

[Home](#)

2. Ustekinumab

Ustekinumab

Pronunciation: YOO sti KIN ue mab**Generic name:** Ustekinumab**Brand names:** [Stelara](#), [Wezdana](#), [Imuldosa](#), [Otulfi](#), [Pyzchiva](#), ... [show all 8 brands](#)**Dosage form:** injection for subcutaneous use, intravenous infusion**Drug class:** [Interleukin inhibitors](#)Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Feb 4, 2025.[Uses](#) [Side effects](#) [Warnings](#) [Before taking](#) [Dosage](#) [Interactions](#) [FAQ](#)

What is ustekinumab?

Ustekinumab injection is used to treat [plaque psoriasis](#), [ulcerative colitis](#), [Crohn's disease](#), and [psoriatic arthritis](#), which are autoimmune disorders. **Ustekinumab injection works by** blocking proteins (IL-12 and IL-23) which are part of the immune system, this helps reduce inflammation, pain, swelling, and skin symptoms in these conditions.

Ustekinumab's mechanism of action (MOA) is an [interleukin inhibitor](#) that targets and blocks proteins IL-12 (interleukin-12) and IL-23 (interleukin-23) in the immune system, which improves symptoms in these conditions.

Ustekinumab is usually given as an injection under the skin (subcutaneous injection) for most doses except initial doses for Crohn's disease and ulcerative colitis which is given as an infusion into a vein (intravenous infusion). Ustekinumab maintenance dose is every 8 to 12 weeks, depending on the condition being treated.

Ustekinumab injection FDA approval was first granted on September 25, 2009, under the brand name Stelara. Since then, FDA approval has been received for ustekinumab biosimilars and an interchangeable biosimilar.

What is ustekinumab used for?

Ustekinumab injection used to treat:

- **moderate or severe psoriasis** (patients 6 years and older)*
- **psoriatic arthritis** (patients 6 years and older)
- **Crohn's disease that is** moderately to severely active (patients 18 years and older)
- **ulcerative colitis** that is moderate to severely active (patients 18 years and older).

*For moderate or severe psoriasis, you will only be prescribed if your doctor believes your psoriasis will be improved by taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).his medicine

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

Ustekinumab biosimilars and brand names

Ustekinumab brand names are [Stelara](#), [Wezlana](#), [Selarsdi](#), [Pyzchiva](#), [Otulfi](#), [Imuldosa](#), [Yesintek](#), [Steqeyma](#).

Ustekinumab reference product. The first brand of ustekinumab FDA-approved was Stelara which is called the reference product. Since then other brands of ustekinumab have been approved.

Ustekinumab biosimilars:

- **Wezlana is an interchangeable biosimilar of Stelara (ustekinumab)** which means it may be dispensed when the prescription has been written for Stelara without consulting the prescriber, subject to state laws.
- **Ustekinumab biosimilars** are Selarsdi, Pyzchiva, Otulfi, Imuldosa, Yesintek, and Steqeyma.

Ustekinumab side effects

Common ustekinumab side effects

Common ustekinumab side effects may include

- [Itching](#) (2%)
- [Muscle pain](#) (1%)
- Tiredness - fatigue (3%)
- [Headache](#) (5%)
- Backpain (1%)
- [Dizziness](#) (1%)
- Pharyngolaryngeal pain (1%)
- Injection site redness (1%)
- Flu or cold-like symptoms - nasopharyngitis (8%)
- [Upper respiratory tract infection](#) URTI (5%).

The common side effects listed above were experienced by 1% or more of patients treated with ustekinumab (45 mg every 12 weeks) for plaque psoriasis during clinical trials PS STUDY 1 and PS STUDY 2.

Common ustekinumab injection side effects when used for Crohn's disease include:

- Flu or cold-like symptoms - nasopharyngitis (11%)
- Injection site redness (5%)
- [Vaginal yeast infections](#) (5%)
- [Bronchitis](#) (5%)
- [Itchy skin](#) (4%)
- [Urinary tract infection - UTI](#) (4%)

- Sinusitis (3%).

The side effects of ustekinumab for Crohn's disease occurred in 3% or more of patients receiving a maintenance dose of 90 mg (given as a subcutaneous injection every 8 weeks) during clinical trial CD-3.

Common ustekinumab side effects when used for ulcerative colitis include:

- Flu or cold-like symptoms - nasopharyngitis (24%)
- Headache (10%)
- Stomach pain (7%)
- Influenza (6%)
- Fever (5%)
- Diarrhea (4%)
- Sinusitis (4%)
- Tiredness - fatigue (4%)
- Nausea (3%).

Side effects of ustekinumab for ulcerative colitis occurred in 3% or more of patients receiving a weight-based maintenance dose during clinical trial UC-2.

Ustekinumab side effects vary according to the condition being treated.

Serious ustekinumab side effects

Serious side effects of ustekinumab injection include allergic reactions, serious infections, cancers, and posterior reversible encephalopathy syndrome (PRES).

Allergic reactions Get emergency medical help if you have signs of an allergic reaction to Stelara: hives, chest pain, difficulty breathing, feeling light-headed, swelling of your face, lips, tongue, or throat.

Serious infections may occur during treatment with Stelara. Call your doctor right away if you have signs of infection such as fever, chills, muscle pain, shortness of breath, weight loss, diarrhea or stomach pain, burning when you urinate, feeling very tired, skin warmth or redness, painful skin sores, or coughing up blood.

Also, call your doctor at once if you have symptoms of serious side effects, including:

- a mole that has changed in size or color;
- swelling, pain, warmth, or redness anywhere on your body;
- stomach pain that is sudden and severe or comes on slowly, changes in bowel habits (diarrhea or constipation);
- new or worsening cough, sudden chest pain, feeling short of breath;
- pain or burning when you urinate; or
- severe headache, confusion, change in mental status, vision problems, and/or seizure (convulsions).

Also, see the Warnings section.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.

 [Ustekinumab side effects](#) (more detail)

Related/similar drugs

Otezla

Otezla (apremilast) is used to treat plaque psoriasis, psoriatic arthritis, and oral ulcers ...

Reviews & ratings

5.2 / 10

[439 Reviews](#)

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Skyrizi

Skyrizi (risankizumab) is used to treat plaque psoriasis, psoriatic arthritis, ulcerative colitis ...

Reviews & ratings

7.9 / 10

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Entyvio

Entyvio (vedolizumab) is used to treat ulcerative colitis (UC) and Crohn's disease, reducing ...

Reviews & ratings

6.2 / 10

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OmvoH

OmvoH is used to treat moderate to severe ulcerative colitis or Crohn's disease in adults. This ...

Reviews & ratings

[1 Reviews](#)

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Xeljanz

Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor that may be used alone or with other ...

Reviews & ratings

5.7 / 10

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Rinvoq

Rinvoq (upadacitinib) is used to treat rheumatoid arthritis, psoriatic arthritis, atopic ...

Reviews & ratings

7.0 / 10

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Humira

Humira is a tumor necrosis factor blocker that is used to treat many inflammatory conditions such ...

Reviews & ratings

6.4 / 10

[698 Reviews](#)

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Prednisolone

Prednisolone is used to treat many different inflammatory conditions such as arthritis, lupus, and ...

Reviews & ratings

6.4 / 10

[48 Reviews](#)

[View more](#)

Hydrocortisone topical

Hydrocortisone cream is used to treat eczema, dermatitis, psoriasis, hemorrhoids, insect bites or ...

Reviews & ratings

7.0 / 10

[63 Reviews](#)

[View more](#)

Warning

You should not use this medicine if you have received a vaccine to prevent tuberculosis (BCG vaccine) within 1 year before using ustekinumab while using it, or 1 year after you have finished treatment. Before you start treatment with this medicine your doctor may perform tests to make sure you do not have [tuberculosis](#).

When you are being treated with ustekinumab, it can make you more likely to get infections or make an infection that you have worse. Call your doctor right away if you have signs of infection, including fever, chills, muscle pain, shortness of breath, [weight loss](#), [diarrhea](#) or stomach pain, burning when you urinate, feeling very tired, skin warmth or redness, painful skin sores, or coughing up blood.

Ustekinumab may also cause a rare but serious condition affecting the brain. Tell your doctor right away if you have a headache, confusion, vision problems, or a seizure

Before taking this medicine

You should not use ustekinumab injection or infusion if you:

- are allergic to the active ingredient ustekinumab or any of the inactive ingredients contained in the medicine.
- have active tuberculosis; or
- have received a BCG (Bacillus Calmette and Guérin) vaccine within the past 12 months.

Tell your doctor if you have ever had [tuberculosis](#), if anyone in your household has tuberculosis, or if you have recently traveled to an area where tuberculosis is common.

To make sure ustekinumab is safe for you, tell your doctor if you have:

- signs of infection (fever, chills, cough, muscle aches, painful skin sores, diarrhea, pain when you urinate, feeling very tired)
- chronic infections
- new or changing skin lesions
- a latex allergy as the needle cover on the prefilled syringe contains latex
- phototherapy (light therapy)
- allergy shots

- if you recently received or are scheduled to receive any vaccine, people who take this medicine 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.

Some people using this medicine have developed [skin cancer](#) (non-melanoma). However, these people may have had a higher risk of skin cancer. Talk to your doctor about this risk and what skin symptoms to watch for. You may need to have regular skin exams.

Pregnancy

It is **not** known whether this medicine will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant, your name may be listed on a pregnancy registry to track the effects of ustekinumab on the baby.

Breastfeeding

It may **not** be safe to breastfeed while using this medicine. It is thought that ustekinumab passes into your breast milk in small amounts. Talk to your doctor about the best way to feed your baby if you receive this medicine.

i [Ustekinumab pregnancy and breastfeeding warnings](#) (more detail)

How will I receive ustekinumab?

If you have psoriasis, you will be given ustekinumab as an injection under the skin (subcutaneous injection). Once you have had your first injection, you will have your next injection after 4 weeks, and from then on you will have an injection every 12 weeks.

If you have Crohn's disease or ulcerative colitis, your first dose is given slowly as an infusion into a vein by your doctor or nurse. The next doses you have will be every 8 weeks as an injection under the skin (subcutaneous injection).

You will be able to inject yourself or have a caregiver give you your injection once you have been shown how to do this by your doctor or nurse.

The dose your healthcare provider will give you will depend on how much you weigh and whether you have psoriasis, Crohn's disease or ulcerative colitis.

How to use ustekinumab injection

- Inject ustekinumab 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 ustekinumab.
- If you inject more ustekinumab than prescribed, call your doctor right away.
- Be sure to keep all of your scheduled follow-up appointments.

i [Detailed Ustekinumab dosage information](#)

What happens if I miss a dose?

Call your doctor for instructions if you miss a dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What other drugs will affect ustekinumab?

Other drugs may interact with ustekinumab, including prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Tell your doctor about all your current medicines and any medicine you start or stop using. Not all possible interactions are listed here.

i [Ustekinumab drug interactions](#) (more detail)

Does ustekinumab interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

+

Add

Storage

Stelara vials and prefilled syringes

- Refrigerate at 2°C to 8°C (36°F to 46°F).
- Store ustekinumab vials upright.
- Keep the product in the original carton to protect it from light until the time of use.
- Do not freeze.
- Do not shake.

Ingredients

Active ingredient: ustekinumab

Inactive ingredients:

Stelera:

Single-dose prefilled syringe for subcutaneous use: 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.

Selarsdi:

Inactive ingredients (**single-dose prefilled syringe for SC use**): histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.

Inactive ingredients (**single-dose vial for intravenous infusion**): edetate disodium, histidine, L-histidine monohydrochloride monohydrate, methionine, polysorbate 80, sucrose, and water for injection.

Selarsdi is available as a 45 mg/0.5 mL single-dose prefilled syringe and a 90 mg/mL single-dose prefilled syringe.

Selarsdi is also available as a 130 mg/26 mL (5 mg/mL) solution in a single-dose vial for intravenous infusion.

Imuldosa

Inactive ingredients (**single-dose prefilled syringe for subcutaneous use**): histidine, histidine hydrochloride monohydrate, polysorbate 80, and sucrose.

Inactive ingredients (**single-dose vial for intravenous infusion**): edetate disodium, histidine, histidine hydrochloride monohydrate, methionine, polysorbate 80, and sucrose.

Imuldosa is available as a 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe for SC use.

Imuldosa is also available as a 130 mg/26 mL (5 mg/mL) solution in a single-dose vial for intravenous infusion.

Otulfi

Inactive ingredients (**single-dose prefilled syringe for subcutaneous use**): histidine, polysorbate 80, sucrose and hydrochloric acid (to adjust pH).

Inactive ingredients (**single-dose vial for intravenous infusion**): edetate disodium, histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 80, and sucrose.

Otulfi is available as a 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe for SC use.

Otulfi is also available as a 130 mg/26 mL (5 mg/mL) solution in a single-dose vial for intravenous infusion.

Pyzchiva

Inactive ingredients (**single-dose prefilled syringe for subcutaneous use**): histidine, histidine hydrochloride monohydrate, polysorbate 80, and sucrose.

Inactive ingredients (**single-dose vial for intravenous infusion**): edetate disodium, histidine, histidine hydrochloride monohydrate, methionine, polysorbate 80, and sucrose.

Pyzchiva is available as a 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe for SC use.

Pyzchiva is available as a 130 mg/26 mL (5 mg/mL) solution in a single-dose vial for intravenous infusion.

Wezlana

Inactive ingredients (**single-dose prefilled syringe for subcutaneous use**): histidine, histidine hydrochloride

monohydrate, Polysorbate 80, and sucrose.

Inactive ingredients (**single-dose vial for subcutaneous use**): histidine, histidine hydrochloride monohydrate, Polysorbate 80, and sucrose.

Inactive ingredients (**single-dose vial for intravenous infusion**) edetate disodium, histidine, histidine hydrochloride monohydrate, methionine, Polysorbate 80, and sucrose.

Yesintek

Inactive ingredients (**single-dose prefilled syringe for subcutaneous use**): histidine, L-histidine monohydrochloride monohydrate, Polysorbate 80, and sucrose. Hydrochloric acid and sodium hydroxide added to adjust the pH.

Inactive ingredients (**single-dose vial for subcutaneous use**): histidine, L-histidine hydrochloride monohydrate, Polysorbate 80, and sucrose. Hydrochloric acid and sodium hydroxide are added to adjust the pH.

Inactive ingredients (**single-dose vial for intravenous infusion**): edetate disodium, histidine, L-histidine hydrochloride monohydrate, methionine, Polysorbate 80, and sucrose. Hydrochloric acid and sodium hydroxide are added to adjust the pH.

Steqeyma

Inactive ingredients (**single-dose prefilled syringe for subcutaneous use**): histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, and Water for Injection.

Inactive ingredients (**single-dose vial for intravenous infusion**): edetate disodium, histidine, L-histidine monohydrochloride monohydrate, methionine, polysorbate 80, sucrose, and Water for Injection.

Company

Stelara: Janssen Biotech, Inc.

Selarsdi: Alvotech and Teva Pharmaceutical Industries.

Steqeyma: Celltrion Inc.

Imuldosa: Dong-A ST and Meiji Seika Pharma.

Otulf: Fresenius Kabi.

Pyzchiva: Samsung Bioepis Co., Ltd., makes Pyzchiva for Sandoz Inc.

Wezlana: Amgen, Inc.

Yesintek: Biocon Biologics Inc.

Ustekinumab Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for ustekinumab.

Stelara (ustekinumab) - Janssen Biotech, Inc.



Formulation type	Strength
Pre-Filled Syringe	45 mg/0.5 mL
Pre-Filled Syringe	90 mg/mL
Single-Dose Vial	130 mg/26 mL (5 mg/mL)
Single-Dose Vial	45 mg/0.5 mL
Single-Dose Vial	90 mg/mL Discontinued

View [Stelara](#) information in detail.

Stelara interchangeable products

Interchangeable biosimilar products can be dispensed by a pharmacist without the intervention of the prescriber of the reference product.

Pharmacy laws for biosimilar prescribing may vary by state.

Wezlana (ustekinumab-auub) - Amgen Inc.



Stelara biosimilar products

Biosimilar products can only be dispensed in place of the **reference product** if the healthcare provider specifically prescribes the biosimilar product by name.

Pharmacy laws for biosimilar prescribing may vary by state

Imuldosa (ustekinumab-srlf) - Accord BioPharma Inc.



Otulfi (ustekinumab-aaaz) - Fresenius Kabi USA, LLC



Pyzchiva (ustekinumab-ttwe) - Samsung Bioepis Co., Ltd.



Selarsdi (ustekinumab-aekn) - Alvotek USA Inc.



Steqeyma (ustekinumab-stba) - CELLTRION, Inc.



Wezlana (ustekinumab-auub) - Amgen Inc.



Yesintek (ustekinumab-kfce) - Biocon Biologics Inc.



Popular FAQ

Do I qualify for the Stelara copay card, how much can I save?



What is the mechanism of action of Stelara and how does it work?



More FAQ

- [What are the new drugs for plaque psoriasis?](#)
- [What biosimilars have been approved in the United States?](#)
- [How quickly or how long before Stelara starts to work?](#)
- [How long can you keep Stelara in or out of the fridge?](#)
- [Can you get a flu shot or take antibiotics while on Stelara?](#)
- [How is Stelara injected or administered?](#)
- [What blood tests are needed for Stelara?](#)

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References

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2. [Food and Drug Administration \(FDA\) Stelara Product Label](#)
3. [Wezlana Prescribing Information](#)
4. [Steqeyma Package Insert](#)
5. [Ustekinumab-AEKN Package Insert](#)
6. [Imuldosa Prescribing Information](#)
7. [Pyzchiva Prescribing Information](#)
8. [Otulfi prescribing Information](#)
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11. [Alice Gottlieb and Kirti Narang. Ustekinumab in the treatment of psoriatic arthritis: latest findings and clinical potential. Ther Adv Musculoskelet Dis. 2013 Oct; 5\(5\): 277–285.](#)
12. [Selarsdi Package Insert](#)

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- [Compare alternatives](#)
- [Reviews \(268\)](#)

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Patient resources

- [Ustekinumab-auub advanced reading](#)

Other brands

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Professional resources

- [Ustekinumab monograph](#)
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- [Crohn's Disease, Active](#)
- [Plaque Psoriasis](#)
- [Psoriasis](#)

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.


[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only

[Pregnancy & Lactation](#)

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



User Reviews & Ratings

7.5 / 10

[268 Reviews](#)

Images

[Stelara \(ustekinumab\) 45 mg/0.5 mL single-dose prefilled syringe](#)



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