



## INFORMED CONSENT FOR TREATMENT WITH VEDOLIZUMAB (ENTYVIO)

VEDOLIZUMAB (ENTYVIO) is approved by the US Food and Drug Administration (FDA) for treatment of Crohn's disease and ulcerative colitis. VEDOLIZUMAB (ENTYVIO) is a synthetic antibody that binds to a specific protein called integrin alpha-4-beta-7. Integrins control the movement of inflammatory white blood cells, and integrin alpha-4-beta-7 is found in the intestinal tract. When VEDOLIZUMAB (ENTYVIO) binds integrin alpha-4-beta-7, the movement of white blood cells into the intestinal tract is interrupted, which may reduce inflammation in patients with Crohn's or ulcerative colitis and thus improve symptoms.

### WARNINGS:

VEDOLIZUMAB (ENTYVIO) may reduce symptoms from Crohn's or ulcerative colitis; however, the medication has been associated with side effects, including serious side effects with the potential to cause death.

Infusion reactions – either while receiving an infusion or a within a few hours after an infusion – can include symptoms such as rash/itching; flushed skin; swelling of the face, lips, tongue, or throat; difficulty breathing; dizziness; or a fast heart rate. The most common side effects of VEDOLIZUMAB (ENTYVIO) are the common cold, headache, joint pain, nausea, fever, sinus infections, tiredness, cough, and back pain.

Serious infections, including bacterial (and mycobacterial), fungal, and/or viral infections, may occur at any time in patients on VEDOLIZUMAB (ENTYVIO) (or may be made worse by the use of VEDOLIZUMAB (ENTYVIO)). Mycobacterial infections can include tuberculosis (TB). Other bacterial infections can include Salmonella in the blood, Listeria in the spinal fluid, or abscesses in the anal area. Viral infections include cytomegalovirus (CMV). The risk of serious infection is increased if you are on other drugs that suppress your immune system, such as azathioprine (Imuran), 6-mercaptopurine (6-MP), or methotrexate.

Liver injury can occur, which can lead to yellowing of the skin (jaundice) and/or abnormal values on blood tests.

Progressive multifocal leukoencephalopathy (PML), a rare and usually fatal brain illness caused by reactivation of the John Cunningham (JC) virus, has been associated with TYSABRI, another antibody against an integrin. VEDOLIZUMAB (ENTYVIO) has not been associated with PML, likely because the integrin that VEDOLIZUMAB (ENTYVIO) targets is found mostly in the gastrointestinal system. While

experts suspect it is unlikely, it remains possible that VEDOLIZUMAB (ENTYVIO) could eventually become associated with PML.

## **IMPORTANT SAFETY INFORMATION:**

In deciding to use a medication, the risks of taking the medicine must be weighed against its benefits. Your Northwest Gastroenterology (NWGI) gastroenterologist should discuss these risks and benefits before you decide to start VEDOLIZUMAB (ENTYVIO).

Before starting VEDOLIZUMAB (ENTYVIO), you should inform your doctor if you have:

- A history of tuberculosis (TB) or exposure to someone with TB. Even if you have no history of TB or exposure to TB, your NWGI gastroenterologist will likely check you for TB with either a skin test or a blood test (for example, QuantiFERON Gold), as well as a chest x-ray. If you appear to have inactive tuberculosis, you may need to begin anti-TB treatment before you start VEDOLIZUMAB (ENTYVIO);
- Infections that keep returning, uncontrolled diabetes, or a problem with your immune system;
- Liver problems;
- Plans to receive vaccines (see below); or
- Become pregnant or plan to become pregnant.

**Vaccinations:** You should not receive live vaccines (e.g., Varicella [chickenpox] vaccine, Zoster [shingles] vaccine, or live polio vaccine) while on VEDOLIZUMAB (ENTYVIO), if at all possible. The injected flu and pneumonia vaccines can be safely administered while on VEDOLIZUMAB (ENTYVIO). The nasal spray version of the flu vaccine is a live vaccine and should be avoided while on VEDOLIZUMAB (ENTYVIO). Please inform your doctor if someone in your household has received a live virus vaccine.

## **PREGNANCY AND BREASTFEEDING:**

Please tell your NWGI gastroenterologist if you are pregnant, planning to become pregnant, or breastfeeding. This will allow you and your gastroenterologist to discuss appropriate measures related to your disease and medications. DO NOT stop your Crohn's or ulcerative colitis medications, including VEDOLIZUMAB (ENTYVIO), without telling your gastroenterologist. As pregnant patients were excluded from trials with VEDOLIZUMAB (ENTYVIO), it is unknown if VEDOLIZUMAB (ENTYVIO) is associated with any human birth defects; animal studies at high doses of VEDOLIZUMAB (ENTYVIO) showed no obvious birth defects, though this does not always predict accurately the effect in humans. It is also not known if VEDOLIZUMAB (ENTYVIO) is passed into human breast milk.

**MEDICATION INTERACTIONS:**

Please tell your NWGI gastroenterologist if you start new prescription or non-prescription medications, including vitamins and herbal supplements, while receiving VEDOLIZUMAB (ENTYVIO). This is especially important if you start other immune suppressants such as Remicade, Humira, Cimzia, Simponi, Actemra, Enbrel, Kineret, Orenzia, Rituxan, azathioprine (Imuran), or 6-mercaptopurine (6-MP).

**MEDICATION ADMINISTRATION:**

VEDOLIZUMAB (ENTYVIO) is administered as a single intravenous infusion lasting just over 30 minutes. You will see your NWGI gastroenterologist periodically to monitor your progress and response to VEDOLIZUMAB (ENTYVIO).

If you have any questions, you can call our office at (360) 734-1420 on Monday through Friday from 8 am to 5 pm.

*By signing, I indicate that I have read and understand this consent form and agree to receive VEDOLIZUMAB (ENTYVIO) infusions. I have had an opportunity to discuss this treatment with my physician and have had my questions answered.*

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Patient Signature

Date

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Patient Printed Name