

# PATIENT GUIDE TO FREQUENTLY ASKED QUESTIONS



## GENERAL INFUSION QUESTIONS



### WHAT IS AN INTRAVENOUS INFUSION?

An infusion is a procedure that **delivers medication directly** into your veins.



### WHO ADMINISTERS MY INFUSION TREATMENT?

**A trained healthcare professional** such as a doctor, physician's assistant, or nurse will prepare you for your infusion, administer your treatment, and monitor you after the infusion is completed.



### WHERE CAN I GO FOR MY INFUSIONS?

**There are different location options** for infusion treatments. Consult your doctor or the [ENTYVIO Infusion Center Locator](#) to find the best location for you and your needs.

#### Physician's Office

Your doctor may have the capability to do in-office infusions or refer you to providers close to you that offer in-office infusion treatments.

#### Home Infusion Service

Some treatments may be able to be administered at home. Talk to your doctor about your home infusion options.

#### Freestanding Infusion Center

These are independent centers located within a community. Select pharmacies may also offer infusion treatment services.

#### Hospital Outpatient Department

Hospitals often have outpatient services that offer infusion treatments. These services are offered in a hospital or at a hospital-owned facility.

## What is ENTYVIO?

ENTYVIO is a prescription medicine used in adults for the treatment of moderate to severe ulcerative colitis (UC) and moderate to severe Crohn's disease (CD).



## HOW DO I GET READY FOR MY INFUSION?

You will need a form of identification (eg, a driver's license) and insurance card to check in for your appointment. You may want to bring things to keep you occupied during your infusion.

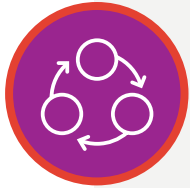
### Here are some ideas:

- Music player with headphones
- A book
- Laptop or tablet with streaming capabilities
- A sketchpad, crossword, or word search



## CAN I BRING SOMEONE TO MY APPOINTMENT?

**Each infusion center has its own policies** regarding guests, so please contact your infusion center for more details.



## WHAT DOES THE PROCESS LOOK LIKE ONCE I ARRIVE FOR MY APPOINTMENT?

**Many infusion centers ask that you arrive 10 to 15 minutes early** to your appointment to fill out necessary paperwork. After checking in, a healthcare provider will check your vital signs in preparation for the infusion.



The infusion site on your arm will be prepared for the insertion of a needle. After the needle is inserted, **you will be monitored to ensure that the treatment is going smoothly.**

### Important Safety Information

- **Do not receive ENTYVIO<sup>®</sup> if you** have had an allergic reaction to ENTYVIO or any of its ingredients.

## QUESTIONS SPECIFIC TO ENTYVIO



### HOW LONG WILL IT TAKE TO RECEIVE MY ENTYVIO INFUSION?

**ENTYVIO infusions typically take 30 minutes**, but you may have to stay longer if the healthcare professional wants to continue monitoring you.



### WILL MY DOCTOR BE PRESENT AT MY INFUSION?

Depending on the location of your infusion, your doctor may or may not be present. However, **a trained healthcare professional will monitor you** during and after the ENTYVIO infusion for side effects to see if you have a reaction to the treatment.



### WHAT ARE THE POSSIBLE SIDE EFFECTS FROM ENTYVIO?

**ENTYVIO may cause serious side effects, including:**

**Infusion-related and serious allergic reactions** can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get immediate medical help if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).



### WILL I BE ALLOWED TO EAT/DRINK DURING MY INFUSION?

Fasting is not required for infusions of ENTYVIO. However, each infusion center may have its own policy regarding food and drink.

### Important Safety Information (continued)

- **ENTYVIO may cause serious side effects, including:**
  - **Infusion-related and serious allergic reactions** can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get immediate medical help if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).

Please see additional Important Safety Information on [page 5](#).



## HOW OFTEN DO I NEED TO GO IN FOR AN ENTYVIO INFUSION?

Your healthcare provider will assess your response to therapy and need for continued treatment.

### Starting doses



Week 0



Week 2



Week 6

### Maintenance doses



Every 8 weeks

At the start, you will receive starting doses of ENTYVIO 300 mg by infusion at Weeks 0, 2, and 6. After that, maintenance treatments are given every 8 weeks.



## IS MY INFUSION COVERED BY INSURANCE?

Insurance coverage depends on each patient's insurance plan. It's best to check with your insurance company to confirm coverage before you begin treatment with ENTYVIO.

### This typically involves 2 steps:

- **Benefits Verification:** Your doctor's office will work with your insurance company to determine if ENTYVIO can be covered under your benefit plan.
- **Prior Authorization:** Your doctor's office will submit a request to your insurance company to get approval for you to start treatment with ENTYVIO. Keep in mind that the authorization process may take several weeks. Your doctor's office will be in touch if they need additional information.



To learn more about ENTYVIO, go to **Entyvio.com** or call **1-844-ENTYVIO** (1-844-368-9846)

## EntyvioCONNECT

Takeda wants to ensure that patients receive the treatment they need.

**Enroll in EntyvioConnect** for access to additional patient resources and financial support. Visit **EntyvioConnect** for additional terms and conditions.

### Important Safety Information (continued)

- **ENTYVIO may cause serious side effects, including:**
  - **Infections.** ENTYVIO may increase your risk of getting a serious infection. Before receiving and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or symptoms of an infection, such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.

Please see additional Important Safety Information on [page 5](#).

## Important Safety Information

- **Do not receive ENTYVIO® if you** have had an allergic reaction to ENTYVIO or any of its ingredients.
- **ENTYVIO may cause serious side effects, including:**
  - **Infusion-related and serious allergic reactions** can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get immediate medical help if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).
  - **Infections.** ENTYVIO may increase your risk of getting a serious infection. Before receiving and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or symptoms of an infection, such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.
  - **Progressive Multifocal Leukoencephalopathy (PML).** People with weakened immune systems can get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). Although unlikely while receiving ENTYVIO, a risk of PML cannot be ruled out. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare provider right away if you have any of the following symptoms: confusion or problems thinking, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of the body, blurred vision, or loss of vision.
  - **Liver problems** can happen in people who receive ENTYVIO. Tell your healthcare provider right away if you have any of the following symptoms: tiredness, loss of appetite, pain on the right side of your abdomen, dark urine, or yellowing of the skin and eyes (jaundice).
- **The most common side effects of ENTYVIO include:** common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, pain in extremities, and with injections under the skin; pain, swelling, or redness at the injection site. These are not all the possible side effects of ENTYVIO. Call your healthcare provider for medical advice about side effects.
- **Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you:** have or think you may have an infection or have infections that keep coming back; have liver problems; have tuberculosis (TB) or have been in close contact with someone with TB; have recently received or are scheduled to receive a vaccine; or if you are pregnant, breastfeeding, plan to become pregnant, or plan to breastfeed.
- **Tell your healthcare provider about all the medicines you take, especially if you take or have recently taken** Tysabri (natalizumab), Tyruko (natalizumab-sztn), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

**Please see accompanying full Prescribing Information, including the Medication Guide, for ENTYVIO and talk with your healthcare provider.**

**ENTYVIO is available for:**

- **intravenous (IV) infusion: 300 mg vedolizumab.**
- **subcutaneous (SC) injection: 108 mg vedolizumab.**

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

### What is ENTYVIO?

ENTYVIO is a prescription medicine used in adults for the treatment of:

- moderately to severely active ulcerative colitis (UC).
- moderately to severely active Crohn's disease (CD).

It is not known if ENTYVIO is safe and effective in children under 18 years of age.