SEE HOW THE CONDITION AFFECTS YOU

Ask your doctor how ulcerative colitis is different from other types of inflammatory bowel disease, and where it affects your gastrointestinal (GI) tract.

ENTYVIO is for adult patients with moderate to severe ulcerative colitis when certain other medicines have not worked well enough or cannot be tolerated.

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).
  - 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.
  - 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, and pain in extremities. 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.

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
### HOW THE DRUG WORKS

**Anti-integrin**
- Anti-a4B7 integrins block gut-directed white blood cells involved in the inflammatory response from moving out of the blood vessels and into the gut tissue by blocking a protein on the surface of these cells.

**Anti-TNFα**
- Blocks a protein called tumor necrosis factor α (TNF-α), which promotes inflammation in the intestine.

**Anti-interleukin**
- Blocks interleukin proteins, which are associated with the inflammation process.

**JAK Inhibitor**
- Blocks Janus kinase (JAK) enzymes involved in inflammation.

### WHERE IT WORKS

- Blocks interleukin proteins, which are associated with the inflammation process.

### WHO IT’S FOR

#### FOR ADULTS:

- Entyvio® (vedolizumab)
  - For adults with moderately to severely active ulcerative colitis.
  - Oral dose once or twice a day for at least 8 weeks.
  - IV infusion dose every 8 weeks.

- Humira® (adalimumab)
  - For adults with moderately to severely active ulcerative colitis.
  - SC dose every 4 weeks.
  - SC dose at Days 1 and 15.

- Remicade® (infliximab)
  - For adults with moderately to severely active ulcerative colitis.
  - IV infusion dose at Weeks 0, 2, and 6.

- Simponi® (golimumab)
  - For adults with moderately to severely active ulcerative colitis.
  - SC dose at Weeks 0 and 2.
  - SC dose at Weeks 0 and 6.

- Stelara® (ustekinumab)
  - For adults with moderately to severely active ulcerative colitis.
  - SC dose at Week 0.

- Xeljanz®/Xeljanz XR® (tofacitinib)
  - For adults with moderately to severely active ulcerative colitis.
  - Oral dose once or twice a day for at least 8 weeks.

#### FOR CHILDREN 6 YEARS AND OLDER AND ADULTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS WHO HAVE NOT RESPONDED WELL TO OTHER MEDICINES

- Entyvio® (vedolizumab)
  - Oral dose once or twice a day for at least 8 weeks.

- Simponi® (golimumab)
  - SC dose every 8 weeks.

- Xeljanz®/Xeljanz XR® (tofacitinib)
  - Oral dose once or twice a day for at least 8 weeks.

### DOSING SCHEDULE AND ROUTE OF ADMINISTRATION

- **Entyvio®**
  - IV infusion dose at Weeks 0, 2, and 6.
  - SC dose at Days 1 and 15.

- **Humira®**
  - SC dose every 4 weeks.

- **Remicade®**
  - SC dose every 8 weeks.
  - IV infusion dose at Weeks 0, 2, and 6.

- **Simponi®**
  - SC dose at Weeks 0 and 2.

- **Stelara®**
  - SC dose at Week 0.

- **Xeljanz®/Xeljanz XR®**
  - Oral dose once or twice a day for at least 8 weeks.

### APPROVED TREATMENTS FOR ULCERATIVE COLITIS

- **Entyvio®** (vedolizumab)
  - For adults with moderately to severely active ulcerative colitis.
  - Oral dose once or twice a day for at least 8 weeks.

- **Humira®** (adalimumab)
  - For adults with moderately to severely active ulcerative colitis.
  - SC dose every 4 weeks.

- **Remicade®** (infliximab)
  - For adults with moderately to severely active ulcerative colitis.
  - IV infusion dose at Weeks 0, 2, and 6.

- **Simponi®** (golimumab)
  - For adults with moderately to severely active ulcerative colitis.
  - SC dose at Weeks 0 and 2.

- **Stelara®** (ustekinumab)
  - For adults with moderately to severely active ulcerative colitis.
  - SC dose at Week 0.

- **Xeljanz®/Xeljanz XR®** (tofacitinib)
  - For adults with moderately to severely active ulcerative colitis.
  - Oral dose once or twice a day for at least 8 weeks.

### CLASSES OF TREATMENTS FOR ULCERATIVE COLITIS

- **Anti-integrin**
  - Anti-a4B7 integrins block gut-directed white blood cells involved in the inflammatory response from moving out of the blood vessels and into the gut tissue by blocking a protein on the surface of these cells.

- **Anti-TNFα**
  - Blocks a protein called tumor necrosis factor α (TNF-α), which promotes inflammation in the intestine.

- **Anti-interleukin**
  - Blocks interleukin proteins, which are associated with the inflammation process.

- **JAK Inhibitor**
  - Blocks Janus kinase (JAK) enzymes involved in inflammation.

### SAFETY CONSIDERATIONS

- **ENTYVIO®** (vedolizumab)
  - 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 while receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of serious infections. Although unlikely, progressive multifocal leukoencephalopathy (PML), a rare, serious brain infection caused by a virus, cannot be ruled out. Liver problems can occur with ENTYVIO.

### CLASSIFICATIONS

- **Anti-α4β7 integrins**
  - Block gut-directed white blood cells involved in the inflammatory response from moving out of the blood vessels and into the gut tissue by blocking a protein on the surface of these cells.

- **Anti-TNFα**
  - Blocks a protein called tumor necrosis factor α (TNF-α), which promotes inflammation in the intestine.

- **Anti-interleukin**
  - Blocks interleukin proteins, which are associated with the inflammation process.

- **JAK Inhibitor**
  - Blocks Janus kinase (JAK) enzymes involved in inflammation.

### CLASSES OF TREATMENTS FOR ULCERATIVE COLITIS

- **Entyvio®** (vedolizumab)
  - For adults with moderately to severely active ulcerative colitis.

- **Humira®** (adalimumab)
  - For adults with moderately to severely active ulcerative colitis.

- **Remicade®** (infliximab)
  - For adults with moderately to severely active ulcerative colitis.

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  - For adults with moderately to severely active ulcerative colitis.

- **Stelara®** (ustekinumab)
  - For adults with moderately to severely active ulcerative colitis.

- **Xeljanz®/Xeljanz XR®** (tofacitinib)
  - For adults with moderately to severely active ulcerative colitis.

### USES OF ENTYVIO®

ENTYVIO® is a prescription medicine used in adults for the treatment of:
- Moderately to severely active ulcerative colitis.
- Moderate to severe ulcerative colitis when certain other medicines have not worked well enough.

Please refer to each product’s Prescribing Information for additional information.

### Important Safety Information

- Safety Considerations:
  - 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 while receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of serious infections. Although unlikely, progressive multifocal leukoencephalopathy (PML), a rare, serious brain infection caused by a virus, cannot be ruled out. Liver problems can occur with ENTYVIO.

- Please see Important Safety Information on page 1.