

MEDICATION GUIDE
STARJEMZA™ (star jem' zah)
(ustekinumab-hmny)
injection, for subcutaneous or intravenous use

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

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

Serious infections. STARJEMZA 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 ustekinumab products, 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 STARJEMZA.
- If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with STARJEMZA and during treatment with STARJEMZA.
- Your doctor should watch you closely for signs and symptoms of TB while you are being treated with STARJEMZA. You should not start taking STARJEMZA if you have any kind of infection unless your doctor says it is okay.

Before starting STARJEMZA, 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 or have any open cuts.
- 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 STARJEMZA, call your doctor right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. STARJEMZA 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 STARJEMZA may also be more likely to get these infections.

Cancers. STARJEMZA 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 ustekinumab products and have risk factors for skin cancer have developed certain types of skin cancers. During your treatment with STARJEMZA, tell your doctor if you develop any new skin growths.

Posterior Reversible Encephalopathy Syndrome (PRES). PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES 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 STARJEMZA?

STARJEMZA is a prescription medicine used to treat:

- adults and children 6 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 and children 6 years and older with active psoriatic arthritis.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

It is not known if STARJEMZA is safe and effective in children less than 6 years of age.

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

Before you receive STARJEMZA, 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 STARJEMZA?”**
- ever had an allergic reaction to ustekinumab products. 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 STARJEMZA 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 STARJEMZA or one year after you stop receiving STARJEMZA.**
- 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 STARJEMZA. STARJEMZA 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 plan to become pregnant. It is not known if STARJEMZA can harm your unborn baby. You and your doctor should decide if you will receive STARJEMZA. See “What should I avoid while using STARJEMZA?”
- received STARJEMZA while you were pregnant. It is important that you tell your baby’s healthcare provider before any vaccinations are given to your baby.
- are breastfeeding or plan to breastfeed. STARJEMZA can pass into your breast milk.
- Talk to your doctor about the best way to feed your baby if you receive STARJEMZA.

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 STARJEMZA?

- Use STARJEMZA exactly as your doctor tells you to.
- **The needle cover on the STARJEMZA prefilled syringe contains latex. Do not handle the needle cover if you are sensitive to latex.**
- Adults with Crohn’s disease and ulcerative colitis will receive the first dose of STARJEMZA 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 STARJEMZA as an injection under the skin (subcutaneous injection) 8 weeks after the first dose of STARJEMZA, as described below.
- Adults with psoriasis or psoriatic arthritis, and children 6 years and older with psoriasis or psoriatic arthritis will receive STARJEMZA as an injection under the skin (subcutaneous injection) as described below.
- **Injecting STARJEMZA under your skin**
 - STARJEMZA is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that STARJEMZA be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STARJEMZA at home, you should receive training on the right way to prepare and inject STARJEMZA. Your doctor will determine the right dose of STARJEMZA for you, the amount for each injection, and how often you should receive it. Do not try to inject STARJEMZA yourself until you or your caregiver have been shown how to inject STARJEMZA by your doctor or nurse.
 - Inject STARJEMZA 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 STARJEMZA.
 - If you inject more STARJEMZA 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 STARJEMZA, and how to properly throw away (dispose of) used needles and syringes. The syringe, needle and vial must never be re-used. After the rubber stopper is punctured, STARJEMZA can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused portion of STARJEMZA.

What should I avoid while using STARJEMZA?

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

What are the possible side effects of STARJEMZA?

STARJEMZA may cause serious side effects, including:

- See **“What is the most important information I should know about STARJEMZA?”**
- **Serious allergic reactions.** Serious allergic reactions can occur with STARJEMZA. Stop using STARJEMZA 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 ustekinumab products, 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 STARJEMZA.

Common side effects of STARJEMZA include:

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| • nasal congestion, sore throat, and runny nose | • redness at the injection site |
| • upper respiratory infections | • vaginal yeast infections |
| • fever | • urinary tract infections |
| • headache | • sinus infection |
| • tiredness | • bronchitis |
| • itching | • diarrhea |
| • nausea and vomiting | • stomach pain |

These are not all of the possible side effects of STARJEMZA. 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 Hikma Pharmaceuticals USA Inc. at 1-877-845-0689.

How should I store STARJEMZA?

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

If needed, individual STARJEMZA prefilled syringe may also be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. Discard the prefilled syringe if not used within 30 days at room temperature storage.

An individual 45 mg vial may be stored at room temperature, up to 25°C (77°F) out of the original carton for up to 8 hours. After filling STARJEMZA into the syringe with attached needle, the filled syringe with needle can be stored at up to 25°C (77°F) for up to 4 hours before injection. Once the prefilled syringe or the 45 mg vial has been stored at room temperature, it should not be returned to the refrigerator. Do not use STARJEMZA after the expiration date on the carton or on the prefilled syringe or on the 45 mg vial.

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

General information about the safe and effective use of STARJEMZA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use STARJEMZA for a condition for which it was not prescribed. Do not give STARJEMZA 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 STARJEMZA that was written for health professionals.

What are the ingredients in STARJEMZA?

Active ingredient: ustekinumab-hmny

Inactive ingredients: **Single-dose prefilled syringe for subcutaneous use** contains histidine, L-histidine hydrochloride monohydrate, polysorbate 80, and sucrose. **Single-dose vial for subcutaneous use** contains histidine, L-histidine hydrochloride monohydrate, polysorbate 80 and sucrose. **Single-dose vial for intravenous infusion** contains edetate disodium, histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 80, and sucrose.

Manufactured by: Bio-Thera Solutions, Ltd., 155 Yaotianhe Street, Huangpu District, Guangzhou, Guangdong, China 511356

Distributed by: Hikma Pharmaceuticals USA Inc., Berkeley Heights, NJ 07922

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For more information, go to www.hikma.com or call 1-877-845-0689.

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

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