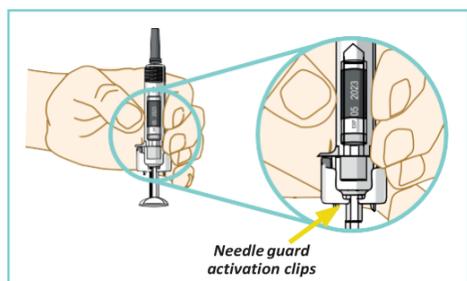
Take the carton containing the Stelara® pre-filled syringe out of the refrigerator and allow the syringe to sit outside the carton for 30 minutes.

This will allow it to reach room temperature. If you inject your patient with cold Stelara® it will be uncomfortable.

Check to make sure that the number of syringes and dosage are correct.

TIP: Take the pre-filled syringe out of the carton and wait 30 minutes.

2 Check the pre-filled syringe



Hold the Stelara® pre-filled syringe by the body with the covered needle pointing upward.

Make sure not to touch the needle guard activation clips.

Check the syringe to make sure that it has not been damaged and that the expiration date has not passed.

Make sure that the liquid is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow.

Do not inject the liquid if it is cloudy or discoloured, or has any foreign particles in it.

TIP: You may notice an air bubble – this is normal.

3 Gather the supplies for the injection and wash your hands

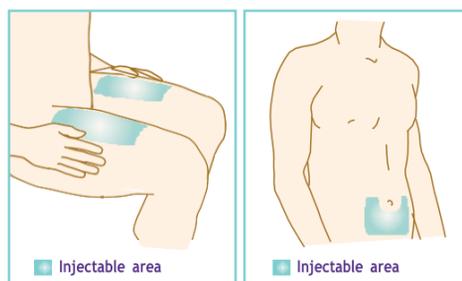


Make sure you have all the injection supplies available including the Stelara® pre-filled syringe, an antiseptic wipe, cotton ball or gauze and a sharps container for disposal of the used syringe.

Wash your hands well with soap and warm water.

TIP: Make sure everything is ready BEFORE you wash your hands and that your patient is able to sit down comfortably.

4 Prepare the injection site

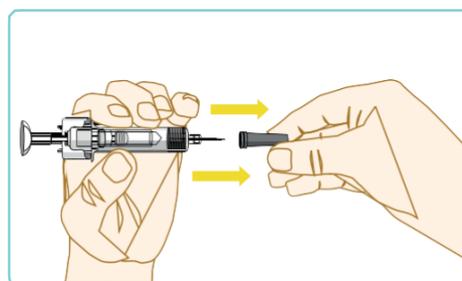


Good places for the injection are the upper thigh or around the stomach, but at least 5 cm away from the belly button. If your patient is also suffering from psoriasis (a condition sometimes associated with Crohn's disease), do not inject into a lesion.

Wipe the area you will inject with the antiseptic wipe. Do not touch this area again before giving the injection.

TIP: If your patient also has psoriasis, choose a place away from lesions where it is comfortable for you to inject them.

5 Remove the needle cover



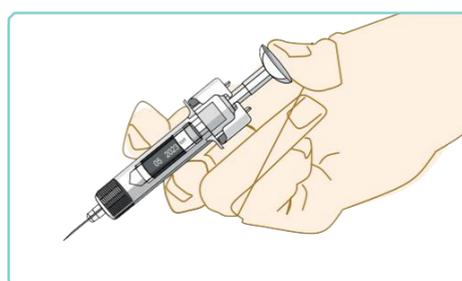
Hold the body of the pre-filled syringe with one hand and pull the needle cover straight off. Take care not to touch the needle or the plunger while removing the needle cover.

You need to inject Stelara® promptly after the needle cover has been removed.

Do not remove the needle cover until you are ready to inject Stelara®.

TIP: You may notice a drop of liquid at the end of the needle – this is normal.

6 Position the syringe

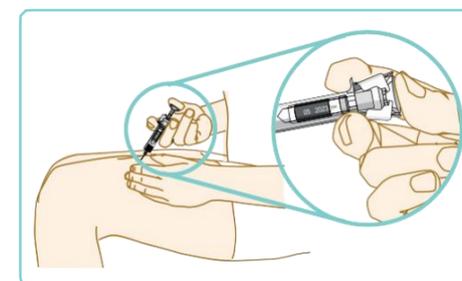


Hold the body of the Stelara® pre-filled syringe in one hand between your middle and index fingers and place your thumb on top of the plunger head. Make sure you don't pull back on the plunger at any time.

Use your other hand to gently pinch the area of the patient's skin that you previously cleaned.

TIP: Gently pinch the area of skin where you will inject Stelara® and hold firmly.

7 Inject the product

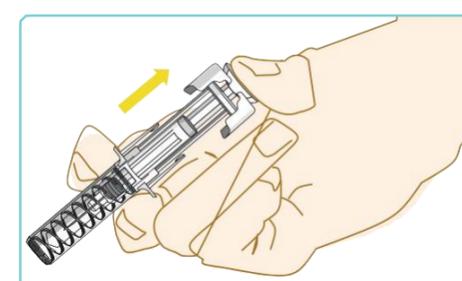


Use a quick, dart-like motion to insert the needle into the pinched skin as far as it will go.

Inject all of the medicine by using your thumb to push 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, keep pressure on the plunger head.

TIP: Count to 5 to ensure that the product is injected slowly.

8 Take the needle out of the patient's skin



Take the needle out and let go of the skin.

Slowly take your thumb off the plunger head.

This will let the empty syringe move up until the entire needle is covered by the needle guard.

TIP: Remove the needle carefully then let go of the patient's skin.

9 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, which is normal. Press a cotton ball or gauze over the injection site for about 10 seconds.

Do not rub the patient's skin. Put the used syringe in a sharps container.

TIP: If needed, you can cover the injection site with a small adhesive bandage.

10 Congratulations!

You have successfully finished the injection.



For additional information, please refer to the Summary of Product Characteristics (SmPC) or contact Janssen Medical Information by using one of the following methods:

Phone: 00356 2397 6888

Email: pv@ammangion.com

To report SUSPECTED ADVERSE REACTIONS, contact AM Mangion Ltd on any of the following:

Phone (24/7): 00356 23976333

Email: pv@ammangion.com

Address: AM Mangion Ltd, Mangion Building, N/S Off Valletta Road, Luqa, LQA 6000, MALTA

Reporting of side effects:

If you get any side effects, talk to your doctor or nurse.

You can also report side effects directly on www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

