

Stelara[®] pre-filled syringe:

Instructions for use for Crohn's disease patients

For medical queries, kindly contact AM Mangion Ltd on:
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To reporting a suspected adverse reactions:
www.medicinesauthority.gov.mt/adrportal

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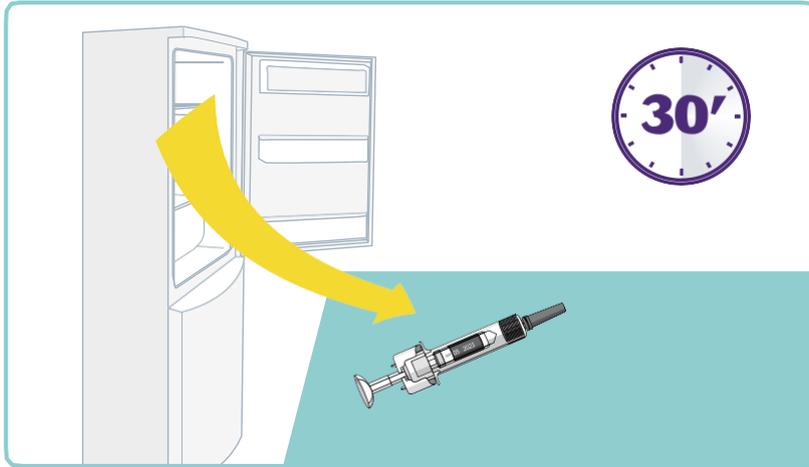
This material is intended for patients with Crohn's disease who are being treated with Stelara[®] (ustekinumab). This guide has been developed to help you administer your Stelara[®] injections using the Stelara[®] pre-filled syringe. Below are step-wise instructions showing you how to prepare and inject your Stelara[®] treatment. Please note that you should not try to inject Stelara[®] yourself until you have been shown the right way to self-administer the injections by your doctor or nurse.

These instructions are not meant to replace the instructions for use that came with your Stelara[®] pre-filled syringe. When it is time to take your medication, please thoroughly read the Instructions For Use and the Medication Guide enclosed in the carton and discuss any questions you may have with your doctor.

When self-administering Stelara[®], be aware that a hypersensitivity reaction could occur. **Tell your doctor straight away if you notice any sign of the following serious side effects - you may need urgent medical treatment:** 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; fever; feeling tired or short of breath; persistent cough; flu-like symptoms; night sweats; diarrhoea; dental problems; burning sensation when urinating; dizziness or light-headedness; warm, red and painful skin; or a painful skin rash with blisters.

Note that Stelara[®] is not recommended for use in children and adolescents with Crohn's disease below the age of 18. Caution should be used in treating patients aged 65 and older because there is a higher incidence of infections in this patient population.

1 Allow the product to warm to room temperature



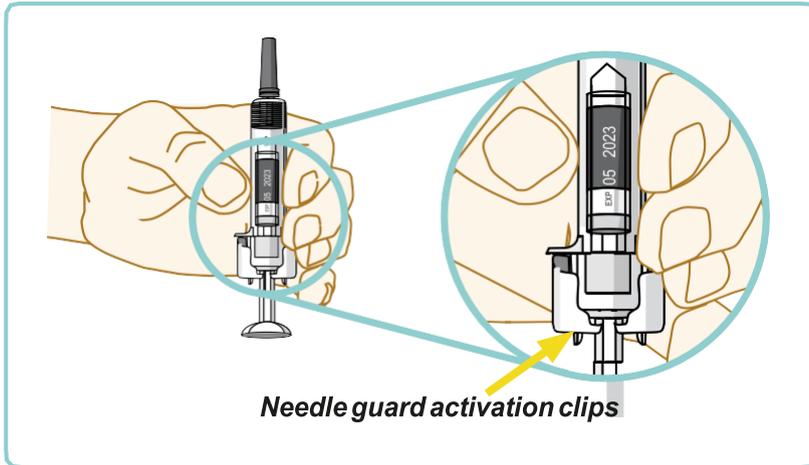
Take the carton containing your Stelara® pre-filled syringe out of the refrigerator and allow the syringe to sit outside the carton for 30 minutes.

This will allow it to reach room temperature. If you inject yourself 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



Needle guard activation clips

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

Make sure not to touch the needle guard activation clips.

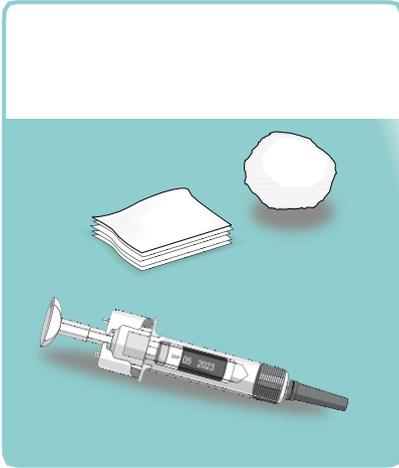
Check the syringe to make sure that it has not been damaged and that the expiration date has not passed.

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 your injection and wash your hands

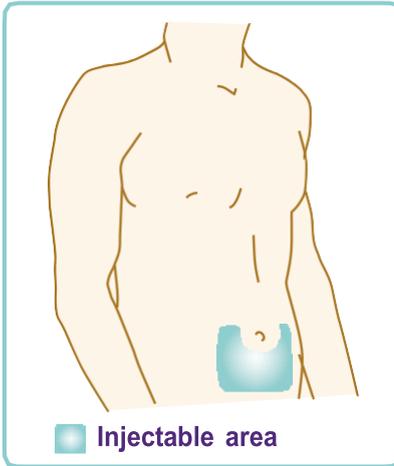


Make sure you have all your injection supplies available including your Stelara® pre-filled syringe, an antiseptic wipe, cotton ball or gauze and your sharps container for disposal of the used syringe.

Wash your hands well with soap and warm water.

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

4 Prepare the injection site

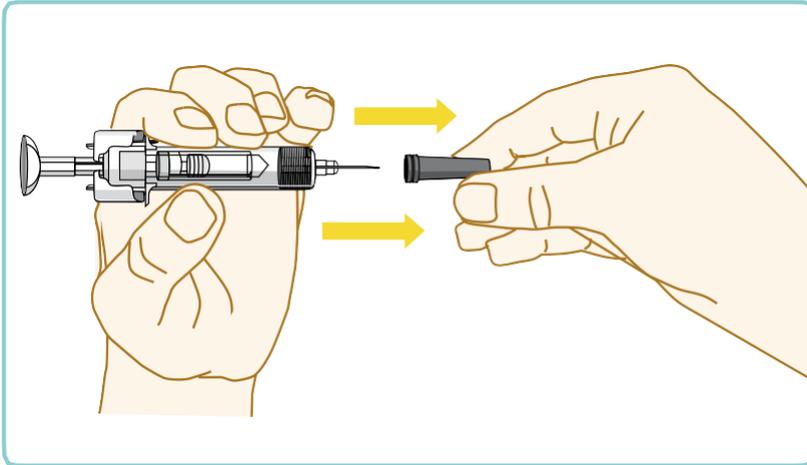


Good places for the injection are the upper thigh or around the stomach, but at least 5 cm away from the belly button. If you are also suffering from psoriasis (a condition sometimes associated with Crohn's disease), do not inject into a lesion.

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

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

5 Remove the needle cover



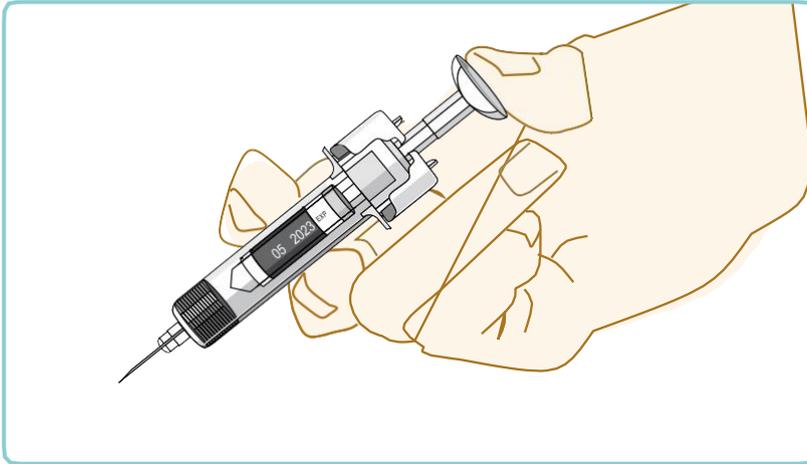
Hold the body of the pre-filled syringe with one hand and pull the needle cover straight off. Take care not to touch the needle or the plunger while removing the needle cover.

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

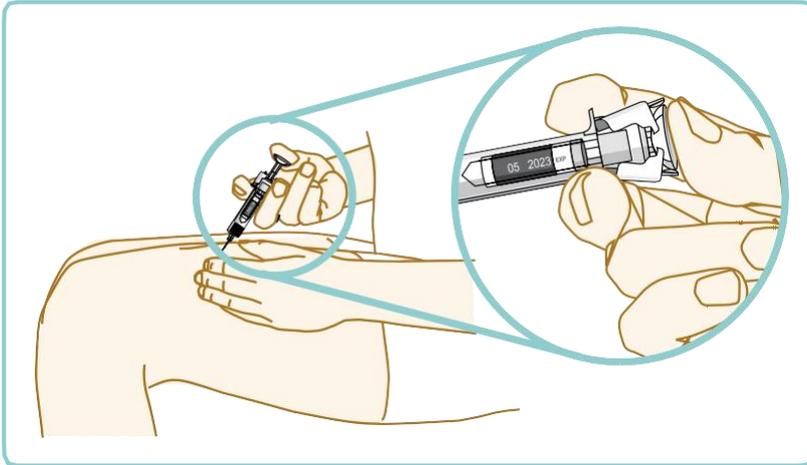


Hold the body of your Stelara® pre-filled syringe in one hand between your middle and index fingers and place your thumb on top of the plunger head. Make sure you don't pull back on the plunger at any time.

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

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

7 Inject the product

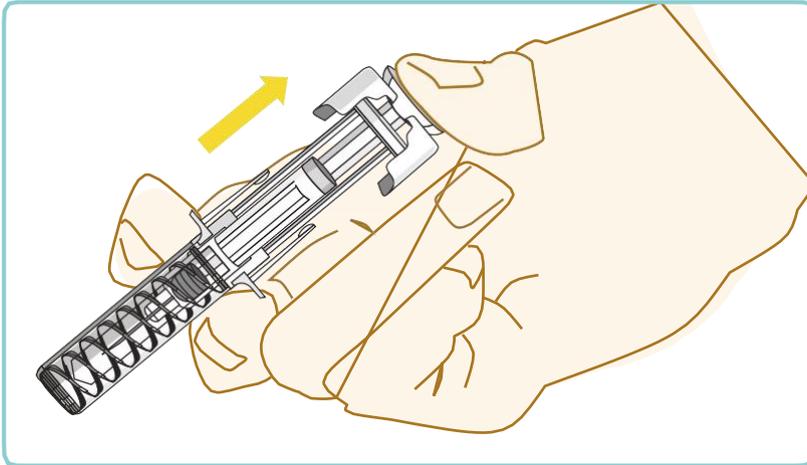


Use a quick, dart-like motion to insert the needle into the pinched skin as far as it will go.

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 your skin



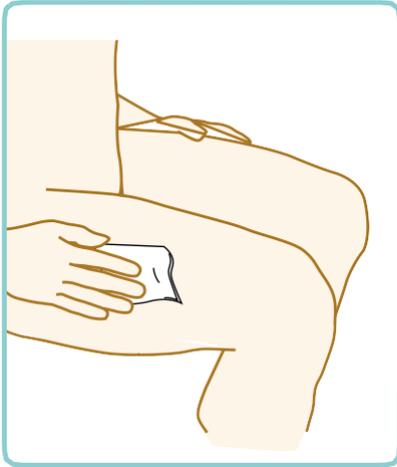
Take the needle out and let go of your skin.

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 your 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 your skin.

Put your used syringe in your sharps container.

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

10 **Congratulations!**

You have successfully finished your injection.

11 Injection Calendar

Year: _____

Enter date of dose in the relevant week	
Week 1	
Week 2	
Week 3	
Week 4	

Date of initial dose: _____

Enter date of dose in the relevant week	
Week 5	
Week 6	
Week 7	
Week 8	

Enter date of dose in the relevant week	
Week 9	
Week 10	
Week 11	
Week 12	

Enter date of dose in the relevant week	
Week 13	
Week 14	
Week 15	
Week 16	

12 Injection Calendar

Year: _____

Enter date of dose in the relevant week	
Week 17	
Week 18	
Week 19	
Week 20	

Enter date of dose in the relevant week	
Week 25	
Week 26	
Week 27	
Week 28	

Date of initial dose: _____

Enter date of dose in the relevant week	
Week 21	
Week 22	
Week 23	
Week 24	

Enter date of dose in the relevant week	
Week 29	
Week 30	
Week 31	
Week 32	

13 Injection Calendar

Year: _____

Date of initial dose: _____

Enter date of dose in the relevant week	
Week 33	
Week 34	
Week 35	
Week 36	

Enter date of dose in the relevant week	
Week 37	
Week 38	
Week 39	
Week 40	

Enter date of dose in the relevant week	
Week 41	
Week 42	
Week 43	
Week 44	

Enter date of dose in the relevant week	
Week 45	
Week 46	
Week 47	
Week 48	

14 Injection Calendar

Year: _____

Enter date of dose in the relevant week	
Week 49	
Week 50	
Week 51	
Week 52	
Enter date of dose in the relevant week	
Week 57	
Week 58	
Week 59	
Week 60	

Date of initial dose: _____

Enter date of dose in the relevant week	
Week 53	
Week 54	
Week 55	
Week 56	
Enter date of dose in the relevant week	
Week 61	
Week 62	
Week 63	
Week 64	