Patient & Family Guide

Vedolizumab (Entyvio®) Therapy



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Your health care provider believes treatment with a medication called **vedolizumab** may help to manage your inflammatory bowel disease (IBD), ulcerative colitis, or Crohn's disease. The brand name for vedolizumab is Entyvio[®].

This pamphlet gives information about vedolizumab to help you make an informed decision about whether or not to use it. This pamphlet does not take the place of any information or instructions your health care provider gives you.

What is vedolizumab?

Vedolizumab is a biologic medication. A biologic medication is a special medication that treats inflammation (swelling). Vedolizumab specifically targets the chronic (ongoing) inflammation in your gastrointestinal (GI) tract.

Who should take this medication?

Vedolizumab is prescribed for adults with moderate to severe (very bad) IBD when other medications have not worked well or cannot be taken. Vedolizumab can lower symptoms, help you reach and keep up remission (temporary recovery), and lower or end the use of corticosteroids.

How does this medication work?

- As part of your natural immune response, your white blood cells are sent to different tissues in your body to fight off infections.
- When you have IBD, your immune system cannot tell the difference between foreign (from outside your body) substances and your body's own tissues. Inflammation and other symptoms of IBD are caused by more white blood cells entering your GI tract, causing inflammation and other symptoms.
- Vedolizumab works to block the white blood cells from moving into the GI tract, helping to control inflammation and other symptoms.

How is vedolizumab given?

- Vedolizumab is given by intravenous (IV) infusion, through a small, flexible tube inserted (put in) in a vein in your arm. Once the IV is in place, the infusion takes about 30 minutes.
- When you start treatment, infusions will be given at weeks 0, 2, and 6, then every 8 weeks. Infusions will take place at a private infusion clinic in your area.
- Each time you have an infusion, a report will be sent to your health care provider. It will have your weight, dose, and information on how you are doing.
- Any side effects will be treated right away, as needed. It is important to tell the health care provider giving the infusion if you have any side effects during your infusion. If you have any side effects at home after your infusion, tell your health care provider right away (see pages 6 and 7).
- Vedolizumab is now also available as a subcutaneous (under the skin) injection. You may choose to switch to the injection if you have had at least 2 vedolizumab infusions and are feeling well. The nurse at the infusion clinic will teach you how to inject vedolizumab yourself. You will then inject it at home every 2 weeks.

How long will I need to take vedolizumab?

- Your health care provider will check how you are responding to the medication and decide if you should continue treatment.
 Vedolizumab can take up to 4 months to become fully effective.
- You can check if the medication is working by monitoring your IBD symptoms or having your health care provider do tests such as:
 - > Stool (poop) sample
 - Colonoscopy (scope of the bowel)
- If the medication is working well and you are not having major side effects, your health care provider may want you to stay on vedolizumab long-term (years) to treat your IBD.

What are your questions?

Please ask. We are here to help you.

How much does vedolizumab cost?

- Biologic medications like vedolizumab are very expensive and can cost thousands of dollars a month.
- The vedolizumab patient support program will work with your insurance company or Nova Scotia Pharmacare. Any part of the cost that is not covered by your insurance or Pharmacare is usually paid for by the patient support program.
- A nurse coordinator for the vedolizumab patient support program will stay in contact with you and your IBD health care providers. They will help you with any paperwork that may be needed to cover the cost of this medication.

Precautions before you start taking vedolizumab:

- You will have a tuberculin skin test, a chest X-ray, and blood tests to check for tuberculosis (TB) or other active infections.
- Your health care provider may suggest updating your vaccinations, such as tetanus, varicella (chicken pox), or pneumococcal (pneumonia) vaccines. Tell your health care provider if you are due for vaccinations or plan to be vaccinated.

- Be sure to tell your health care provider about any other health problems you have, since vedolizumab may make them worse.
- Have regular blood tests and check-ups with your health care provider.

What are the possible side effects of this medication?

- Like any medication, vedolizumab has possible side effects.
- You may have an allergic reaction to vedolizumab while you are getting an infusion or several hours later. You may need treatment if you have an allergic reaction.
- If you take vedolizumab injections, you may have swelling or redness around the injection area. If this happens, tell your health care provider right away. They will tell you how to treat this.

Call your health care provider if you have any of the following more severe symptoms, during or after the infusion:

- Rash
- Itching
- Swelling of your lips, tongue, throat, or face
- Chills
- Muscle aches
- Cough

- Shortness of breath or trouble breathing
- Wheezing
- Dizziness
- Feeling hot
- Palpitations (fast, irregular heartbeat)

If you cannot reach your health care provider, call 911 or go to the nearest Emergency Department right away.

Vedolizumab may increase your risk of getting a serious infection.

Avoid being near people who are sick and wash your hands often if you are around people who have been sick.

Tell your health care provider if you have ever had an infection that would not go away or an infection that kept coming back.

BEFORE your infusion, tell your health care provider if you think you have an infection or have any of the following symptoms:

- Fever (temperature above 38.5° C/101.3° F)
- Chills
- Muscle aches
- Cough
- Shortness of breath or trouble breathing

- Runny nose
- Sore throat
- Red or painful skin or sores
- Tiredness
- Pain when urinating (peeing)

Vedolizumab may cause liver problems. Tell your health care provider if you have any of these symptoms:

- Tiredness
- Loss of appetite (not feeling hungry)
- Pain on the right side of your abdomen (stomach area)
- Dark urine (pee)
- Yellowing of the skin and eyes (jaundice)

We will ask you to have blood tests done every 3 months to check your liver.

Most patients tolerate vedolizumab very well. But you should **tell your health** care provider if you have any of these symptoms, as they could be side effects of vedolizumab:

- Common cold
- Headache
- Joint pain
- Nausea (upset stomach)
- Fever
- Nose, throat, or sinus infection
- Tiredness
- Cough
- Flu

- Back pain
- Rash
- Itching
- Sore throat
- Bronchitis

 (inflammation of the lining of your bronchial tubes, which carry air to and from your lungs)

There is a very small chance that vedolizumab may increase your risk of getting a rare brain infection called PML (progressive multifocal leukoencephalopathy). There have been no reports of PML caused by vedolizumab in patients taking this medication.

Call your health care provider right away if you have:

- Back pain
- Blurred vision
- Confusion
- Dizziness
- Drowsiness

- Fever
- Headache
- Seizures (loss of body control)
- Unusual tiredness or weakness

Pregnancy and breastfeeding

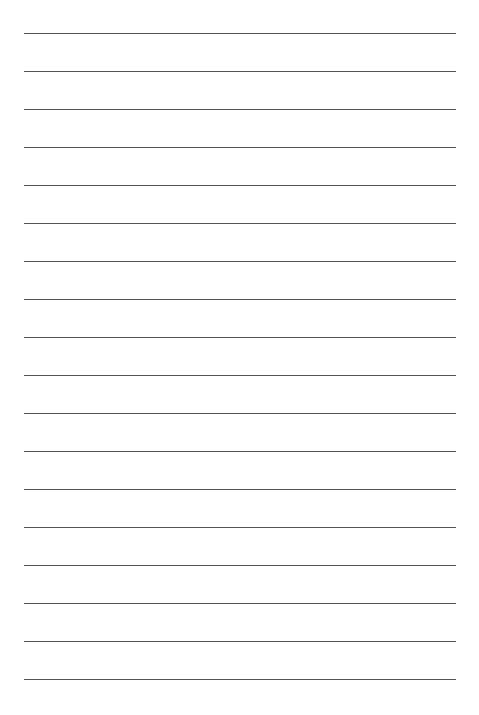
- Tell your health care provider if you are pregnant, plan to get pregnant, or do get pregnant while taking vedolizumab.
- Vedolizumab is considered safe to use during pregnancy. Your health care provider may adjust the timing of your treatments in the third trimester of your pregnancy.
- Important: Talk to your health care provider about whether your baby can have live vaccines in their first year.
- Tell your health care provider if you are breastfeeding or plan to breastfeed. Because vedolizumab is a very large protein, it is not likely that very much of the medication is able to pass into breast milk.

Important

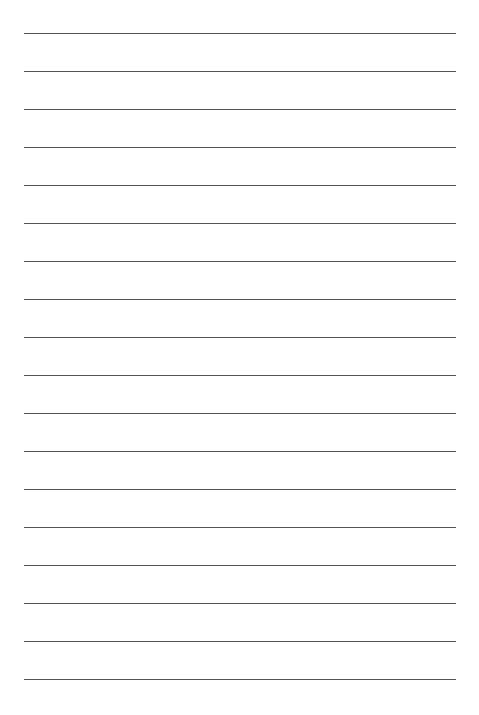
- Always talk with your health care provider about other medications you are taking. This includes prescription and non-prescription (over-the-counter) medications, and herbal or vitamin supplements.
- It is very important that your health care provider check your progress at regular visits to make sure this medication is working properly. You may also need regular blood tests. Ask your health care provider when you can expect a follow-up appointment. Use the space at the bottom of this page to record this information.
- If you notice any side effects or side effects that do not go away, tell your health care provider right away so adjustments can be made. Side effects can usually be controlled with other medications, but you may need to lower your dose or stop taking vedolizumab.

My follow-up appointment:	
Date:	
Time:	_
Place:	_

Questions for my health care provider:



Questions for my health care provider:



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 Connect with a registered nurse in Nova Scotia any time: call 811 or visit https://811.novascotia.ca
 Learn about other programs and services in your community: call 211 or visit http://ns.211.ca

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