

MEDICATION GUIDE
Ustekinumab (yü-stə-kin-ü-mab)
injection, for subcutaneous or intravenous use

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

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

- **Serious infections.** Ustekinumab may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have serious infections during treatment with Ustekinumab, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses. Some people have to be hospitalized for treatment of their infection.
 - Your healthcare provider should check you for TB before starting Ustekinumab.
 - If your healthcare provider feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Ustekinumab and during treatment with Ustekinumab.
 - Your healthcare provider should watch you closely for signs and symptoms of TB while you are being treated with Ustekinumab.

You should not start Ustekinumab if you have any kind of infection unless your healthcare provider says it is okay.

Before starting Ustekinumab, tell your healthcare provider 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 Ustekinumab, call your healthcare provider right away if you get 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. Ustekinumab 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 Ustekinumab may also be more likely to get these infections.
- **Cancers.** Ustekinumab may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your healthcare provider if you have ever had any type of cancer. Some people who are receiving Ustekinumab and have risk factors for skin cancer have developed certain types of skin cancers. During your treatment with Ustekinumab, tell your healthcare provider if you develop any new skin growths.

What is Ustekinumab?

Ustekinumab is a prescription medicine used to treat:

- adults and children 6 years of age and older with moderate to severe plaque 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 of age and older with active psoriatic arthritis.
- adults and children 2 years of age and older with moderately to severely active Crohn's disease.
- adults and children 2 years of age and older with moderately to severely active ulcerative colitis.

It is not known if Ustekinumab is safe and effective in children less than 2 years of age with Crohn's disease, in children less than 2 years of age with ulcerative colitis or in children less than 6 years of age with plaque psoriasis or psoriatic arthritis.

Who should not use Ustekinumab?

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

Before you use or receive Ustekinumab, tell your healthcare provider 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 Ustekinumab?"**
- ever had an allergic reaction to Ustekinumab. Ask your healthcare provider 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 are being treated with Ustekinumab should avoid receiving live vaccines. Tell your healthcare provider 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 avoid receiving the BCG vaccine during the 1 year before receiving Ustekinumab or 1 year after you stop receiving Ustekinumab.**

- 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 Ustekinumab. Ustekinumab may also increase your risk of having an allergic reaction to an allergy shot.
- receive or have received phototherapy for your psoriasis.
- 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 that may be triggered by some tick bites).
- are pregnant or plan to become pregnant. It is not known if Ustekinumab can harm your unborn baby. You and your healthcare provider should decide if you will receive Ustekinumab.
- are breastfeeding or plan to breastfeed. Ustekinumab can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive Ustekinumab.

Tell your healthcare provider 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 healthcare provider and pharmacist when you get a new medicine.

How should I use Ustekinumab?

- Use Ustekinumab exactly as the healthcare provider tells you to. The healthcare provider will determine the right dose of Ustekinumab, the amount for each injection, and how often it should be given. Be sure to keep all scheduled follow-up appointments.
- **The needle cover on the Ustekinumab prefilled syringe contains latex. Do not handle the needle cover if you are sensitive to latex.**
- Adults and children 2 years of age and older with Crohn's disease and ulcerative colitis will receive the first dose of Ustekinumab 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. Ustekinumab will then be received as an injection under the skin (subcutaneous injection) 8 weeks after the first dose of Ustekinumab, as described below.
- Adults and children 6 years of age and older with plaque psoriasis or psoriatic arthritis will receive Ustekinumab as an injection under the skin as described below.
- **Injecting Ustekinumab under the skin**
 - Ustekinumab is intended for use under the guidance and supervision of a healthcare provider.
 - In children, it is recommended that Ustekinumab be administered by a healthcare provider. If a healthcare provider decides that you or a caregiver may give the injections of Ustekinumab at home, you or a caregiver should receive training on the right way to prepare and inject Ustekinumab.
 - Do not try to inject Ustekinumab until you have been shown how to inject Ustekinumab by a healthcare provider.
 - Ustekinumab can be injected under the skin in the 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 Ustekinumab.

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

What should I avoid while using Ustekinumab?

You should avoid receiving a live vaccine during treatment with Ustekinumab. See **"Before you use or receive Ustekinumab, tell your healthcare provider about all of your medical conditions, including if you:"**

What are the possible side effects of Ustekinumab?

Ustekinumab may cause serious side effects, including:

- See **"What is the most important information I should know about Ustekinumab?"**
- **Serious allergic reactions.** Serious allergic reactions including death can occur with Ustekinumab. Stop using Ustekinumab and get medical help right away if you get any of the following symptoms of a serious allergic reaction:
 - feeling faint
 - swelling of your face, eyelids, tongue, or throat
 - chest discomfort
 - trouble breathing
 - skin rash

- **Posterior Reversible Encephalopathy Syndrome (PRES).** PRES is a rare condition that affects the brain and can cause death. Tell your healthcare provider right away if you get any symptoms of PRES during treatment with Ustekinumab, including:
 - headache
 - confusion
 - seizures
 - vision problems
- **Lung inflammation.** Cases of lung inflammation have happened in some people who receive Ustekinumab and may be serious. These lung problems may need to be treated in a hospital. Tell your healthcare provider right away if you develop shortness of breath or a cough that doesn't go away during treatment with Ustekinumab.

The most common side effects of Ustekinumab 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 |
| • influenza | • joint pain |

These are not all of the possible side effects of Ustekinumab. 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 1-800-526-7736.

How should I store Ustekinumab?

- Store Ustekinumab vials and prefilled syringes in a refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- Store Ustekinumab vials standing up straight (upright).
- Store Ustekinumab in the original carton to protect it from light until time to use it.
- Do not freeze Ustekinumab.
- Do not shake Ustekinumab.
- If needed, individual Ustekinumab prefilled syringes 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.
- After a prefilled syringe has been stored at room temperature, do not return it to the refrigerator.
- Throw away (discard) the prefilled syringe if it is not used within 30 days at room temperature storage.
- Do not use Ustekinumab after the expiration date on the carton or on the prefilled syringe.

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

General information about the safe and effective use of Ustekinumab.

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

What are the ingredients in Ustekinumab?

Active ingredient: ustekinumab

Inactive ingredients: **Single-dose prefilled syringe and single-dose vial for subcutaneous use** contain L-histidine, L-histidine monohydrochloride 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, USA. U.S. License No. 1864

For patent information: www.janssenpatents.com

For more information call 1-800-526-7736.

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

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