

STELARA[®] INJECTION

Ustekinumab (rmc)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about STELARA (pronounced stel-ahr-uh). It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using STELARA against the benefits this medicine is expected to have for you.

If you have any concerns about using STELARA, ask your doctor or pharmacist.

It is important that you read this leaflet. Keep this leaflet with your medicine. You may need to read it again.

What STELARA is used for

STELARA is a prescription medicine that is used to treat:

- 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, an inflammatory disease of the bowel
- adults with moderate to severe ulcerative colitis, an inflammatory disease of the bowel.

STELARA contains the active ingredient ustekinumab, a

monoclonal antibody.

Monoclonal antibodies are proteins that recognise and bind to other unique proteins.

Ustekinumab 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, Crohn's disease or ulcerative colitis, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body like the skin and nails.

Ustekinumab can block IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use STELARA

When you must not use it

Do not use STELARA if you have an allergy to:

- ustekinumab, the active ingredient in the medicine
- any of the other ingredients in STELARA. See **Product Description** at the end of this leaflet for a list of ingredients.

Symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

Do not use STELARA if the packaging is torn or shows signs of tampering, or if the liquid is discoloured or cloudy.

Do not use STELARA beyond the expiry date (month and year) printed on the pack.

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

Before you start to use it

You must tell your doctor about all of your medical conditions before each treatment, including if you:

- 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. Patients receiving STELARA should not receive live vaccines. 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 allergy immunotherapy.
- are pregnant, planning to become pregnant, or breastfeeding. Ask your doctor for advice before taking this medicine. Adequate contraception should be used to avoid falling pregnant. 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. The needle cover on the pre-filled syringe and the needle cover in the bottom cap of the pre-filled pen (One-Press[®] patient-controlled injector) contain dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex.

Your doctor will examine you for tuberculosis (TB). If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with STELARA and during treatment with STELARA.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given STELARA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

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 received any vaccines, including live vaccines, such as the BCG vaccine (used to prevent

tuberculosis), rotavirus vaccine or any other live vaccines.

Using STELARA

For the treatment of **psoriasis** or **psoriatic arthritis** STELARA is given by injection just under the skin (subcutaneously).

For the treatment of **Crohn's Disease** or **ulcerative colitis**, the first dose of STELARA will be given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. After this starting dose, all future doses of STELARA are given by injection just under the skin (subcutaneously).

All STELARA injections are for single use in one patient only.

STELARA is intended for use under the guidance and supervision of your doctor. When you start treatment, STELARA may be injected by your healthcare provider. If your doctor determines that it is appropriate, you may self-inject or your caregiver may be able to administer STELARA to you under the skin if you wish, after proper training in injection technique. (See **How much to use** and **Injecting STELARA under the skin yourself**.)

It is important to remember that the first dose of STELARA for the treatment of **Crohn's Disease** or **ulcerative colitis** (intravenous infusion) will always be administered by your healthcare provider.

How much to use

- Your doctor will determine the correct dose of STELARA for you 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.

Injecting STELARA under the skin yourself

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. If you would like to self-inject STELARA under your skin, you must be trained by a healthcare professional to prepare an injection and give it to yourself. If you have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection.

STELARA is given alone and not mixed with other liquids for injection.

STELARA should not be used:

- after the expiry date on the label;
- if the seal is broken;
- if the liquid is discoloured, 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 being accidentally frozen or heated).

Do not shake STELARA at any time. Prolonged vigorous shaking may damage the product. If STELARA has been shaken vigorously, don't use it. STELARA is not to be mixed with other liquids for injection.

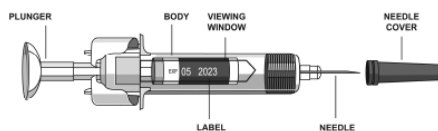
STELARA injection under the skin (subcutaneous) is available in vial, pre-filled syringe and pre-filled pen.

Instructions for use for the pre-filled syringe and pre-filled pens are provided below.

How to inject STELARA from a pre-filled syringe

To reduce the risk of accidental needle stick injuries 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 syringe(s) out of the refrigerator. Make sure that it is the right dose. If your dose is 45 mg you will receive one 45 mg syringe. If your dose is 90 mg, you may receive two 45 mg syringes. If you receive two 45 mg syringes for a 90 mg dose, you will need to give yourself two injections one right after the other. Check with your healthcare provider.

Check Expiration Date

Open the box and remove the 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.

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 vial to make sure that it is not cloudy and not frozen.

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.

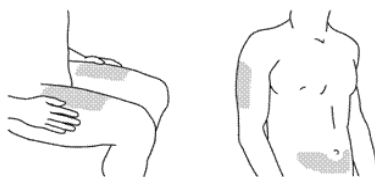
DO NOT remove the needle cover from the pre-filled syringe.

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

2. CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site*

Good sites are the top of the thigh



*Areas in gray are recommended injection sites.

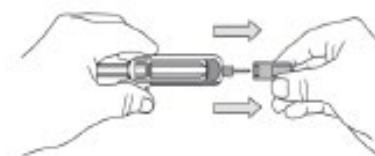
and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.

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.

3. INJECTING THE MEDICATION

Remove the Needle Cover



When you are ready to inject, pick up the pre-filled syringe with one hand and pull the needle cover straight off.

Throw the needle cover into the rubbish.

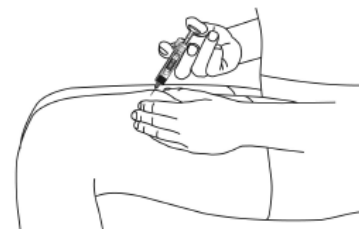
You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. Do not touch the needle or allow it to touch any surface.

Note: The needle cover should **NOT** be removed until you are ready to inject the dose. Do not use the 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.

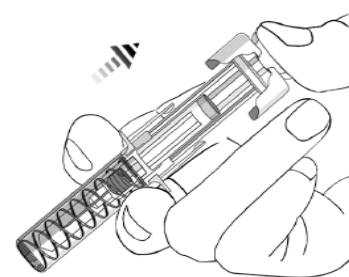
4. INJECT THE MEDICATION

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 gently 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.

5. 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. See 'After using STELARA - Disposal'.

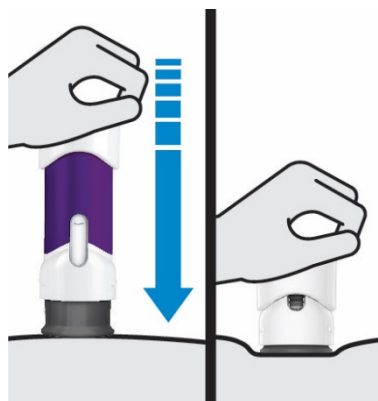
Use a Cotton Ball or Gauze

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 syringes you may need to give a second injection right after the first. Choose a different site for the second injection.

How to inject STELARA from a pre-filled pen (One-Press patient-controlled injector)



Important

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 is for single use only. 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 you 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.

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.

One-Press/pre-filled pen injector parts



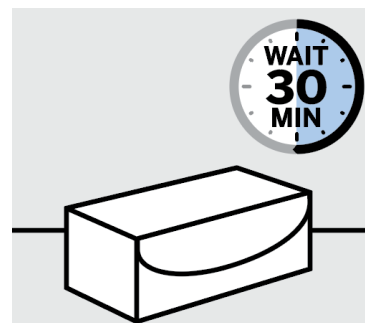
Gather the following supplies. Provided in the carton:

- One-Press/pre-filled pen injector

Not provided in the carton:

- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps container (See Step 3)

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.

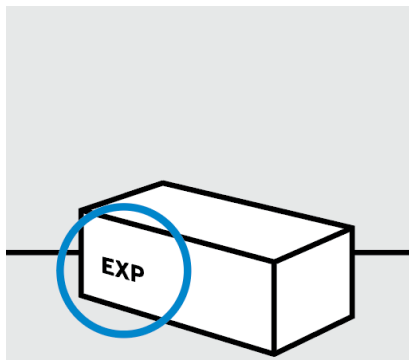
Leave at **room temperature for at least 30 minutes** before use.

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.

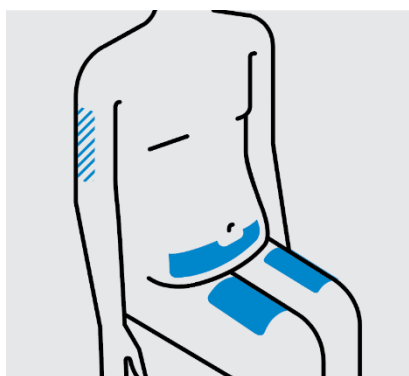
Choose a different injection site for the second injection.



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:

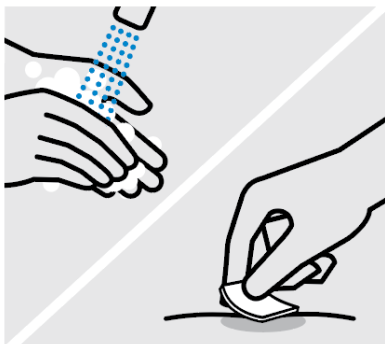
- Front of thighs
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)

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.



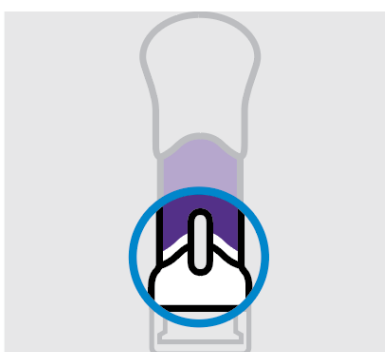
Wash hands

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

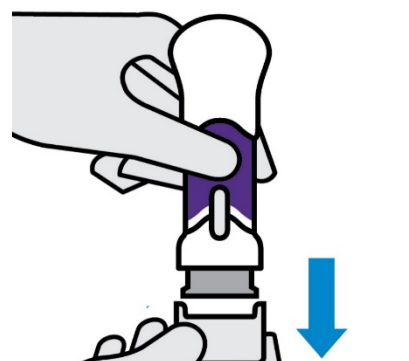
Choose a well-lit, clean, flat work surface.

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



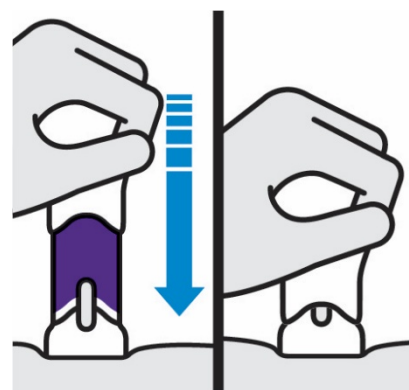
Pull off bottom cap

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.



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

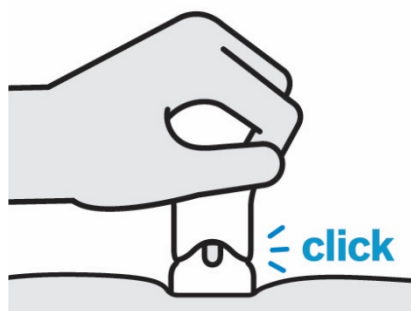
DO NOT LIFT PRE-FILLED PEN during injection!

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.

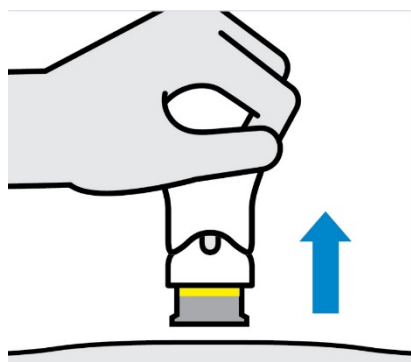
The medication injects as you push. Do this at a speed that is comfortable for you.



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



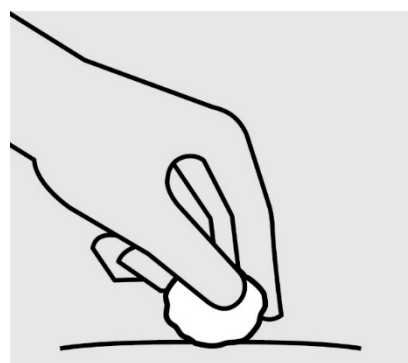
Dispose of your pre-filled pen

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

Do not throw away your 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.**

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to use it

- Make the next injection as soon as you remember, and then continue to use it as you would normally.
- Do not administer a double dose to make up for the dose you missed.

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 have used too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, 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.

Poisons Information Centre telephone numbers:

- New Zealand: 0800 POISON or 0800 764 766
- Australia 13 11 26

Keep these telephone numbers handy.

While you are using STELARA

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 used STELARA while pregnant, tell your baby's doctor about your STELARA use before the baby received any vaccines, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine or any other live vaccines.
- If you develop headache, vision problems, seizures or

change in mental status (for example confusion), tell your doctor immediately.

- 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.
- Do not use STELARA to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following common side effects:

- Upper respiratory tract infections such as sinus infection and colds
- Dizziness, headache
- Sore throat
- Diarrhoea
- Nausea, vomiting
- Pruritis (itching)
- Back or muscle pain
- Joint Pain
- Injection site pain or redness
- Fatigue (tiredness)
- Sinus infection

Other uncommonly reported side effects include:

- Painful skin rash (Herpes Zoster infection)
- Cellulitis
- Dental infections
- Viral upper respiratory tract infection
- Vaginal yeast (fungal) infection
- Depression
- Blocked or stuffy nose
- Acne
- Injection site reactions (including bleeding, bruising, hardness, swelling and itch)
- Feeling weak
- A change in psoriasis with redness and new, tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Worsening reddening or shedding/peeling of the skin

Tell your doctor immediately or go to hospital as you need urgent medical attention:

- A serious allergic reaction. Signs of a serious allergic reaction may include a skin rash, a swollen face, lips, mouth or throat, or wheezing, dizziness, cough, fever, trouble swallowing or breathing.

STELARA is a medicine that may decrease the activity of your immune system. It can increase your chances of getting serious side effects. Tell your doctor immediately if you notice any of the following, as you may need urgent medical care:

- Serious Infections. STELARA may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection, 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 have any open cuts or sores, tell your

healthcare provider right away.

- 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 side effects not listed above may also occur in some people. Tell your doctor if you notice any other side effects, particularly if they bother you or do not go away.

After using STELARA

Storage

Store STELARA between 2°C and 8°C in the refrigerator. Do not freeze. Keep the product in the original carton to protect from light until the time of use. Do not shake.

Keep your medicines out of reach of children.

Do not store STELARA, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy some medicines.

If needed, you may store STELARA pre-filled syringes and pre-filled pens at room temperature up to 30°C for one period of up to 30 days.

- Write the date on the carton, when removed from the refrigerator.
- If your pre-filled syringe or pre-filled pen has reached room temperature, do not put it back in the refrigerator.
- Throw away the pre-filled syringe or pre-filled pen if it has been kept at room temperature for 30 days and has not been used or reached its original expiry.

Disposal

After injecting STELARA, place the used syringe or pre-filled pen immediately into a sharps container. Do not have a sharps disposal container, put the used syringe or pen into your normal household or recycling waste.

The syringe or pen should never be re-used. Discard any unused portion of STELARA.

If your doctor tells you to stop using STELARA, or it has passed its expiry date, ask your pharmacist what to do with any that may be left over.

Product Description

What it looks like

STELARA injection for subcutaneous use is a colourless to light yellow solution and may contain a few small translucent or white particles of protein. This appearance is not unusual for solutions containing protein.

STELARA solution for intravenous use is a clear, colourless to light yellow product.

STELARA for subcutaneous use is available in pre-filled syringes or pre-filled pens (One-Press patient-controlled injectors) containing 45 mg ustekinumab in 0.5 mL or 90 mg ustekinumab in 1.0mL. Each box contains 1 syringe.

STELARA for intravenous use is available in glass vials containing 130 mg ustekinumab in 26 mL.

Ingredients

STELARA 45 mg or 90 mg solution for injection for subcutaneous administration

Each mL of STELARA contains 90 mg of ustekinumab.

Inactive ingredients: histidine/histidine hydrochloride monohydrate, sucrose, polysorbate 80, and water for injections.

No preservatives are present.

STELARA 130 mg solution for intravenous infusion

Each mL of STELARA contains 5 mg of ustekinumab.

Inactive ingredients: histidine, histidine hydrochloride monohydrate, sucrose, polysorbate 80, methionine, EDTA disodium salt dihydrate, and water for injection.

No preservatives are present.

Sponsor

Janssen-Cilag (New Zealand) Ltd
507 Mt Wellington Highway
AUCKLAND 1060
Telephone: 0800 800 806

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