

STELARA[®] SOLUTION FOR INJECTION IN PREFILLED SYRINGE

Ustekinumab (45mg/0.5ml, 90mg/1ml)

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What Stelara[®] is used for

Stelara is a prescription medicine that is approved for the treatment of:

- Adults with moderate to severe plaque psoriasis that is chronic (doesn't go away)
- Adults with active psoriatic arthritis, an inflammatory disease of the joints that is usually accompanied by psoriasis
- Adults with moderately to severely active Crohn's disease or ulcerative colitis

How Stelara[®] works

Stelara blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). IL-12 and IL-23 are made by your body's immune system. In people with psoriasis, psoriatic arthritis or Crohn's disease, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body. Stelara can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

Before you use Stelara[®]

- When you must not use it

You should not receive Stelara if you have:

- had an allergic reaction to Stelara, or any of the other ingredients in Stelara. See the end of this labeling for a complete list of ingredients in Stelara.

- Before you start to use it

Your doctor will assess your health before

each treatment.

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 an allergy to alpha-gal or have been diagnosed with alpha-gal syndrome (a type of food allergy to certain meats or meat products).
- have any kind of infection, even if it is very minor
- have an infection that won't go away or a history of infection that keeps coming back.
- have had TB (tuberculosis), or if you have recently been near anyone who might have TB.
- have or have had any type 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 receiving or have received 'allergy shots', especially for serious allergic reactions.
- are pregnant, planning to become pregnant, or breastfeeding. Ask your doctor for advice before taking this medicine. Stelara should be used during a 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.
- have an allergy to latex.

- Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

How to use Stelara[®]

- For treatment of psoriasis and psoriatic arthritis, Stelara is given by injection under the skin.
- For treatment of Crohn's disease or ulcerative colitis, the first dose of Stelara is given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. This dose is given by your healthcare provider. After that, Stelara is given by injection under the skin.
- Stelara is intended for use under the guidance and supervision of your doctor. If your doctor determines that it is appropriate, you may be able to administer Stelara under the skin to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "**Instructions for Injecting Stelara under the skin yourself**").
- Your doctor will determine the right dose of Stelara for you, the amount for each injection and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

Instructions for Injecting Stelara under the skin yourself

Your first Stelara may be administered by your healthcare provider. However, your healthcare provider may decide that it is right for you or your caregiver to learn how to inject Stelara under the skin (subcutaneously) yourself. **Before you self-inject Stelara, you must be trained by a healthcare professional. If you have not been trained, please contact your healthcare provider to schedule a**

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training session. Call your healthcare provider if you have any questions about giving yourself an injection.

Stelara should not be used:

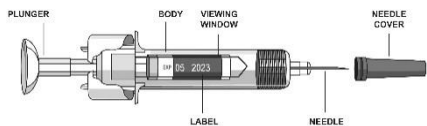
- after the expiry date on the label;
- if the seal is broken;
- if the liquid is discolored, cloudy or you can see other particulate matter floating in it;
- if you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

Always keep medicine out of the reach of children.

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.

Do not shake Stelara at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

STEP 1: PREPARING FOR PRE-FILLED SYRINGE USE



Take the Syringe out of the Refrigerator

Check the package to make sure that it is the right dose, **either 45 mg or 90 mg as prescribed by your healthcare provider.**

Check Expiration Date

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 Additional Supplies

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.

Check Solution in Syringe

Hold the pre-filled syringe with the covered needle pointing upward. 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 colorless to slightly yellow. **DO NOT** use if it is frozen, discolored, cloudy or contains large particles and contact your healthcare provider for assistance.

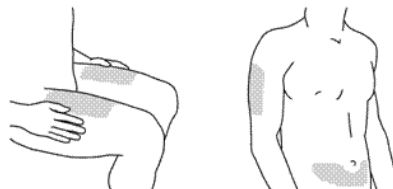
DO NOT remove the needle cover from the pre-filled syringe.

DO NOT pull back on the plunger head at any time.

STEP 2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the injection site*

Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches 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.



*Areas in gray are recommended injection sites.

Prepare the Injection Site

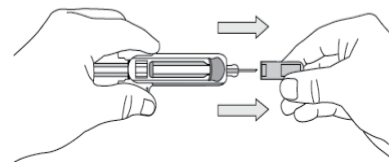
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. **DO NOT** touch this area again before giving the injection.

STEP 3: INJECTING THE MEDICATION

Remove the Needle Cover

When you are ready to inject, pick up the

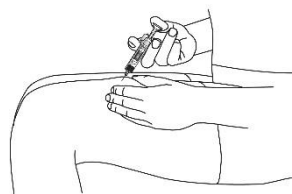
pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. 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 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 healthcare provider for assistance.

Inject the Medication

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



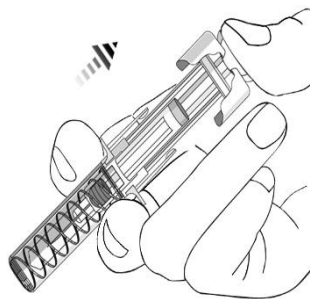
Push the syringe needle into the pinched skin.

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 pinched.

When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle. Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.

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STEP 4: AFTER THE INJECTION

Dispose of the Empty Syringe

Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations.



Use a Cotton Ball or Gauze

There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

If your dose amount is 90 mg, and you receive two 45 mg vials you may need to give a second injection right after the first. Use a new needle and syringe. Choose a different site for the second injection.

This information sheet summarizes the most important information about Stelara. You can ask your healthcare provider for information about Stelara that is written

for healthcare professionals.

- How much to use

Your doctor will determine the right dose of Stelara for you, the amount for each injection and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Stelara for as long as your doctor recommends.

- If you forget to use it

Make the next injection as soon as you remember. Do not double up the injections.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Always follow your doctor's instructions carefully.

- Tell your doctor about your medical conditions before each treatment (see *Before you use Stelara*).
- Tell your doctor if you become pregnant while using Stelara.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using Stelara.

- Things you must not do

- You should not receive a live vaccine while taking 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 the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.
- Medicines are sometimes prescribed for purposes that are not mentioned in patient information sheets. Do not use Stelara for a condition for which it was not prescribed.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- Things to be careful of

Driving and using machines

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

Side effects

Stelara is a medicine that may decrease the activity of your immune system. It can increase your chances of getting serious side effects including:

Serious Infections

- Stelara may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Stelara. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your doctor will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with

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medicine for TB before you begin treatment with Stelara and during treatment with Stelara.

Cancer

- Many drugs such as Stelara that may decrease the activity of the immune system may increase the risk of cancer. Tell your doctor if you have ever had any type of cancer.

Other serious side effects may occur including allergic reactions. Signs of a serious allergic reaction may include a skin rash, a swollen face, lips, mouth or throat or wheezing, dizziness, trouble swallowing or breathing. Tell your doctor or get emergency medical help right away if you think you are having an allergic reaction.

In rare cases, symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction to Stelara.

Allergy to latex

The needle cover on the pre-filled syringe contain dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex. Tell your doctor if you have ever had an allergic reaction to latex and developed any allergic reaction to Stelara injection.

The most common side effects of Stelara are:

- Upper respiratory infections such as common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired

- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

These are not all of the side effects with Stelara. Tell your doctor about any side effect that bothers you or does not go away. Ask your doctor or pharmacist for more information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.moh.gov.my [Consumers → Reporting side effects to medicines (ConSERF) or vaccines (AEFI)].

Storage and Disposal of Stelara[®]

- Storage

If you are using Stelara at home, it is important to store the product in your refrigerator although not in the freezer compartment. Stelara should not be frozen. Keep the product in the original carton to protect from light until the time of use.

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 with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the space provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

- Disposal

Used syringes should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your local regulations. Empty vials, antiseptic wipes,

and other supplies can be placed in your regular trash. The syringe, needle and vial must never be re-used. Discard any unused portion of Stelara in accordance with local requirements.

Product Description

- What it looks like

Stelara is a colourless to light yellow product and may contain a few small translucent or white particles of protein. This appearance is not unusual for solutions containing protein.

- Ingredients

- Active ingredients
The active ingredient is ustekinumab.

- Inactive ingredients
The inactive ingredients include: L-histidine, L-histidine monohydrochloride monohydrate polysorbate 80, sucrose and water for injection. No preservatives are present.

- MAL number

MAL20112139AZ
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Manufacturer

Cilag AG,
Hochstrasse 201, 8200, Schaffhausen,
Switzerland.

Product Registration Holder

Johnson & Johnson Sdn Bhd (3718-D)
Level 8, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
46150, Petaling Jaya, Selangor, Malaysia

Date of revision

16/03/2026 (MY PI based on CCDS v12Feb2026)

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