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2. Vedolizumab

Vedolizumab

Generic name: vedolizumab**Brand name:** [Entyvio](#)**Dosage form:** intravenous infusion (300 mg single-dose vial), subcutaneous injection (108 mg/0.68 mL prefilled syringe), (108 mg/0.68 mL prefilled pen)**Drug class:** [Selective immunosuppressants](#)Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Feb 23, 2024.[Uses](#) [Side effects](#) [Warnings](#) [Before taking](#) [Dosage](#) [Interactions](#) [FAQ](#)

What is vedolizumab?

Vedolizumab ([Entyvio](#)) is used for [ulcerative colitis](#) (UC) or [Crohn's disease](#) to help improve symptoms, induce remission, and may also reduce the need for steroid medicines to control symptoms long-term. Vedolizumab is a selective immunosuppressant that works to control inflammation and symptoms of ulcerative colitis or Crohn's disease by preventing too many white blood cells from entering your GI tract (intestine). Vedolizumab works selectively in the gut to decrease inflammation and does not usually lead to system-wide immunosuppression.

Vedolizumab infusion is used for ulcerative colitis or Crohn's disease. Vedolizumab Pen (Entyvio Pen) or prefilled syringe is used for the maintenance treatment of UC and is given as an injection under the skin (subcutaneous injection).

Vedolizumab infusion first became an FDA-approved medicine on May 20, 2014., its indications are moderate to severe ulcerative colitis (UC) or Crohn's disease in adults. Vedolizumab Pen (subcutaneous) became FDA-approved on September 27, 2023, for maintenance treatment of UC in adults.

Vedolizumab's brand name is Entyvio, and currently, no biosimilars of vedolizumab have been approved by the FDA.

How does Vedolizumab work?

Vedolizumab belongs to a class of drugs called integrin receptor antagonists. Vedolizumab's mechanism of action (MOA), or how it works, is by binding to a protein (integrin receptor) on the surface of a type of white blood cell called memory T-lymphocytes that plays a key role in causing the chronic inflammation seen in people with UC and Crohn's disease. By blocking integrin receptors, the Vedolizumab improves inflammation and symptoms.

Vedolizumab side effects

Common Vedolizumab side effects

The most common Vedolizumab side effects include fever, sore throat, flu symptoms; cold [symptoms](#) such as stuffy nose,

sinus pain, sneezing, cough with mucus, shortness of breath, chest discomfort, pain in your arms or legs, tiredness; headache, joint [pain](#), [back](#) pain, rash, itching, or nausea.

Serious Vedolizumab side effects

Get emergency medical help if you have signs of an allergic reaction to Vedolizumab: [hives](#), difficulty breathing, swelling of your face, lips, tongue, or throat.

Some serious Vedolizumab side effects may occur during the injection. Tell your caregiver if you feel dizzy, nauseated, light-headed, itchy, sweaty, or have a headache, chest tightness, [back pain](#), trouble breathing, or swelling in your face.

Vedolizumab may cause a serious brain infection that can lead to disability or death. Call your doctor right away if you have problems with speech, thought, vision, or muscle movement. These symptoms may start gradually and get worse quickly.

Call your doctor at once if you have:

- fever, chills, body aches, cold or flu symptoms, mouth and throat ulcers, skin sores;
- pain, warmth, swelling, or oozing around your anal area;
- nausea, [vomiting](#), severe [diarrhea](#), diarrhea that is watery or bloody, stomach cramps, [weight loss](#);
- cough, pain when swallowing; or
- liver problems - nausea, upper stomach pain, itching, tired feeling, loss of appetite, dark urine, clay-colored stools, [jaundice](#) (yellowing of the skin or eyes).

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.

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

Related/similar drugs

Omvox

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

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Tremfya (guselkumab) injection is used to treat plaque psoriasis, psoriatic arthritis, ulcerative ...

Reviews & ratings

7.2 / 10

[99 Reviews](#)

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Warnings

Vedolizumab infusion and pen can cause serious side effects on your brain or liver and may cause a serious infection. Call your doctor right away if you have a fever, tiredness, muscle aches, [sore throat](#), shortness of breath, skin sores, painful urination, loss of appetite, upper stomach pain, dark urine, yellowing of your skin and eyes, or problems with speech, thought, vision, or muscle movement.

Tell your caregivers if you have any reactions during the injection, such as [dizziness](#), [nausea](#), itching, [headache](#), chest tightness, trouble breathing, or facial swelling.

Do not receive a "live" vaccine while using this medicine.

Before taking this medicine

You should not use this medicine if you are allergic to the active ingredient vedolizumab or any inactive ingredient.

To make sure this medicine is safe for you, tell your doctor if you have ever had:

- an active or recent infection;
- liver disease;
- signs of infection such as fever, cough, or flu symptoms;
- if you are scheduled to receive any vaccines.

Tell your doctor if you have ever had [tuberculosis](#) or if anyone in your household has tuberculosis. Also, tell your doctor if you have recently traveled. Tuberculosis and some fungal infections are more common in certain parts of the world, and you may have been exposed during travel.

You should be up to date with all needed vaccinations before receiving this medicine.

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant. Having active ulcerative colitis or Crohn's disease symptoms during pregnancy may increase the risk of premature birth or low birth weight. The benefit of treating these conditions may outweigh any risks to the baby.

If you use Vedolizumab infusion or pen while you are pregnant, make sure any doctor caring for your new baby knows that you used the medicine during pregnancy. Being exposed to vedolizumab in the womb could affect your baby's vaccination schedule during the first few months of life.

If you are pregnant, your name may be listed on a pregnancy registry to track the effects of vedolizumab on the baby.

Breastfeeding

Tell your doctor if you are breastfeeding or plan to breastfeed. Vedolizumab passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take this medicine.

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

How will I receive vedolizumab?

Vedolizumab infusion is given into a vein in your arm for UC and CD, and the injection is given under the skin as a subcutaneous injection (maintenance therapy for UC). Before you start treatment with this medicine, your doctor may perform tests to make sure you do not have tuberculosis or other infections.

How is vedolizumab intravenous given for UC and CD?

Vedolizumab is given as an infusion into a vein, usually once every 2 to 8 weeks. A healthcare provider will give you this infusion.

This medicine must be given slowly, and the infusion can take at least 30 minutes to complete.

You will be watched closely for a short time after receiving this medicine to make sure you do not have an allergic reaction.

It may take up to several weeks before your symptoms improve. Keep using the medication as directed, and tell your doctor if your symptoms do not improve after 14 weeks of treatment.

How is vedolizumab pen given for UC?

Vedolizumab can be given subcutaneously (an injection under the skin) using an Entyvio Pen or a single-dose prefilled syringe for maintenance of UC after at least 2 intravenous infusions.

See the detailed Instructions for Use that come with this medicine about the right way to prepare and give this medicine.

Your healthcare provider will prescribe the type of device that is best for you.

If your healthcare provider decides you or your caregiver can give your injections at home, you or your caregiver should be shown the right way to prepare and inject this medicine. Do not inject this medicine until you or your caregiver have been shown the right way by your healthcare provider.

You may receive your first subcutaneous injection after at least 2 vedolizumab infusions and in place of the next scheduled intravenous infusion.

You may receive vedolizumab as an injection under your skin (subcutaneous) 1 time every 2 weeks.

Vedolizumab can be injected in your upper legs (thighs) or stomach area (abdomen). The upper arms may also be used if a caregiver gives the injection.

You should use a different injection site each time you use the medicine.

Do not give an injection into moles, scars, bruises, or skin that is tender, hard, red, or damaged.

Always check the label of your prefilled syringe or prefilled pen to make sure you have the correct medicine before each injection.

Do not shake this medicine.

Vedolizumab Dosing information

Usual Adult IV Vedolizumab Infusion Dose for Crohn's Disease or for Ulcerative Colitis:

- 300 mg IV over 30 minutes at Week 0, 2, and 6 and then every 8 weeks thereafter.

Usual Adult SC Vedolizumab Dose for Ulcerative Colitis:

- For Ulcerative Colitis, following the first two vedolizumab intravenous doses administered at Week 0 and Week 2, the dose may be switched to subcutaneous injection at Week 6.
- Week 6 and thereafter: Administer 108 mg subcutaneously once every 2 weeks.
- Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.
- Vedolizumab may be switched from intravenous infusion to subcutaneous injection for patients in clinical response or remission beyond Week 6. To switch patients to subcutaneous injection, administer the first subcutaneous dose in place of the next scheduled intravenous infusion and every two weeks thereafter.

Comments:

- Prior to initiating therapy, patients should be brought up to date with all immunizations according to current immunization guidelines.
- Discontinue if no evidence of therapeutic benefit by Week 14.

Uses:

- **Adult Ulcerative Colitis (UC):** Adults with moderately to severely active ulcerative colitis. This drug is used for inducing and maintaining clinical response or remission, improving the endoscopic appearance of the mucosa, or

achieving corticosteroid-free remission.

- **Adult Crohn's Disease (CD):** Adults with moderately to severely active Crohn's Disease. This drug is used for achieving clinical response or remission or achieving corticosteroid-free remission.

i [Detailed Vedolizumab dosage information](#)

What happens if I miss a dose?

If you are not able to have your injection or infusion at your regular scheduled time or you miss a dose of vedolizumab, inject the dose as soon as possible. Then, inject your next dose every 2 weeks thereafter. If you are not sure when you should have your next injection or infusion, call your healthcare provider.

What happens if I overdose?

If you take more vedolizumab than you were told to take, call your healthcare provider.

What should I avoid while receiving vedolizumab?

Do not receive a "live" vaccine while using vedolizumab, 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.

You may receive "killed-virus" vaccines such as a flu shot, polio vaccine, rabies vaccine, or hepatitis A vaccine. Ask your doctor before receiving any vaccine while you are being treated with vedolizumab.

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

What other drugs will affect vedolizumab?

Tell your doctor about all your other medicines, especially:

- [natalizumab](#);
- medicines to treat [psoriasis](#) or [rheumatoid arthritis](#), such as [etanercept](#) or golimumab;
- other medicines to treat Crohn's disease or ulcerative [colitis](#), such as [adalimumab](#), certolizumab, [infliximab](#); or
- other drugs that weaken the immune system such as cancer medicine, steroids, and medicines to prevent organ transplant rejection.

This list is not complete. Other drugs may interact with vedolizumab, including prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Not all possible drug interactions are listed here.

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

Does vedolizumab interact with my other drugs?

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

vedolizumab

+

Enter a drug name

Add

Vedolizumab Package Insert

Review the [Vedolizumab Package Insert \(Entyvio\)](#) here for more detailed information about this medicine. 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 Entyvio for safe and effective use and does not take the place of talking to your doctor about your treatment.

Entyvio Connect

Entyvio Connect is a support program by Takeda Pharmaceuticals.

Ingredients

Entyvio Active ingredient: vedolizumab

Entyvio Inactive ingredients: arginine hydrochloride, histidine, histidine monohydrochloride, polysorbate 80, and sucrose.

Storage

- Store in a refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, the prefilled syringe or prefilled pen can be left out of the refrigerator in its box at room temperature up to 77°F (25°C) for up to 7 days (for example, when traveling).
- Do not use the prefilled syringe or prefilled pen if left out of the refrigerator for more than 7 days or left in direct sunlight.
- Do not freeze.
- Do not use if it has been frozen.
- Keep this medicine in the original package to protect from light until the time of use.
- Entyvio Pen or prefilled syringe is not made with natural rubber latex.
- Keep all medicines out of the reach of children.

Company

Vedolizumab Entyvio brand is manufactured by Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA 02421.

Vedolizumab 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 are 2 for vedolizumab.

Entyvio (vedolizumab) - Takeda Pharmaceuticals U.S.A., Inc.



Formulation type	Strength
Pre-Filled Syringe	108 mg/0.68 mL
Single-Dose Vial	300 mg

View [Entyvio](#) information in detail.

Entyvio Pen (vedolizumab) - Takeda Pharmaceuticals U.S.A., Inc.



Popular FAQ

How much does Entyvio cost per month?



Is Entyvio an immunosuppressant or a biologic?



Can I take antibiotics while on Entyvio?



How long has Entyvio been on the market?



Does Medicaid cover Entyvio?



Is Entyvio used to treat Crohn's disease?



[View more FAQ...](#)

References

1. [Entyvio Package Insert FDA](#)
2. [Molecular Biology of the Cell](#). 4th edition. Integrins
3. [Scribano ML. Vedolizumab for inflammatory bowel disease: From randomized controlled trials to real-life evidence. World J Gastroenterol. 2018;24\(23\):2457-2467. doi:10.3748/wjg.v24.i23.2457](#)

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Further information

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

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DRUG STATUS

Availability

Rx Prescription only


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 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



User Reviews & Ratings

6.2 / 10

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Images

[Entyvio \(vedolizumab\) 108 mg/0.68 mL single-dose prefilled pen](#)



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