Vedolizumab - Medication Information

What is vedolizumab?

Vedolizumab (brand name: Entyvio[®]) is a medication used to treat Crohn's disease and ulcerative colitis. It is an antibody that prevents inflammation causing white blood cells from entering and damaging the intestine. It targets the gastrointestinal (GI) tract rather than your whole body's immune system.

How is vedolizumab given?

Vedolizumab is given into a vein as an infusion. A typical infusion takes 30 minutes. Before the infusions, you may get a dose of steroids, acetaminophen (brand name: Tylenol[®]), and/or diphenhydramine (brand name: Benadryl[®]) to lower your chances of any reactions.

300 mg of vedolizumab is usually given at weeks 0, 2, and 6. After that, it is given every 8 weeks. Some patients may need to change their infusion schedule to every 4-6 weeks. Your provider will work with you to make adjustments as needed.

There is a formulation of vedolizumab that is a subcutaneous (under the skin) injection that is 108 mg given every 2 weeks after the initial IV infusions. At this time, the injection is only FDA approved for patients with ulcerative colitis. Your insurance will likely dictate which formulation is covered for you.

When can I expect vedolizumab to work?

Some patients may feel an improvement in symptoms as soon as 2-3 weeks of starting vedolizumab. Typically, up to 6-8 weeks for patients with ulcerative colitis and 10-14 weeks for patients with Crohn's disease is required to see a big benefit.

Vedolizumab works for most patients. The medication may stop working in up to 10% (1 in 10) of patients every year. To make sure that it keeps working, it is important to stay on track with your infusion schedule and do not miss any infusions. In some cases, your doctor may also have you start a second immunosuppressive medication along with vedolizumab to help it work better and to remain effective longer.

Studies have shown that early effective treatment for Crohn's disease or ulcerative colitis is associated with long-term benefit including lowering the likelihood of needing surgery or hospitalization for health problems related to these conditions.

What tests are needed while I am on vedolizumab?

Before beginning vedolizumab treatment, you will need blood tests to check for hepatitis B and tuberculosis infections. You may also need to test for tuberculosis every year. Blood counts and liver tests are done every 4 months while on vedolizumab. At times, your doctor may also check your vedolizumab level to make sure the dose is working well for you.

What are the potential side effects of vedolizumab?

Side effects with vedolizumab are uncommon, but may include:

Common cold: The most common side effect is the common cold which occurs in less than 6% (6 in 100) of patients.



Allergic reaction: Patients may develop allergic reactions to vedolizumab as with any other medication. Reactions may include rash, hives, swelling of the lips or throat. This is uncommon and can be treated with steroid and antihistamine medications.

Infusion reaction: Fewer than 2% (2 in 100) of patients may develop a reaction during the infusions. This may include fever, rash, trouble breathing, and chest pain. 2-3 days after the infusion, patients may also experience joint aches.

Infection: As with other medications that act on the immune system, vedolizumab can increase your risk of infections. Serious infections are uncommon, but serious medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Cancer: Vedolizumab may increase the risk of cancers. While the risk is very low, it is important to have the check-ups discussed in this handout to help monitor for any signs or symptoms of cancer.

Please see the medication package insert for the full list of potential side effects.

Is vedolizumab safe during pregnancy and breastfeeding?

While little data exists, women and men on vedolizumab have not been associated with fertility problems, miscarriages, birth defects, preterm births, stillbirths, or other pregnancy-related problems. Most patients continue the treatment during their pregnancy. If you are pregnant while on vedolizumab, you may get your last dose of the medication early in the 3rd trimester of your pregnancy. Additionally, live virus vaccines such as the rotavirus vaccine are not recommended for your baby within the first 6 months of age. It is safe to breastfeed while on vedolizumab. This has not been shown to have any negative impacts on the baby.

It is important to discuss with your provider about continuing vedolizumab before, during, and after pregnancy.

How can I take care of my health while on vedolizumab?

It is important to be up to date with your health maintenance while on vedolizumab. This includes being current on all the recommended vaccines such as the flu, COVID-19, pneumococcal, and shingles vaccines. You should only get the recombinant shingles vaccine (brand name: Shingrix[®]). Do not get the older shingles vaccines that contain the live but weakened virus.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and skin check-ups for both men and women.

Speak to your primary care doctor about whether you are up-to-date on all your vaccines and cancer screening.

What if my out-of-pocket costs are high with this treatment?

Our pharmacy team will work with you to see if you qualify for patient assistance and help with the application process.

The manufacturer of vedolizumab has a patient assistance program called EntyvioConnect for patients on the medication. Please go to <u>entyvio.com/entyvio-connect</u> for more information on this program.

What if I have questions about vedolizumab?

Talk with your provider about any questions or concerns you may have about vedolizumab.

This document has been reviewed for plain language by Blum Center staff.

