

**Important Facts**  
**ENTYVIO (en ti' vee oh)**  
(vedolizumab)

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

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

- **Infusion 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).** It may be possible for a person to get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). People with weakened immune systems can get PML. 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:

- **with moderate to severe active ulcerative colitis (UC) when certain other UC medicines have not worked well enough or cannot be tolerated:**
  - to begin helping some of your symptoms
  - in people who respond to ENTYVIO, to help get UC under control (induce remission) and keep UC under control (maintain remission)
  - for people who respond to ENTYVIO, you may be able to reduce or stop the use of corticosteroid medicines
  - to improve the way the lining of your large intestine looks to your healthcare provider during colonoscopy
- **with moderate to severe active Crohn's disease when certain other Crohn's disease medicines have not worked well enough or cannot be tolerated:**
  - to begin helping some of your symptoms
  - in people who respond to ENTYVIO, to help get Crohn's disease under control (achieve remission)
  - for people who respond to ENTYVIO, you may be able to reduce or stop the use of corticosteroid medicines

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.

**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.
- are breastfeeding or plan to breastfeed. It is not known if ENTYVIO passes into your breast milk.

**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), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

**How will I receive ENTYVIO?**

- ENTYVIO is given 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.

**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, and pain in extremities.

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.

**General information about ENTYVIO**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about ENTYVIO that is written for health professionals. Do not use ENTYVIO for a condition for which it was not prescribed.

Manufactured by:  
**Takeda Pharmaceuticals America, Inc.**  
Deerfield, IL 60015  
U.S. License No. 1898

For more information, go to [www.ENTYVIO.com](http://www.ENTYVIO.com) or call 1-877-825-3327  
ENTYVIO is a trademark of Millennium Pharmaceuticals Inc. and is used under license by Takeda Pharmaceuticals America, Inc.  
All other trademark names are the property of their respective owners.  
©2014 – 2018 Takeda Pharmaceuticals America, Inc.  
VMB245 R2\_CFB06/18 L-BZV-0218-20

THIS CONTENT IS CREATED AND CONTROLLED BY WEBMD'S EDITORIAL STAFF

**LIVING WITH**  
**Ulcerative Colitis**

WHAT UC TREATMENT IS BEST FOR YOU? WORK WITH YOUR DOCTOR TO FIND OUT.

By Barbara Brody



Jan Reicher was in her early 20s when she began having symptoms that reminded her of what her father had struggled with for many years. “He was diagnosed with ulcerative colitis when I was 3,” says Reicher, now 52. “It didn’t take long for me to get diagnosed, probably because I was so familiar with the condition,” she says.

Although Reicher says her condition is not as severe as her father’s, she still struggled with flare-ups that began with blood in her stool, followed by mucus in her stool and lots of bloating. In the beginning, she also struggled emotionally. “I thought

it was my fault and that I somehow brought it on by not controlling my stress,” she says.

Fortunately, Reicher connected with a doctor who set her straight. He explained that while stress is sometimes a trigger, it doesn’t cause UC and that the condition often runs in families. He started Reicher on medication, and for nearly two decades she took various versions of mesalamine, a drug that fights inflammation in the colon. It worked, but she eventually developed a rare side effect: It damaged her kidneys. She had to stop taking it, and her symptoms immediately worsened.

Reicher’s doctor suggested that she try a special probiotic called VSL#3. Although it doesn’t help everyone, evidence shows that some patients with mild to moderate UC can achieve remission, in part by restoring the bacterial balance in the gut. It did the trick for Reicher, who has also used dietary changes and alternative treatments, like acupuncture, to manage her health. Today she rarely has flare-ups. She now takes medication for chronic constipation, which she says is uncomfortable yet far less dangerous than UC symptoms like bloody diarrhea.

**BE PROACTIVE**

While there’s no known cure for UC or a single path to remission, people can take steps to stay as healthy as possible, says **Siddharth Singh, MD**, a gastroenterologist at UC San Diego Medical Center.

**FOLLOW DOCTOR'S DIRECTIONS**

Take medication exactly as prescribed, and don’t try over-the-counter options (including probiotics) without first talking to your doctor, says Singh. Even if you’re in remission, you should be getting checkups at least every six months. Depending on which drugs you’re on, your doctor should also order blood tests to keep tabs on your blood counts and kidney and liver function and check for signs of inflammation.

**CONSIDER YOUR DIET**

Although there isn’t much scientific evidence that dietary changes can treat UC, they’re worth a try. Reicher says she’s benefitted from the specific carbohydrate diet (SCD), which nixes all starches, sugar, alcohol, and most dairy. Singh says his patients have also experimented with the low FODMAP diet—which eliminates certain carbs that may trigger gas and bloating—the Mediterranean diet, and the Paleo diet. “Like most things in medicine, it is not one-size-fits-all,” he says.

**BE OPEN TO OTHER APPROACHES**

Assemble your own team of experts, says Reicher. “I see Western doctors, integrative medical doctors, and Chinese medicine doctors,” she says. Singh agrees with this approach: Complementary therapy, such as acupuncture, can be helpful for reducing stress and managing depression, which can raise the risk of flares, he says. But he cautions that these treatments should be used along with medication, not as a replacement for it.

Reviewed by  
**Neha Pathak, MD**  
WebMD Medical Editor

GETTY IMAGES