

## **VEDOLIZUMAB**

### **What is Vedolizumab?**

Vedolizumab (Entyvio®) is an antibody that prevents the migration of pro-inflammatory white blood cells to the site of active inflammation and damage in the intestine. It acts primarily on the gastrointestinal tract with less of an effect on the systemic whole body immune response. It is approved for the treatment of Crohn's disease and ulcerative colitis.

### **How is it administered?**

Vedolizumab is administered intravenously via infusion. A typical infusion takes 30 minutes. You may receive a dose of steroids, acetaminophen (Tylenol®), or Benadryl® prior to the infusions to reduce likelihood of reactions.

Vedolizumab is typically administered at a dose of 300mg at weeks 0, 2, and 6 followed by every 8 week infusions. Some patients may need to reduce the interval between the infusions to every 4-6 weeks.

### **When can I expect to respond to Vedolizumab?**

Some patients may feel a benefit within 2-3 weeks of therapy. Typically, it takes up to 6-8 weeks in ulcerative colitis and 10-14 weeks in Crohn's disease to achieve a significant benefit.

Approximately 7 out of 10 patients will respond to Vedolizumab. The medication may stop working in up to 10% of patients every year. To ensure that it remains effective, it is important to receive regular infusions without gaps in treatment. Sometimes your doctor will also start a second immunosuppressive medication along with Vedolizumab to help it work better and to remain effective longer.

Studies have shown that early effective therapy for Crohn's disease or ulcerative colitis is associated with long-term benefit including decreasing likelihood of needing surgery or hospitalization for these conditions.

### **What testing is needed on Vedolizumab therapy?**

You will need blood testing to check for exposure to hepatitis B and tuberculosis infection prior to beginning treatment with Vedolizumab. You may also need testing for tuberculosis exposure annually. Blood counts and liver tests are routinely drawn every 4 months while on Vedolizumab. At times, your doctor may also check your Vedolizumab level to ensure that you are receiving adequate dosing.

### **What are the potential side effects related to Vedolizumab?**

Side effects with Vedolizumab are uncommon. Patients may develop allergic reactions to Vedolizumab as with any other medication. This is uncommon and can be treated

with steroids and anti-histamines. Fewer than 2% of patients may develop an infusion reaction which may occur during the infusions and present with fever, rash, trouble breathing, and chest pain or 2-3 days after the infusion in the form of joint aches.

As with other medications that act on the immune system, Vedolizumab can increase your risk of infections. Serious infections are uncommon, occurring in fewer than 2 or 3 out of 100 people.

Vedolizumab may increase the risk of lymphoma, a form of cancer of the lymph node. The frequency of this in the general population is estimated to be around 2 out of 10,000 people. We do not yet know if vedolizumab increases this risk due to its action primarily on the intestinal immune system. However, based on experimental studies and our experience so far – any increase in risk (if at all) with vedolizumab is likely to be less than 3-4 cases per 10,000 people.

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

### **Is Vedolizumab safe during pregnancy and breast feeding?**

Maternal and paternal use of Vedolizumab has not been associated with impairment of fertility, miscarriage, birth defects, preterm birth, still births, or other adverse pregnancy outcomes. You may get your last dose of Vedolizumab early in the third trimester of your pregnancy. If you are on Vedolizumab during pregnancy, it is recommended that your infant not receive live virus vaccines such as the rotavirus vaccine within the first 6 months. It is safe to breastfeed while on Vedolizumab. This has not been shown to have any adverse impact of the baby. It is important to discuss with your provider about continuing Vedolizumab before and during and after pregnancy, but most patients will continue the treatment during their pregnancy.

### **Health maintenance on Vedolizumab therapy**

It is important to be up to date with your health maintenance while on Vedolizumab therapy. This includes being current on all the recommended vaccines including annual influenza vaccine and pneumococcal vaccines.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and dermatologic (skin check-ups) for both men and women. Make sure to speak to your primary care doctor about whether you are up-to-date on all your cancer screening and immunizations.

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

There are a number of foundations that provide assistance to cover cost for patients on Vedolizumab therapy. The manufacturer of Vedolizumab has a patient assistance program for patients on Vedolizumab, called EntyvioConnect. Please go to <https://www.entyvio.com/entyvio-connect> for more information on this program.