



Vedolizumab



Description

Vedolizumab is a humanized monoclonal antibody that selectively binds to the $\alpha 4\beta 7$ integrin and inhibits the migration of memory T-lymphocytes into inflamed gastrointestinal tissue.



Dosage Forms

Powder For concentrate for solution for IV Injection: 300 mg per vial.



Indications

Vedolizumab is indicated for the treatment of:

- Crohn disease, moderately to severely active
- Ulcerative colitis, moderate to severe
- Pouchitis: in adult patients with moderately to severely active chronic pouchitis (EMA-approval)
- Colitis, immune checkpoint inhibitor induced (off-label)



Dosing: Adults

Crohn disease, moderately to severely active

IV: 300 mg at weeks 0, 2, and 6, followed by 300 mg every 8 weeks.

In patients with inadequate or loss of response, maintenance dosing may be intensified to 300 mg every 4 to 6 weeks in selected patients.

Treatment should be discontinued in patients with no evidence of therapeutic benefit by week 10 to 14.

Ulcerative colitis, moderate to severe

Induction: IV 300 mg at weeks 0, 2, and 6, followed by 300 mg every 8 weeks.

Treatment should be discontinued in patients with no evidence of therapeutic benefit by week 14.

Pouchitis

300 mg administered by intravenous infusion at 0, 2, and 6 weeks and then every 8 weeks thereafter. Discontinuation of treatment should be considered if no evidence of therapeutic benefit is observed by 14 weeks of treatment with vedolizumab. Treatment with vedolizumab should be initiated in parallel with a standard-of-care antibiotic.

Colitis, immune checkpoint inhibitor induced (off-label use):

Note: For grade 2, 3, or 4 colitis with either high-risk endoscopic features on initial endoscopy examination or with persistent symptoms despite 3 days of corticosteroid therapy, consider adding vedolizumab to the treatment regimen.

IV: 300 mg at 0, 2, and 6 weeks and then (if needed) once every 8 weeks thereafter; use in combination with a corticosteroid.



Dosing: Pediatrics

Inflammatory bowel disease — limited data available

Children and adolescents:

IV: 10 mg/kg/dose at weeks 0, 2, and 6, followed by the same dose every 8 weeks thereafter.

Maximum dose: 300 mg/dose.

The dosing interval may be shortened from every 8 weeks to every 4 to 6 weeks in patients who do not achieve remission or who lose response after achieving remission.





Administration

IV: Infuse over approximately 30 minutes. Do not administer by IV push or bolus. Following infusion, flush with 30 mL of sterile 0.9% sodium chloride injection or lactated Ringer's solution. Patients should be observed during the infusion and monitored for hypersensitivity reactions; discontinue treatment if a reaction occurs.



Adverse Reactions

>10%

- Nervous system: Headache (12%)
- Neuromuscular & skeletal: Arthralgia (12%)
- Respiratory: Nasopharyngitis (13%)



Reproductive Considerations

Vedolizumab may be continued in patients with inflammatory bowel disease who are planning pregnancy. When biologic therapy is required, treatment should be optimized prior to conception.



Pregnancy and Breastfeeding Considerations

Vedolizumab crosses the placenta, but available data show no increased risk of major birth defects. IBD treatment may continue during pregnancy; if timed, the last dose can be given 6–10 weeks before delivery (4–5 weeks with Q4W dosing) and resumed 48 hours postpartum.

Vedolizumab appears in breast milk at low levels, with minimal infant exposure and expected GI degradation, and is considered compatible with breastfeeding.



Contraindications

Serious or severe hypersensitivity to vedolizumab or any component of the formulation. Patients with active severe infections or opportunistic infections.



Monitoring Parameters

- Infusion-related hypersensitivity reactions during and after infusion
- Liver Function Tests (LFTs)
- Tuberculosis screening according to local practice
- Signs and symptoms of infection
- Signs and symptoms of Progressive Multifocal Leukoencephalopathy (PML), including new or worsening neurological symptoms
- Disease activity measures, including:
 - Endoscopic evidence of ongoing mucosal inflammation in ulcerative colitis
 - Fecal calprotectin
 - Serial C-Reactive Protein (CRP)

REFERENCES

Vedolizumab Drug Information - UpToDate [September 2026]

Vedolizumab - FDA Label [Revised: 09/2026]

Vedolizumab - EMA SMPC [Last updated: 09/2026]