Entyvio®
vedolizumab

The ACG Recommends Entyvio (vedolizumab) as a Biologic Therapy Option for the Induction and Maintenance of Remission in Adults With Moderately to Severely Active Ulcerative Colitis[1]

Please refer to the publication for a full list of recommendations from the ACG clinical guidelines for ulcerative colitis in adults.

> *"The anti-integrin drug vedolizumab is an **effective therapy** for induction of remission of moderately to severely active UC. The mechanism of this therapy (inhibition of alpha-4 beta-7 integrins) targets the mucosal immune system of the gut..."*[1]
>
> —
>
> Excerpted from "ACG Clinical Guideline 2019: Ulcerative Colitis in Adults"

INDICATION

Adult Ulcerative Colitis (UC)

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active UC.

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see additional Important Safety Information on page 3.

Takeda

ACG=American College of Gastroenterology; UC=ulcerative colitis.

Select ACG Recommendations for Entyvio (vedolizumab)[1]

ACG Recommendations for the Induction of Remission in Moderately to Severely Active UC[1]

In adult patients with moderately to severely active UC, the ACG recommends vedolizumab for the induction of remission (strong recommendation, moderate quality of evidence)

In adult patients with moderately to severely active UC who have previously failed anti-TNF therapy, the ACG recommends vedolizumab for induction of remission (strong recommendation, moderate quality of evidence)

ACG Recommendations for the Maintenance of Remission in Patients With Moderately to Severely Active UC[1]

The ACG recommends continuing vedolizumab to maintain remission in patients with previously moderately to severely active UC now in remission after vedolizumab induction (strong recommendation, moderate quality of evidence)

ACG Assessment of the Strength of the Recommendation and Quality of Evidence Based on the GRADE Process[1]

- A "strong" recommendation is made when the benefits clearly outweigh the negatives and/or the result of no action
- "Moderate" quality of evidence is associated with moderate confidence in the effect estimate, although further research would be likely to have an impact on the confidence of the estimate

Please refer to the publication for a full list of recommendations from the ACG clinical guidelines for ulcerative colitis in adults.

IMPORTANT SAFETY INFORMATION

- Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

Please see additional Important Safety Information on page 3.

ACG=American College of Gastroenterology; GRADE=Grading of Recommendations, Assessments, Development, and Evaluation; TNF=tumor necrosis factor; UC=ulcerative colitis.

Entyvio® vedolizumab

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.
- Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.
- Progressive multifocal leukoencephalopathy (PML), a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML is caused by the John Cunningham (JC) virus and typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported in the post marketing setting (e.g., human immunodeficiency virus [HIV] infection with a CD4 count of 300 cells/mm^3 and prior and concomitant immunosuppression). Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.
- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.
- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please see accompanying full Prescribing Information, including Medication Guide.

Entyvio (vedolizumab) is a First-Line Biologic Therapy Option in Adults for the Treatment of Moderately to Severely Active Ulcerative Colitis[2]

- Entyvio (vedolizumab) is for adults with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a **tumor necrosis factor (TNF) blocker** or **immunomodulator**, or had an inadequate response with, were intolerant to, or demonstrated dependence on **corticosteroids**.[2]

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see additional Important Safety Information on page 3.

REFERENCES:

1. Rubin DT et al. *Am J Gastroenterol*. 2019;114(3):384-413. **2.** Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.

Entyvio® vedolizumab

Takeda