



[Home](#)

2. Stelara

# Stelara

**Pronunciation:** *stel-ar'-a*

**Generic name:** [ustekinumab](#) [ YOO-sti-KIN-ue-mab ]

**Dosage form:** subcutaneous injection (prefilled syringe, vial), intravenous Infusion (vial)

**Drug class:** [Interleukin inhibitors](#)

Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Mar 26, 2025.

[Uses](#)   [Side effects](#)   [Warnings](#)   [Before taking](#)   [Dosage](#)   [Interactions](#)   [FAQ](#)

## What is Stelara?

Stelara (ustekinumab) is used to treat types of [Crohn's disease](#), [plaque psoriasis](#), [psoriatic arthritis](#), and [ulcerative colitis](#), which are all autoimmune conditions. Stelara injection is an [interleukin inhibitor](#) that works by blocking certain proteins in your body called IL-12 (interleukin-12) and IL-23 (interleukin-23) that cause inflammation in these autoimmune conditions. Stelara works by blocking the activity of IL-12 and IL-23, which reduces inflammation, pain, swelling, and skin symptoms that you may have.

Stelara is usually given as an injection under the skin (subcutaneous injection), and Stelara infusion is given into a vein, for the first dose for Crohn's disease and ulcerative colitis.

Stelara was first FDA-approved on September 25, 2009, for adults with moderate to severe psoriasis, and since then, approval has been extended to include other conditions. Stelara Crohns disease FDA approval was on Sept. 26, 2016.

Stelara is a biologic medicine and was the first brand of [ustekinumab](#) to be FDA-approved, so it is called the reference product. An interchangeable Stelara biosimilar is available called [Wezlana](#). Other Stelara biosimilars (not interchangeable) are [Pyzchiva](#), [Selarsdi](#), [Imuldosa](#), [Otulfi](#) , [Yesintek](#), and [Steqeyma](#). See [ustekinumab](#) for an overview of all the ustekinumab biosimilars.

## What is Stelara used for?

**Stelara is FDA-approved to treat:**

- Crohn's disease (moderately to severely active) in adults.
- Plaque psoriasis (moderate to severe) in patients 6 years and older who are candidates for phototherapy or systemic therapy.
- Psoriatic arthritis (active) in patients 6 years and older.
- Ulcerative colitis (moderately to severely active ) in adults.

**Crohn's** disease is often written as **Crohns** disease.

## Stelara side effects

### Common Stelara side effects

Common Stelara 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 Stelara (45 mg every 12 weeks) for plaque psoriasis during clinical trials PS STUDY 1 and PS STUDY 2.

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

Stelara side effects vary according to the condition being treated.

## Serious Stelara side effects

Serious side effects of Stelara 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.

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

## Related/similar drugs

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# Stelara's mechanism of action

**Stelara mechanism of action (MOA) is as an [interleukin inhibitor](#) (interleukin-12 and interleukin-23 agonist).**

Stelara works by targeting immune system proteins called interleukin (IL)-12 and IL-23, which are thought to contribute to long-lasting inflammation in conditions like Crohn's disease, plaque psoriasis, psoriatic arthritis, and ulcerative colitis. By blocking interleukin Stelara helps reduce inflammation and relieve symptoms of these conditions.

## Warnings

You should not use this medicine if you have received a BCG (Bacillus Calmette and Guérin) vaccine within 1 year prior to, during, or 1 year following treatment.

Before you start treatment with this injection, your doctor may perform tests to make sure you do not have [tuberculosis](#).

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.

Ustekinumab may also cause a rare but serious condition affecting the brain called Posterior Reversible Encephalopathy Syndrome (PRES). Tell your doctor right away if you have a headache, confusion, vision problems, or a seizure.

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

## Before taking this medicine

You should **not** use Stelara injection or infusion if you:

- are allergic to the active ingredient ustekinumab or any of the inactive ingredients contained in the medicine. See the full list of Stelara ingredients at the bottom of this page.
- 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 Stelara 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 Stelara 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.

 [Stelara pregnancy and breastfeeding warnings](#) (more detail)

## How should I use Stelara?

Before you start treatment with this medicine, your doctor may perform tests to make sure you do not have tuberculosis or other infections.

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed. Stelara is intended for use under the guidance and supervision of your doctor. Prepare your injection only when you are ready to give it. Do not use if the medicine looks cloudy, has changed colors, or has particles in it. Call your pharmacist for new medicine.

For Stelara Crohn's disease and ulcerative colitis the first dose is given through a vein in the arm (intravenous infusion) in a healthcare facility by your healthcare provider. It takes at least 1 hour to receive the infusion. Your next doses will be given as an injection under the skin (subcutaneous injection).

Psoriasis or psoriatic arthritis Stelara is given as an injection under the skin (subcutaneous injection) as described below.

Injecting Stelara under your skin

- In children 6 years and older, it is recommended that this medicine be administered by a healthcare provider.
- If your doctor decides that you or a caregiver may give your injections at home, you should receive training on the right way to prepare and inject Stelara.
- Your doctor will determine the right dose for you, the amount for each injection, and how often you should receive it. Your dose needs may change if you gain or lose weight.
- Do not try to inject yourself unless you or your caregiver have been shown how to use it by your doctor or nurse.
- Inject Stelara under the skin 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 this medicine.
- Use a needle and syringe only once and then place them in a puncture-proof "sharps" container. Follow state or local laws about how to dispose of this container. Keep it out of the reach of children and pets.
- Be sure to keep all of your scheduled follow-up appointments.

 [Stelara patient tips](#) (more detail)

## Stelara Dosing information

Stelara dose in psoriasis and psoriatic arthritis dose is given as a subcutaneous injection initially and 4 weeks later, then a dose is given every 12 weeks.

For Stelara Crohn's disease and ulcerative colitis the first dose is given as an infusion, then it is given as a subcutaneous injection every 8 weeks thereafter.

The dose is dependent on the patient's weight.

 [Detailed Stelara dosage information](#)

## Stelara Dosage Forms and Strengths

### Subcutaneous Injection

- single-dose prefilled syringe 45 mg/0.5 mL or 90 mg/mL
- single-dose vial 45 mg/0.5 mL

### Intravenous Infusion

- single-dose vial 130 mg/26 mL (5 mg/mL)

## 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 should I avoid while using Stelara?

Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.

Do not receive a "live" vaccine while using this medicine, and avoid coming into contact with anyone who has recently received a live vaccine. There is a chance that the virus could be passed on to you. Live vaccines include measles, mumps, rubella (MMR), rotavirus, typhoid, yellow fever, varicella (chickenpox), zoster (shingles), and nasal flu (influenza) vaccine.

BCG vaccine should not be given for at least 1 year after you receive your last dose of Stelara.



Non-live vaccines (including flu shots) may not work as well during your treatment, and may not fully protect you from disease. Make sure you are current on all vaccines before you begin treatment with this medicine.

## What other drugs will affect Stelara?

Other drugs may interact with Stelara, 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.

It is important to tell your doctor if you are taking any of the following:

- anticoagulants (blood thinners) such as warfarin (Coumadin, Jantoven)
- medications that suppress the immune system such as azathioprine (Azasan, Imuran), cyclosporine (Gengraf, Neoral, Sandimmune), methotrexate (Otrexup, Rasuvo, Trexall, Xatmep), sirolimus (Rapamune), and tacrolimus (Astagraf, Envarsus, Prograf)
- oral steroids such as dexamethasone (Hemady), methylprednisolone (Medrol), and prednisone (Rayos).

Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Not all possible interactions are listed here.

 [Stelara drug interactions](#) (more detail)

## Does Stelara interact with my other drugs?

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

Stelara

+

Enter a drug name

Add

## Stelara Package Insert

The [Stelara Package Insert](#) contains for more detailed information about this medicine, including Indications and Usage, Dosage and Administration, Adverse Reactions, Clinical Pharmacology, Clinical Studies, Drug Interactions, and more. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

The Package Insert is sometimes called Stelara Prescribing Information (PI) or the FDA label.

## Stelara and Medicare

Because of the prescription drug law, known as the Inflation Reduction Act, Medicare is able to negotiate directly with drug companies to improve access to some of the costliest single-source brand-name Medicare Part B and Part D drugs.

Stelara is one of 10 drugs covered under Medicare Part D that were selected in 2024 for the first cycle of negotiation

based on Total Expenditures under Part D and other criteria as required by the law. Negotiations with participating drug companies are ongoing, and any negotiated prices for the first cycle of negotiation is effective from 2026.

## Stelara copay card

With the **Stelara copay card**, you may pay as little as \$5.00 for each dose, depending on your insurance plan and pharmacy. Stelara copay card is available through **Stelara withMe Savings Program**.

To find out more about the Stelara copay card see "[Do I qualify for the Stelara copay card, how much can I save?](#)"

## Storage

### Stelara vials and prefilled syringes

- Store vials and prefilled syringes in a refrigerator between 36°F to 46°F (2°C to 8°C)
- Vials should be stored standing up straight.
- This medicine should be stored in the original carton to protect it from light until time to use it.
- Do not freeze.
- Do not shake.
- If needed, individual Stelara prefilled 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 to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. 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.
- Do not use this medicine after the expiration date on the carton or on the prefilled syringe.

### Diluted Stelara infusion

- If necessary, the diluted infusion solution may be kept at room temperature up to 25°C (77°F) for up to 7 hours.
- Storage time at room temperature begins once the diluted solution has been prepared.
- The infusion should be completed within 8 hours after the dilution in the infusion bag (cumulative time after preparation including the storage and the infusion period).
- Do not freeze.
- Discard any unused portion of the infusion solution.

## Ingredients

**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: L-histidine, L-histidine hydrochloride monohydrate, Polysorbate 80 and sucrose.

Single-dose vial for intravenous infusion: EDTA disodium salt dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, Polysorbate 80, and sucrose.

## Stelara Manufacturer

**Stelara manufacturer Janssen Biotech**, Inc., Horsham, PA 19044, US License No. 1864

## Stelara 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 Stelara.

### 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 <b>Discontinued</b>

## 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.



Otulfii (ustekinumab-aaaz) - Fresenius Kabi USA, LLC	▼
Pyzchiva (ustekinumab-twe) - Samsung Bioepis Co., Ltd.	▼
Selarsdi (ustekinumab-aekn) - Alvotech USA Inc.	▼
Stegeyma (ustekinumab-stba) - CELLTRION, Inc.	▼
Wezlana (ustekinumab-auub) - Amgen Inc.	▼
Yesintek (ustekinumab-kfce) - Biocon Biologics Inc.	▼

## Popular FAQ

What are 7 key Stelara side effects to watch out for?	▼
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Is Stelara a biologic?	▼
Does Stelara cause weight gain?	▼
Do I qualify for the Stelara copay card, how much can I save?	▼

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### References

1. [Food and Drug Administration \(FDA\) Stelara Product Label](#)
2. [National Library Of Medicine: Ustekinumab](#)

## More about Stelara (ustekinumab)

- [Check interactions](#)

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## Patient resources

### Other brands

[Selarsdi](#), [Pyzchiva](#), [Wezlana](#), [Otulfi](#), ... +3 more

## Professional resources

- [Stelara prescribing information](#)
- [Ustekinumab \(AHFS Monograph\)](#)

### Other brands

[Selarsdi](#), [Pyzchiva](#), [Wezlana](#), [Otulfi](#), ... +2 more

## Related treatment guides

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

**10+ years** FDA approved 2009



## User Reviews & Ratings

7.6 / 10

[252 Reviews](#)

## Images

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



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