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2. Entyvio

Entyvio

Pronunciation: *en ti' vee oh*

Generic name: [vedolizumab](#) [*VE-doe-LIZ-ue-mab*]

Dosage form: intravenous infusion, subcutaneous injection

Drug class: [Selective immunosuppressants](#)

Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Apr 14, 2025.

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What is Entyvio?

Entyvio ([vedolizumab](#)) is a biologic medicine used to treat [ulcerative colitis \(UC\)](#) and [Crohn's disease \(CD\)](#).

Entyvio rapidly reduces inflammation, improves symptoms, may help achieve remission, and decreases the use of steroid medications. Entyvio is a monoclonal antibody that works by preventing immune cells (T-lymphocytes) from entering your GI tract (intestine) to control inflammation and symptoms of ulcerative colitis or Crohn's disease.

Entyvio Pen and prefilled syringe are subcutaneous (under-the-skin) injections used every 2 weeks for the maintenance treatment of ulcerative colitis and Crohn's disease. Entyvio Pen and syringe can be self-administered at home, offering a more convenient option for long-term disease management.

Entyvio infusion (IV) is used in a healthcare setting for the first two doses (induction treatment), then the patient can continue with the infusion every 8 weeks as a maintenance dose or choose to transition to subcutaneous injections for ongoing maintenance.

Entyvio infusion became an FDA-approved medicine on May 20, 2014. It can be used to treat moderate to severe ulcerative colitis or Crohn's disease in adults. **Entyvio Pen** (subcutaneous) became FDA-approved on September 27, 2023. The FDA has approved no biosimilars of vedolizumab.

How does Entyvio work?

In ulcerative colitis and Crohn's disease, inflammation in the gastrointestinal (GI) tract is triggered by an overactive immune response, involving a specific protein called integrin on white blood cells.

Entyvio mechanism of action (MOA) is targeting and blocking $\alpha 4 \beta 7$ integrin, a protein that plays a role in gut inflammation. This stops the interaction between $\alpha 4 \beta 7$ integrin and mucosal addressin cell adhesion molecule-1 (MAdCAM-1), preventing immune cells (T-lymphocytes) from migrating into the gastrointestinal tract. This reduces inflammation and helps improve ulcerative colitis (UC) and Crohn's disease symptoms.

Entyvio class of medicine is an integrin receptor antagonist that specifically targets immune system activity in the gut.

Entyvio side effects

Common Entyvio side effects

The most common Entyvio side effects include:

- Nasopharyngitis (13%)
- [Headache](#) (12%)
- [Joint pain](#) (12%)
- [Fever](#) (9%)
- Nausea (9%)
- Upper respiratory tract infection (7%)
- Tiredness (6%)
- Cough (5%)
- [Back pain](#) (4%)
- Bronchitis (4%)
- Flu symptoms (4%)
- Itching skin (3%)
- Inflamed sinuses (3%)
- [Rash](#) (3%)
- Pain in your arms or legs (3%)
- Sore throat (3%)

The common side effects occurred in 3% of IV Entyvio patients and higher than 1% more than placebo side effects in the UC Trials I and II and CD Trials I and III over 52 weeks.

Serious Entyvio side effects

Infusion-Related Reactions and Hypersensitivity Reactions Get emergency medical help if you have signs of an allergic reaction to this medicine [hives](#), difficulty breathing, swelling of your face, lips, tongue, or throat.

Some Entyvio 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.

Progressive Multifocal Leukoencephalopathy (PML) Entyvio 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.

Infections or Liver Injury 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.

 [Entyvio 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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Xeljanz

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

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Stelara

Stelara (ustekinumab) is used to treat Crohn's disease, ulcerative colitis,

plaque psoriasis, and ...

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Rinvoq

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

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Dexamethasone

Dexamethasone is used to treat inflammatory conditions such as allergies, skin conditions ...

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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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Tremfya

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

Reviews & ratings

7.2 / 10

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How effective is Entyvio?

How Effective is Entyvio for Ulcerative Colitis?

The GEMINI I clinical trial showed that Entyvio (vedolizumab) was more effective in reducing symptoms and achieving remission in patients with ulcerative colitis when compared to placebo.

Symptom Improvement at six weeks

The primary measure of Entyvio's effectiveness for ulcerative colitis is clinical response*, which assesses symptom improvement after six weeks of treatment.

- **47% of patients** Entyvio patients showed symptom improvement.
- **26% of patients** placebo patients experienced improvement.

*A clinical response is defined as a reduction in complete Mayo score by ≥ 3 points and $\geq 30\%$ from baseline and a decrease in rectal bleeding subscore by ≥ 1 point or an absolute rectal bleeding subscore of ≤ 1 point.

Clinical Remission After 52 Weeks

Entyvio also demonstrated long-term effectiveness in helping ulcerative colitis patients achieve clinical remission after one year (52 weeks):

- **42% of Entyvio patients achieved clinical remission.**
- **16% of placebo patients reached remission.**

*Clinical remission is defined as a complete Mayo score of ≤ 2 points with no individual subscore > 1 point.

How Effective is Entyvio for Crohn's Disease?

The GEMINI 2 clinical trial showed that Entyvio was more effective than a placebo in reducing symptoms and achieving remission in patients with Crohn's disease.

Clinical Remission After 6 Weeks

Entyvio also demonstrated effectiveness in helping patients achieve Crohn's disease clinical remission after six weeks:

- **14.5% of Entyvio patients achieved clinical remission.**
- **6.8% of placebo patients reached remission.**

Clinical Remission After 52 Weeks

Entyvio also demonstrated long-term effectiveness in helping Crohn's patients achieve clinical remission* after one year (52 weeks):

- **36.4% of Entyvio patients achieved clinical remission (300 mg IV 4 weekly)**

- **39.0% of Entyvio patients achieved clinical remission** (300 mg IV 8 weekly)
- **21.6 % of placebo patients reached remission.**

*Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score \leq 150 points (GEMINI 2)

Warnings

Entyvio 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 swelling in your face.

Before starting this medication you should be up to date with all immunizations. While patients are receiving Entyvio they may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks. There are no data on the secondary transmission of infection by live vaccines in patients receiving Entyvio.

Before taking this medicine

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

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 Entyvio 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. Entyvio passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take this medicine.

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

How will I receive Entyvio?

Entyvio infusion is given into a vein in your arm for UC and CD. Entyvio single-dose pre-filled pen is given under the skin (subcutaneously) as maintenance therapy for UC and moderate to severely active Crohn's disease. Before you start treatment with Entyvio, your doctor may perform tests to make sure you do not have tuberculosis or other infections.

How is Entyvio infusion given?

Entyvio infusion is given 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 the Entyvio pen given?

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

See the detailed Instructions for Use that come with the Entyvio Pen or prefilled syringe 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 the pen or prefilled syringe 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 Entyvio infusions and in place of the next scheduled intravenous infusion.

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

Entyvio 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 Entyvio pen or prefilled syringe to make sure you have the correct medicine before each injection.

Do not shake this medicine.

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

Entyvio Dosing information

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

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

Usual Adult SC Entyvio Dose for Crohn's Disease or Ulcerative Colitis:

Following the first two Entyvio intravenous doses administered at Week 0 and Week 2, the dose may be switched to subcutaneous injection at Week 6.

- Week 6 and there after: Administer 108 mg subcutaneously once every 2 weeks.
- Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.

Comments:

- Before initiating therapy, patients should be brought up to date with all immunizations according to current immunization guidelines.

 [Detailed Entyvio 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 Entyvio, 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 Entyvio than you were told to take, call your healthcare provider.

What should I avoid while receiving Entyvio?

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

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 Entyvio?

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.

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

Does Entyvio interact with my other drugs?

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

+

Add

Entyvio PI

HCPs and patients often use the [Entyvio PI](#) for more detailed information about this medicine. The Entyvio PI (prescribing information) contains more comprehensive information on Indications and Usage, Dosage and Administration, Clinical Pharmacology, Clinical Studies, Drug Interaction, and more. Discuss any medical questions you have with your HCP (health care professional). 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 PI is sometimes called the **Entyvio Package Insert** or FDA label.

Entyvio J code

Entyvio J code J3380 (1 mg injection).

J codes are used for medicines that are not taken orally and include injections, inhalations, and chemotherapies. J codes are important for accurate and consistent coding for billing and reimbursement purposes.

Your physician will need the Entyvio J-code when filling out forms for your treatment.

Entyvio Connect

Entyvio Connect is a support program from Takeda Pharmaceuticals designed to help patients manage costs, understand insurance requirements, and access ongoing support and educational resources.

With the **Entyvio copay assistance**, you may pay as little as \$5 per dose out of pocket if you qualify.

For more information on Entyvio Connect and Entyvio copay assistance, see our [Entyvio Prices, Coupons, Copay Cards & Patient Assistance](#) page or [How does Entyvio copay assistance work?](#)

Ingredients

Active ingredient: vedolizumab

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

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

Entyvio 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 Entyvio.

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



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

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



Popular FAQ

Can you get a flu shot while taking Entyvio?



How much does Entyvio cost per month?



Is Entyvio an immunosuppressant or a biologic?



How long does it take Entyvio to start working?



Can I drink alcohol while taking Entyvio?



Can I take antibiotics while on Entyvio?



Does Entyvio increase the risk of cancer?



Does Entyvio cause weight gain?



Entyvio and the COVID vaccine, what should I know?



[View more FAQ...](#)

References

1. [Vedolizumab for inflammatory bowel disease: From randomized controlled trials to real-life evidence](#)
2. [Entyvio Package Insert](#)
3. [Entyvio BILLING AND CODING](#)
4. [Vedolizumab as Induction and Maintenance Therapy for Ulcerative Colitis](#)

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- [Vedolizumab \(AHFS Monograph\)](#)

Related treatment guides

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- [Crohn's Disease, Maintenance](#)
- [Crohn's Disease](#)

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

 FDA approved 2014



User Reviews & Ratings

6.2 / 10

[162 Reviews](#)

Images

Entyvio 108 mg/0.68 mL single-dose prefilled pen



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