

Vedolizumab (Entyvio[®]) Therapy for Inflammatory Bowel Disease (IBD)

Vedolizumab (Entyvio®) Therapy for IBD

- Your health care provider feels that treatment with vedolizumab may help you manage your inflammatory bowel disease (IBD) (Crohn's disease or ulcerative colitis).
- The brand name for vedolizumab is Entyvio®.
- This pamphlet gives basic information about vedolizumab. It can help you choose whether to use this treatment. It does **not** take the place of information or instructions given to you by your health care provider or pharmacist.

What is vedolizumab?

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

Who should take vedolizumab?

- Vedolizumab is prescribed for people with moderate to severe (very bad) IBD when other medications have not worked well or cannot be taken.

How does vedolizumab work?

- When your immune system is healthy, it uses white blood cells to defend itself when you are sick and to attack germs.
- When you have IBD, your immune system attacks your body's own tissues. This sends more white blood cells to your GI tract.
- When you have too many white blood cells in your GI tract, it causes inflammation and other symptoms.
- Vedolizumab prevents white blood cells from getting into the GI tract. This can help:
 - › Control inflammation and other symptoms
 - › Help you reach and keep up remission (temporary recovery)
 - › Lower or end your need for corticosteroids (like prednisone, budesonide)

How is vedolizumab given?

- Vedolizumab is given through an intravenous (I.V.) injection into a vein in your arm using a needle. Once the I.V. is in place, the infusion lasts about 30 minutes.
- When you start treatment, infusions will be given at weeks 0, 2, and 6, then every 8 weeks. Infusion appointments will be 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 dose (amount) and information on your condition.
- In the rare chance you had an allergic reaction during the infusion, this would be treated right away at the clinic.

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 as soon as possible (see pages 6 and 7).

- **Vedolizumab is also available as a subcutaneous (under the skin) injection.**
 - › You may choose to switch to this if you have had at least 3 vedolizumab infusions and are feeling good.
 - › If you choose to use subcutaneous injections, the nurses at the infusion clinic will teach you how to inject vedolizumab yourself. This will take place 8 weeks after your last infusion. 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 start working well.
- To check if the medication is working, you can monitor your IBD symptoms and have your health care provider do tests, like:
 - › Stool (poop) sample
 - › Colonoscopy (scope of the bowel)
- If the medication is working well and you are not having severe side effects, your health care provider may want you to stay on vedolizumab long-term (years) to treat your IBD.

How much does vedolizumab cost?

- **Vedolizumab is very expensive and can cost thousands of dollars a month.**
- The Patient Support Program (PSP) for vedolizumab will work with your private insurance company or with Nova Scotia Pharmacare.
- The PSP may pay for any part of the cost that is not covered by your private insurance or by Nova Scotia Pharmacare.
- A coordinator for the PSP will stay in contact with you and your IBD health care provider. They will help you with any paperwork that will be needed to cover the cost.

Precautions:

Before starting vedolizumab treatment, you may have:

- › A chest X-ray
- › A blood test (s) to check for tuberculosis (TB) and/or other infections

Your health care provider may suggest updating your vaccinations for:

- › Shingles
- › Pneumococcal (pneumonia)
- › Hepatitis

- Tell your health care provider if you are due for vaccinations or plan to be vaccinated.
- **It is safe to get a yearly flu vaccine (flu shot) and a COVID-19 vaccine while taking vedolizumab.**
- **Be sure to tell your health care provider about any other health problems you have. Vedolizumab may make them worse.**
- Have regular blood tests and check-ups with your health care provider.

What are the possible side effects?

- Like every 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 get subcutaneous injections, you may have swelling or redness around the injection area. If this happens, tell your health care provider before your next injection. They will tell you how to treat this.

If you have any of these severe symptoms of an allergic reaction after your infusion or injection, go to the nearest Emergency Department or call 911 right away.

These symptoms are very rare, but they need to be treated right away.

- › 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)

- Vedolizumab could slightly raise your risk of getting a serious infection.
 - › **Avoid being near people who are sick, if possible. Wash your hands more 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 each infusion or injection:

Tell the health care provider giving the infusion or injection if you think you have an infection or if you have:

- › Fever (temperature above 38 °C or 100.4 °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)

- There is a very small chance that vedolizumab could 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.

What are your questions?

Please ask a member of your health care team. We are here to help you.

Most people tolerate vedolizumab very well. Tell your health care provider if you have any of these symptoms that keep happening or do not go away, as they could be side effects of vedolizumab:

- › A cold
- › Headache
- › Joint pain
- › Nausea (feeling sick to your stomach)
- › Fever (temperature above 38 °C or 100.4 °F)
- › Nasal (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 raise your risk of getting a brain infection called progressive multifocal leukoencephalopathy (PML). There have been no reports of PML caused by vedolizumab in people taking this medication.

If you have any of the following symptoms of this very rare infection, call your health care provider right away. If you cannot reach them and your symptoms are severe, go to the nearest Emergency Department right away.

- › Back pain
- › Blurred vision
- › Confusion
- › Dizziness
- › Drowsiness
- › Fever (temperature above 38 °C or 100.4 °F)
- › 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 get pregnant while taking vedolizumab.
- Vedolizumab is considered safe to use during pregnancy.
 - › Your health care provider may change 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 much of the medication will pass into breast milk.

Important

- Always tell 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 condition regularly to make sure this medication is working well.** You may also need regular blood tests. Ask your health care provider when you can expect a follow-up appointment. There is space at the bottom of this page to write this down.
- **If you have any side effects or side effects that do not go away, tell your health care provider as soon as possible, so they can make changes.** Side effects can usually be controlled with other medications, but you may need to stop taking vedolizumab.

My follow-up appointment:

Date: _____

Time: _____

Place: _____

Notes:

This pamphlet is for educational purposes only. It is not intended to replace the advice or professional judgment of a health care provider. The information may not apply to all situations. If you have any questions, please ask your health care provider.

Find this pamphlet and all our patient resources here:
<https://library.nshealth.ca/Patients-Guides>

Connect with a registered nurse in Nova Scotia any time:
Call 811 or visit: <https://811.novascotia.ca>

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