

**STELARA® (stel-ahr-uh)
(ustekinumab)**

Review this patient information before you start taking STELARA® and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. It is important to remain under a healthcare provider's care while using STELARA®.

What is the most important information I should know about STELARA®?

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 on your body, 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 medicine for TB before you begin treatment with STELARA® and during treatment with STELARA®.

Serious Skin Conditions

- Shedding of Skin – Increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your doctor straight away if you notice any of these signs.

Cancers

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, or notice any changes to your health status (including unusual changes to your skin) while receiving STELARA®.

See also, “**What are the possible side effects of STELARA®?**” below.

What is STELARA®?

STELARA® is a prescription medicine that is approved for the treatment of:

- Adults and pediatric patients (children and adolescents) 6 years and older with moderate to severe plaque psoriasis who cannot use or did not respond to other medicines and phototherapy
 - Adults with active psoriatic arthritis when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate
- Plaque psoriasis is a skin condition that causes inflammation affecting the skin and nails.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given STELARA® by injection under the skin, alone or in combination with methotrexate, to:

- Reduce signs and symptoms of your arthritis;
 - Inhibit damage to your joints;
 - Improve your physical function;
 - Improve your enthesitis (pain and swelling around the joints);
 - Improve your psoriasis;
 - Improve your health-related quality of life.
- Adults with moderately to severely active Crohn's disease or ulcerative colitis
Crohn's disease and ulcerative colitis are inflammatory diseases of the bowels. If you have moderately to severely active Crohn's disease that has not responded to other medications and you are an adult, you will be given STELARA® to:
 - Help relieve your symptoms such as abdominal pain and frequent stools,
 - Help get Crohn's disease or ulcerative colitis under control (induce remission) and keep it under control (maintain remission),
 - Reduce or stop the use of corticosteroid medicines,
 - Improve your health-related quality of life by helping you feel better,
 - Improve the way the lining of your intestine looks to your healthcare provider during colonoscopy.

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

Who should not receive STELARA®?

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®.
- an active infection which your doctor considers important.

What should I tell my doctor before starting treatment with STELARA®?

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 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. STELARA® should only be used during a pregnancy if needed. Women who are breastfeeding should talk to their doctor about whether or not to use STELARA®.
- have an allergy to latex.
- have any open cuts or sores as they might get infected.

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 will I receive 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. In children and adolescents 6 years and older with psoriasis, it is recommended that STELARA® be administered by a health-care provider. If your doctor determines that it is appropriate, you or your caregiver may be able to administer STELARA® 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.

What should I avoid while receiving STELARA®?

You should not receive a live vaccine while taking STELARA®.

What are the possible side effects of STELARA®?

Serious Infections

(see “**What is the most important information I should know about STELARA®?**”).

Serious skin conditions

(see “**What is the most important information I should know about STELARA®?**”).

Cancer

(see “**What is the most important information I should know about STELARA®?**”).

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. Call 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 contains 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 the 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. In general, the side effects of STELARA® in children and adolescents 6 years and older are similar to those in adults. Ask your doctor or pharmacist for more information.

General information about STELARA®

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.

How STELARA® is stored

If you are using STELARA® at home, it is important to store the product at 2°C to 8°C (36°F to 46°F) in your refrigerator although not in the freezer compartment. STELARA® should not be frozen. Do not shake. 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 (86°F) 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 spaces 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.

What are the ingredients in STELARA®?

The active ingredient is ustekinumab.

STELARA® 45 mg or 90 mg for injection under the skin: The inactive ingredients include L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

STELARA® 130 mg for intravenous infusion: The inactive ingredients include EDTA disodium salt dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection. No preservatives are present.

Other important points:

STELARA® is a colorless 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.

STELARA® 130 mg solution is **only for intravenous infusion** and must only be given by a healthcare provider. It is a clear, colorless to light yellow product.

STELARA® is available in the following presentations:

Solution for injection for subcutaneous administration

1 Single-use Pre-filled Syringe:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

1 Single-use Vial:

- 45 mg / 0.5 mL

Concentrate for solution for intravenous infusion

1 Single-use Vial:

- 130 mg / 26 mL

STELARA® should not be used:

- after the expiration 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 sight and reach of children.

How to Dispose of STELARA®

Used syringes should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your state or 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.

Instructions for Injecting STELARA® under the skin yourself

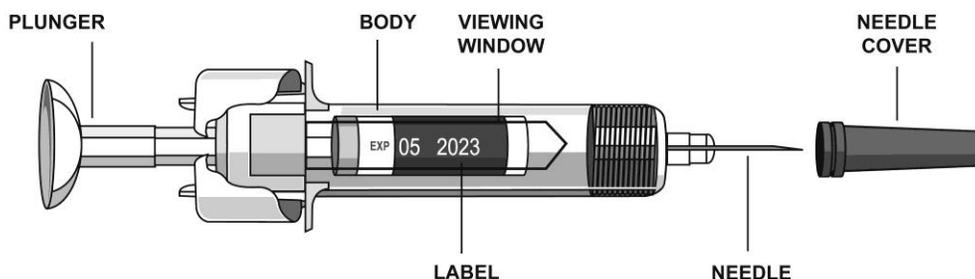
Your first STELARA® injection may be administered by your healthcare provider. In children and adolescents 6 years and older, it is recommended that all doses of STELARA® be administered by a health care provider. However, your healthcare provider may decide that it is right for you or your caregiver to learn how to inject STELARA® under the skin (subcutaneously) yourself. **Before you self-inject STELARA®, you or your caregiver must be trained by a healthcare professional. 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.

INSTRUCTIONS FOR INJECTING STELARA® USING A PRE-FILLED SYRINGE

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 45mg or 90mg as prescribed by your healthcare provider.** Children who weigh 60 kg or more, may use the pre-filled syringe.

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.

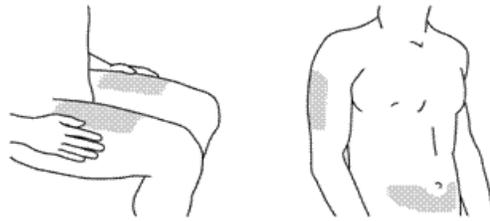
DO NOT remove the needle cover from the pre-filled syringe.

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.

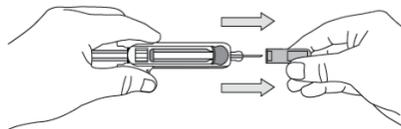
Prepare the Injection Site

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

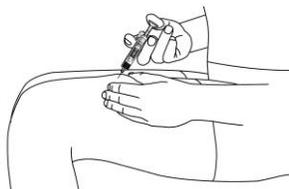
When you are ready to inject, pick up the pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see 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.



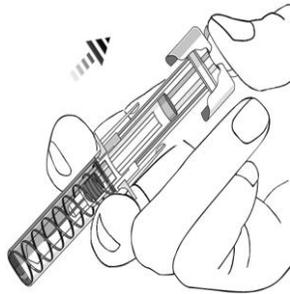
Don't squeeze it.

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.

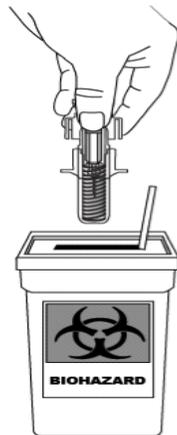
When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle. Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.



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.

INSTRUCTIONS FOR INJECTING STELARA® FROM A VIAL

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. STELARA® is not to be mixed with other liquids for injection.

STEP 1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

Take the Vial(s) out of the Refrigerator

Check the package to make sure that it is the right dose, either 45 or 90 mg as prescribed by your healthcare provider. If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

Check Expiration Date

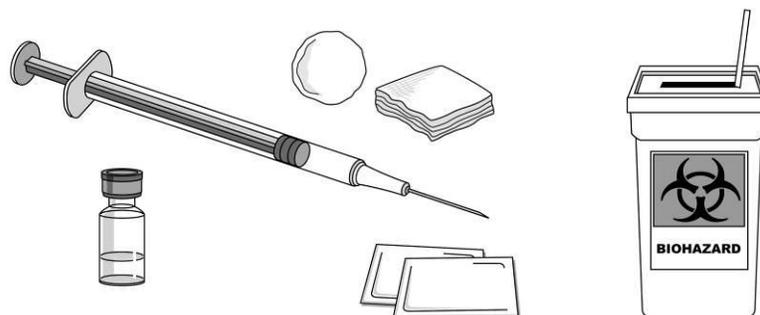
Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

Check Solution in Vial

Make sure the vial is not damaged. Look at the solution or liquid in the vial 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.

Assemble Additional Supplies

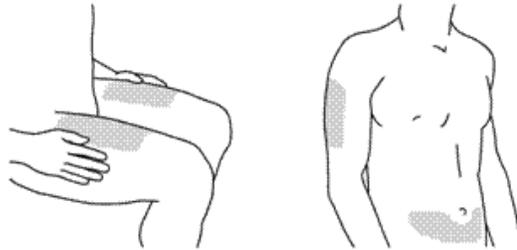
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.



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.

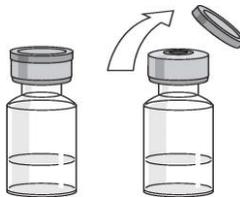
Prepare the Injection Site

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: PREPARING THE DOSE

Remove the cap from the top of the vial but do not remove the stopper.

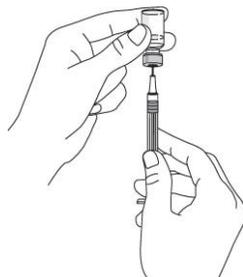
Clean the stopper with an antiseptic wipe.



Remove the needle cover from the syringe. **Do not touch the needle or allow the needle to touch anything.**

Put the vial on a flat surface and push the syringe needle through the rubber stopper.

Turn the vial and the syringe upside down.

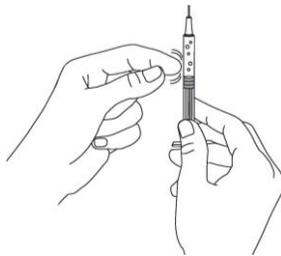


For adults and pediatric patients (children and adolescents) 6 years of age and older, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the amount (volume) of liquid prescribed by your healthcare provider (0.5 mL or 1.0 mL).

For children and adolescents 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your healthcare provider may be less than 0.5 mL. Your healthcare provider will recommend how much liquid is needed.

It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

Remove the needle from the vial. Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



STEP 4: INJECTING 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 is pushed as far as it will go, take out the needle and let go of the skin.

Dispose the Empty Syringe and Vial(s)

Discard any unused portion of STELARA[®] in accordance with local requirements. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of

others, vials, needles and syringes **must NEVER** be re-used. Dispose of sharps container according to your local regulations. Empty vials can be discarded in regular trash.

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 will need to give a second injection right after the first. Use a new needle and syringe. Choose a different site for the second injection.

STEP 5: WHAT TO DO IF YOU FORGET TO USE STELARA®?

If you miss a dose, make the next injection as soon as you remember. Do not double up the injection. If you miss a dose and your psoriasis recurs, call your doctor before taking another injection.

Overdose: Call your doctor if you have used more STELARA® than instructed.

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.

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