

## MEDICATION GUIDE

**ENTYVIO® (en ti' vee oh)  
(vedolizumab)  
for injection, for intravenous use**

**ENTYVIO® (en ti' vee oh)  
(vedolizumab)  
injection, for subcutaneous use**

**ENTYVIO® (en ti' vee oh) PEN  
(vedolizumab)  
injection, for subcutaneous use**

### What is the most important information I should know about ENTYVIO?

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

- **Infusion-related and serious allergic reactions.** These 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 medical help right away 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 ENTYVIO and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or have 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.** 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 stomach (abdomen), dark urine, or yellowing of the skin and eyes (jaundice).

See “**What are the possible side effects of ENTYVIO?**” for more information about side effects.

### 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.

### Who should not receive ENTYVIO?

**Do not receive ENTYVIO if you** have had an allergic reaction to ENTYVIO or any of the ingredients in ENTYVIO. See the end of this Medication Guide for a complete list of ingredients in ENTYVIO.

### Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection, think you may have an infection or have infections that keep coming back (see “**What is the most important information I should know about ENTYVIO?**”).
- 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. Talk to your healthcare provider about bringing your vaccines up-to-date before starting treatment with ENTYVIO.
- are pregnant or plan to become pregnant. It is not known if ENTYVIO will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ENTYVIO.
  - **Pregnancy Registry:** There is a pregnancy registry for women who use ENTYVIO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry or you may contact the registry at 1-877-825-3327 to enroll.
- are breastfeeding or plan to breastfeed. ENTYVIO can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ENTYVIO.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal supplements.

**Especially tell your healthcare provider 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.

**How should I use ENTYVIO?****When given in a vein (intravenously):**

- You may receive ENTYVIO through a needle placed in a vein (intravenous infusion) in your arm.
  - ENTYVIO is given to you over a period of about 30 minutes.
  - Your healthcare provider will monitor you during and after the ENTYVIO infusion for side effects to see if you have a reaction to the treatment.

**When given under the skin (subcutaneously):**

- You may receive ENTYVIO as an injection under your skin (subcutaneous) every 2 weeks. You may receive your first subcutaneous injection after at least 2 intravenous infusions in place of the next scheduled intravenous infusion.
  - **See the detailed Instructions for Use that comes with ENTYVIO about the right way to prepare and give ENTYVIO.**
  - ENTYVIO is provided as single-dose prefilled syringe or single-dose prefilled pen (ENTYVIO PEN) for subcutaneous use. Your healthcare provider will prescribe the type that is best for you.
  - If your healthcare provider decides that you or your caregiver can give your injections of ENTYVIO at home, you or your caregiver should be shown the right way to prepare and inject ENTYVIO.
  - Do not inject ENTYVIO until you or your caregiver have been shown the right way by your healthcare provider.
  - Always check the label of your prefilled syringe or prefilled pen to make sure you have the correct medicine before each injection.
  - Do not shake ENTYVIO.
  - ENTYVIO is injected under your skin (subcutaneously) 1 time every 2 weeks.
  - Inject ENTYVIO under the skin (subcutaneous injection) in your upper legs (thighs) or stomach area (abdomen). The upper arms may also be used if a caregiver gives the injection.
  - Use a different injection site each time you use ENTYVIO.
  - Do not give an injection into moles, scars, bruises, or skin that is tender, hard, red, or damaged.
  - If you are not able to inject ENTYVIO at your regular scheduled time or you miss a dose of ENTYVIO, inject the dose as soon as possible. Then, inject your next dose every 2 weeks thereafter. If you are not sure when to inject ENTYVIO, call your healthcare provider.
  - If you take more ENTYVIO than you were told to take, call your healthcare provider.

**What are the possible side effects of ENTYVIO?**

**ENTYVIO may cause serious side effects, see “What is the most important information I should know about ENTYVIO?”**

**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 of the possible side effects of ENTYVIO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store ENTYVIO?**

- Store ENTYVIO in a refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, the prefilled syringe or prefilled pen can be left out of the refrigerator in its box at room temperature up to 77°F (25°C) for up to 7 days (for example, when traveling). Do not use the prefilled syringe or prefilled pen if left out of the refrigerator for more than 7 days or left in direct sunlight.
- Do not freeze ENTYVIO. Do not use ENTYVIO if it has been frozen.
- Keep ENTYVIO in the original package to protect from light until the time of use.
- ENTYVIO prefilled syringe or prefilled pen is not made with natural rubber latex.

**Keep ENTYVIO and all medicines out of the reach of children.**

**General information about the safe and effective use of ENTYVIO.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ENTYVIO for a condition for which it was not prescribed. Do not give ENTYVIO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ENTYVIO that is written for health professionals.

**What are the ingredients in ENTYVIO?**

**Active ingredient:** vedolizumab

**Inactive ingredients in vial for intravenous infusion:** arginine hydrochloride, histidine, histidine monohydrochloride, polysorbate 80 and sucrose

**Inactive ingredients in prefilled syringe or prefilled pen for subcutaneous injection:** arginine hydrochloride, citric acid monohydrate, histidine, histidine monohydrochloride, polysorbate 80, sodium citrate dihydrate, and Sterile Water for Injection

Manufactured by: **Takeda Pharmaceuticals U.S.A., Inc.**

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For more information, go to [www.ENTYVIO.com](http://www.ENTYVIO.com) or call 1-877-TAKEDA7 (1-877-825-3327).