Entyvio®
vedolizumab

DOSING GUIDE

For adults with moderately to severely active ulcerative colitis (UC) or Crohn's disease.

TREAT FLEXIBLY

ENTYVIO has 2 options for maintenance therapy—
IV infusion or SC injection with the ENTYVIO Pen.[1]

IV=intravenous; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO 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 last page.

IV DOSING

Starting New Patients

START

Start with 300 mg IV infusions for:

Weeks 0 and 2[1]

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q2W
Disp: 2 IV doses
Refills: 0

MAINTAIN

Starting at Week 6, continue with infusions every 8 weeks[1]

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q8W
Disp: 1 IV dose
Refills:

Discontinue ENTYVIO in patients who show no evidence of therapeutic benefit by Week 14.[1]

The efficacy and safety of switching from ENTYVIO SC to ENTYVIO IV have not been studied.

APPROXIMATELY 30 MINUTES

Per infusion

Plus monitoring time

6 INFUSIONS

Per year

8 infusions in year 1

APPROXIMATELY 3 HOURS

Annual infusion time

4 hours in year 1

Prior to administration[1]

Patients should be brought up-to-date with all immunizations prior to starting ENTYVIO IV or SC.

Concomitant therapies[1]

ENTYVIO IV and SC can be administered concomitantly with aminosalicylates, steroids, and immunomodulators.

Administration[1]

ENTYVIO is administered as a 300 mg flat dose over an approximately 30 minute IV infusion. ENTYVIO SC is administered as a 108 mg single-dose prefilled pen.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** 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 last page.

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SC DOSING

Starting New Patients

START

Start with 300 mg IV infusions for:
Weeks 0 and 2[1]

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q2W
Disp: 2 IV doses
Refills: 0

MAINTAIN

Starting at Week 6, begin ENTYVIO 108 mg SC and continue every 2 weeks[1]

Rx: ENTYVIO Pen 108 mg
Sig: 1 single-dose prefilled pen Q2W
Disp: 2 SC pens
Refills:

SWITCH PATIENTS

- Patients responding to ENTYVIO IV after Week 6 may be switched to ENTYVIO SC
- Administer the first SC dose in place of the next scheduled IV dose and Q2W thereafter

Example: Established IV Maintenance Switching to SC Maintenance

Established IV maintenance regimen Q8W

To switch, replace next scheduled IV with SC

Monitoring[1]

ENTYVIO IV should be administered by a healthcare professional prepared to manage hypersensitivity reactions, including anaphylaxis, if they occur. Appropriate monitoring and medical support measures should be available for immediate use. Observe patients during infusion and until the infusion is complete.

Injection education[1]

After proper training on correct subcutaneous injection technique, a patient or caregiver may administer the ENTYVIO Pen if a healthcare professional determines it is appropriate. Patients and caregivers should be instructed to follow the directions for administration of the ENTYVIO Pen in the Instructions For Use section of the Prescribing Information.

For complete Dosage and Administration information, please click for Full Prescribing Information.

IV=intravenous; Q2W=every 2 weeks; Q8W=every 8 weeks; SC=subcutaneous; W=week.

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** 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.
- **Infections:** 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):** 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 typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported. Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms that may 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 neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- **Liver Injury:** 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.
- **Live and Oral Vaccines:** 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.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥3% and ≥1% higher than placebo) were: nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, pain in extremities, and injection site reactions with subcutaneous administration.

DRUG INTERACTIONS

Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab products and with TNF blockers. Upon initiation or discontinuation of ENTYVIO in patients treated with CYP450 substrates, monitor drug concentrations or other therapeutic parameters, and adjust the dosage of the CYP substrate as needed.

INDICATIONS

Adult Ulcerative Colitis (UC):

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

Adult Crohn's Disease (CD):

ENTYVIO is indicated in adults for the treatment of moderately to severely active CD.

DOSAGE FORMS & STRENGTHS:

- ENTYVIO Intravenous (IV) Infusion: 300 mg vedolizumab
- ENTYVIO Subcutaneous (SC) Injection: 108 mg vedolizumab

Please click for Full Prescribing Information.

Reference: 1. ENTYVIO (vedolizumab) prescribing information. Takeda Pharmaceuticals.

If you are a Colorado prescriber, please see the WAC disclosure form. If you are a Connecticut prescriber, please see the WAC disclosure form.

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