

MEDICATION GUIDE
STELARA (stel ar' a)
(ustekinumab)
injection, for subcutaneous or intravenous use

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

STELARA is a medicine that affects your immune system. STELARA can increase your risk of having serious side effects, including:

Serious infections. STELARA may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have serious infections while taking STELARA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses. Some people have to be hospitalized for treatment of their infection.

- Your doctor should check you for TB before starting STELARA.
- 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.
- Your doctor should watch you closely for signs and symptoms of TB while you are being treated with STELARA.

You should not start taking STELARA if you have any kind of infection unless your doctor says it is okay.

Before starting STELARA, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
 - fever, sweat, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal
 - feel very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting STELARA, call your doctor right away if you have any symptoms of an infection (see above). STELARA can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections. These infections can spread throughout the body and cause death. People who take STELARA may also be more likely to get these infections.

Cancers. STELARA may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your doctor if you have ever had any type of cancer. Some people who are receiving STELARA and have risk factors for skin cancer have developed certain types of skin cancers. During your treatment with STELARA, tell your doctor if you develop any new skin growths.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS). RPLS is a rare condition that affects the brain and can cause death. The cause of RPLS is not known. If RPLS is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including:

- headache
- seizures
- confusion
- vision problems

What is STELARA?

STELARA is a prescription medicine used to treat:

- adults and children 12 years and older with moderate or severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults 18 years and older with active psoriatic arthritis. STELARA can be used alone or with the medicine methotrexate.
- adults 18 years and older with moderately to severely active Crohn's disease who have already taken other medicines that did not work well enough or they could not tolerate it.

It is not known if STELARA is safe and effective in children less than 12 years of age.

Do not take STELARA if you are allergic to ustekinumab or any of the ingredients in STELARA. See the end of this Medication Guide for a complete list of ingredients in STELARA.

Before you receive STELARA, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section “**What is the most important information I should know about STELARA?**”
- ever had an allergic reaction to STELARA. Ask your doctor if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can cause serious problems. **You should not receive the BCG vaccine during the one year before receiving STELARA or one year after you stop receiving STELARA.**
- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions. Allergy shots may not work as well for you during treatment with STELARA. STELARA may also increase your risk of having an allergic reaction to an allergy shot.
- receive or have received phototherapy for your psoriasis.
- are pregnant or planning to become pregnant. It is not known if STELARA can harm your unborn baby. You and your doctor should decide if you will receive STELARA. There is a pregnancy registry for women who are treated with STELARA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you are pregnant or become pregnant while receiving STELARA, talk to your doctor about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.
- are breastfeeding or plan to breastfeed. It is thought that STELARA passes into your breast milk in small amounts.
- Talk to your doctor about the best way to feed your baby if you receive STELARA.

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

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

How should I use STELARA?

- Use STELARA exactly as your doctor tells you to.
- **The needle cover on the STELARA prefilled syringe contains latex. Do not handle the needle cover if you are sensitive to latex.**
- Adults with Crohn’s disease will receive the first dose of STELARA through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. It takes at least 1 hour to receive the full dose of medicine. You will then receive STELARA as an injection under the skin (subcutaneous injection) 8 weeks after the first dose of STELARA, as described below.
- Adults with psoriasis or psoriatic arthritis and children 12 years and older with psoriasis will receive STELARA as an injection under the skin (subcutaneous injection) as described below.
- **Injecting STELARA under your skin**
 - STELARA is intended for use under the guidance and supervision of your doctor. In children 12 years and older, it is recommended that STELARA be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA at home, you should receive training on the right way to prepare and inject STELARA. Your doctor will determine the right dose of STELARA for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA yourself until you or your caregiver have been shown how to inject STELARA by your doctor or nurse.
 - Inject STELARA under the skin (subcutaneous injection) in your upper arms, buttocks, upper legs (thighs) or stomach area (abdomen).
 - Do not give an injection in an area of the skin that is tender, bruised, red or hard.
 - Use a different injection site each time you use STELARA.
 - If you inject more STELARA than prescribed, call your doctor right away.
 - Be sure to keep all of your scheduled follow-up appointments.

Read the detailed Instructions for Use at the end of this Medication Guide for instructions about how to prepare and inject a dose of STELARA, and how to properly throw away (dispose of) used needles and syringes. The syringe, needle and vial must never be re-used. After the cap is punctured, STELARA can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused portion of STELARA.

What should I avoid while using STELARA?

You should not receive a live vaccine while taking STELARA. See “**Before you receive STELARA, tell your doctor about all of your medical conditions, including if you:**”

What are the possible side effects of STELARA?

STELARA may cause serious side effects, including:

- See “**What is the most important information I should know about STELARA?**”
- **Serious allergic reactions.** Serious allergic reactions can occur with STELARA. Stop using STELARA and get medical help right away if you have any of the following symptoms of a serious allergic reaction:
 - feeling faint
 - chest tightness
 - swelling of your face, eyelids, tongue, or throat
 - skin rash
- **Lung inflammation.** Cases of lung inflammation have happened in some people who receive STELARA, and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA.

Common side effects of STELARA include:

- upper respiratory infections
- headache
- tiredness
- itching
- vomiting
- vaginal yeast infections
- urinary tract infections
- redness at the injection site

These are not all of the possible side effects of STELARA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Janssen Biotech, Inc. at 1-800 JANSSEN (1-800-526-7736).

How should I store STELARA?

- Store STELARA prefilled syringes in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store STELARA vials standing up straight.
- Store STELARA in the original carton to protect it from light until time to use it.
- Do not freeze STELARA.
- Do not shake STELARA.

Keep STELARA and all medicines out of the reach of children.

General information about the safe and effective use of STELARA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use STELARA for a condition for which it was not prescribed. Do not give STELARA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about STELARA that was written for health professionals.

What are the ingredients in STELARA?

Active ingredient: ustekinumab

Inactive ingredients: **Single-dose prefilled syringe for subcutaneous use** contains L-histidine, L-histidine monohydrochloride monohydrate, Polysorbate 80, and sucrose. **Single-dose vial for subcutaneous use** contains L-histidine, L-histidine hydrochloride monohydrate, Polysorbate 80 and sucrose. **Single-dose vial for intravenous infusion** contains EDTA disodium salt dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, Polysorbate 80, and sucrose.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864

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For more information, go to www.stelarainfo.com or call 1-800-JANSSEN (1-800-526-7736).

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: 06/2018

cp-59524v1

