

HELP YOUR PATIENTS Enjoy^{the} Silence

OF LONG-TERM REMISSION IN UC

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What is the optimal treatment target in ulcerative colitis (UC)?

Disease clearance in moderate-to-severe UC using Entyvio[®] (vedolizumab)¹

 **Entyvio[®]**
vedolizumab

**START
SMART**

Entyvio[®] is indicated for the treatment of adult patients with moderately to severely active UC or Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor alpha (TNF α) antagonist.²

Entyvio is also indicated for the treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone colectomy and ileal pouch anal anastomosis for UC and have had an inadequate response with or lost response to antibiotic therapy.²



Disease clearance is a composite measure aiming for discrete targets^{3,4}

Each target in disease clearance is associated with a distinct benefit:



Symptomatic remission³

The resolution of symptoms, associated with improved patient quality of life^{5,6}



Endoscopic remission³

The absence of inflammatory lesions, predictive of steroid-free remission, prolonged length of remission, and reduced risk of biologic treatment failure⁷⁻⁹



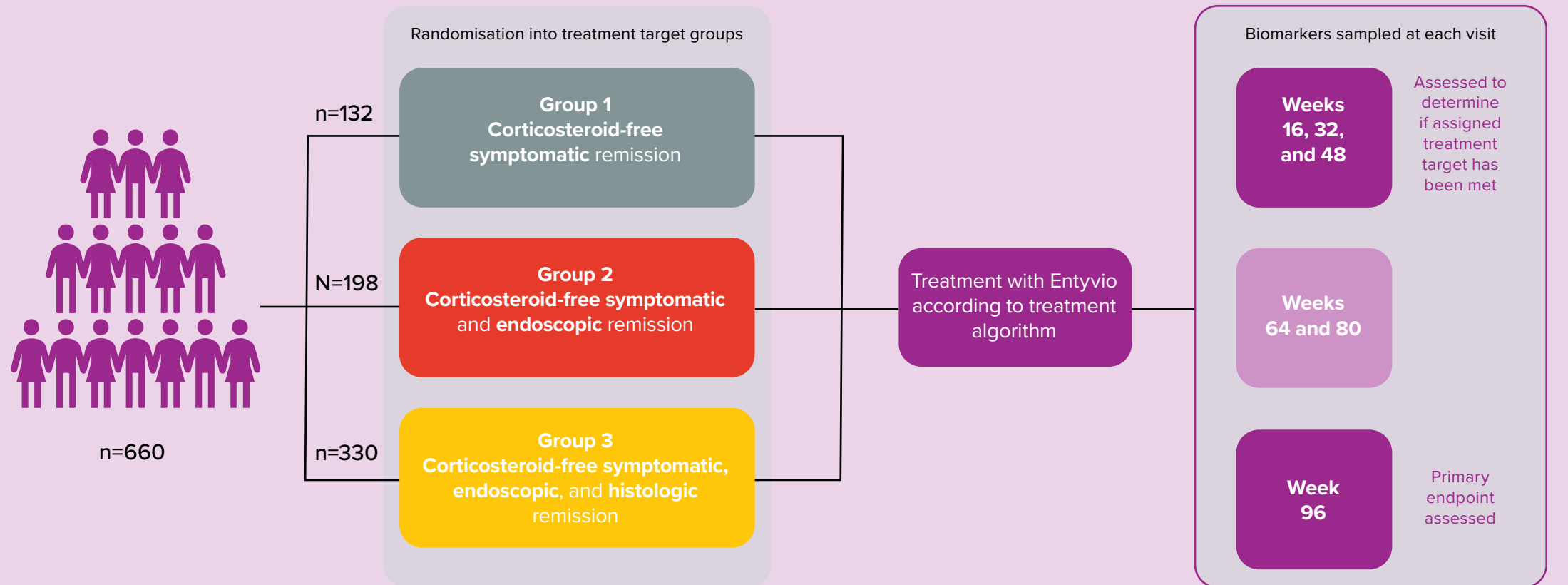
Histological remission³

Having histologically normal mucosa, associated with lower risks of colon cancer, hospitalisation, and surgeries^{4,10}



The VERDICT study aimed to determine the optimal treatment target for patients with moderate-to-severe UC being treated with Entyvio¹

Study design:¹



Primary endpoint:

To determine whether a composite treatment target (group 3) is superior to solely targeting CS-free symptomatic remission (group 1), measured by time from treatment target achievement to a disease-related complication¹



Entyvio achieved disease clearance treatment targets set out in VERDICT¹¹

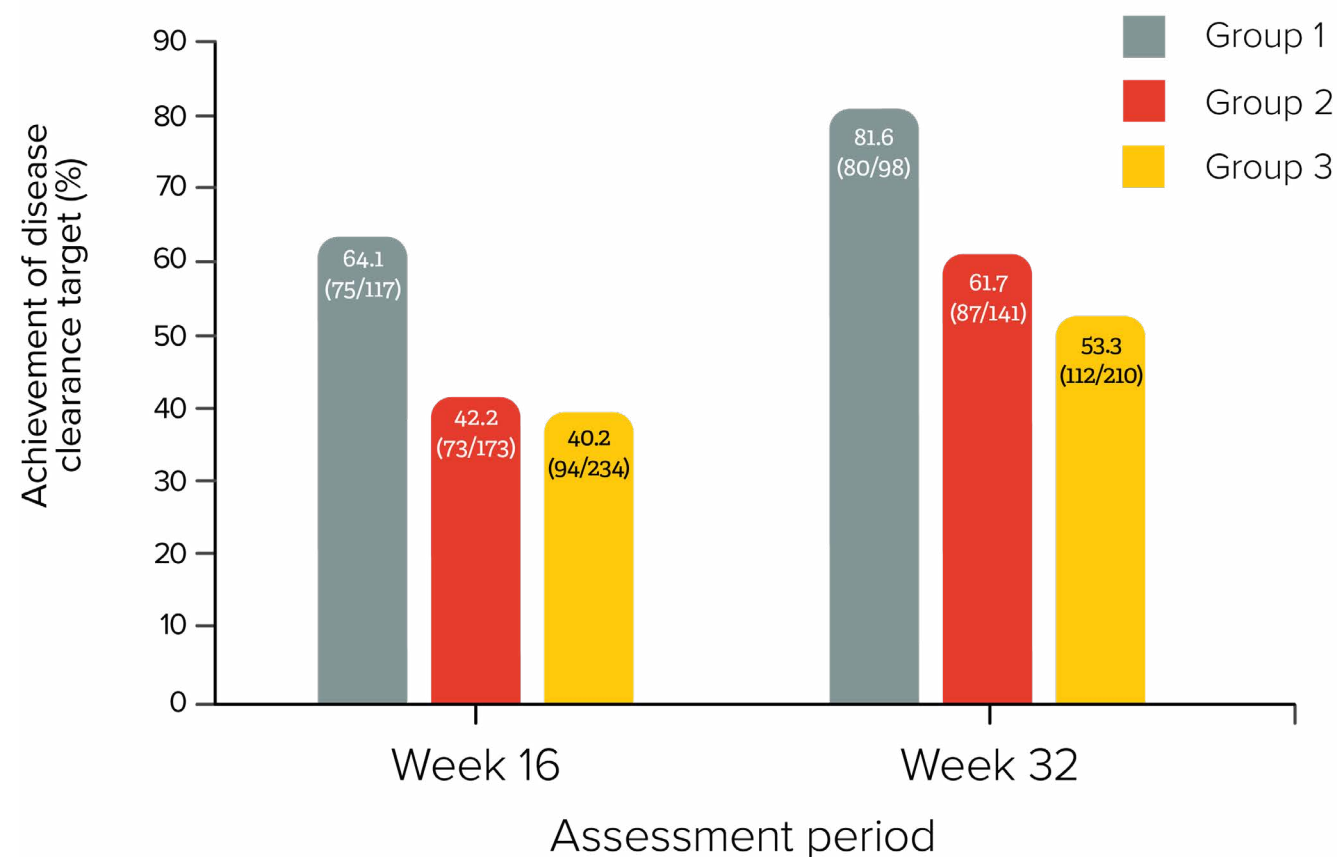
Data gathered as of 29 February 2024



613 patients were enrolled, randomised to the following groups:¹¹

- **Group 1:** Corticosteroid-free symptomatic remission (n=154)
- **Group 2:** Corticosteroid-free symptomatic and endoscopic remission (n=198)
- **Group 3:** Corticosteroid-free symptomatic, endoscopic and histologic remission (n=260)

Treatment targets were achieved across all groups (observed data)¹¹

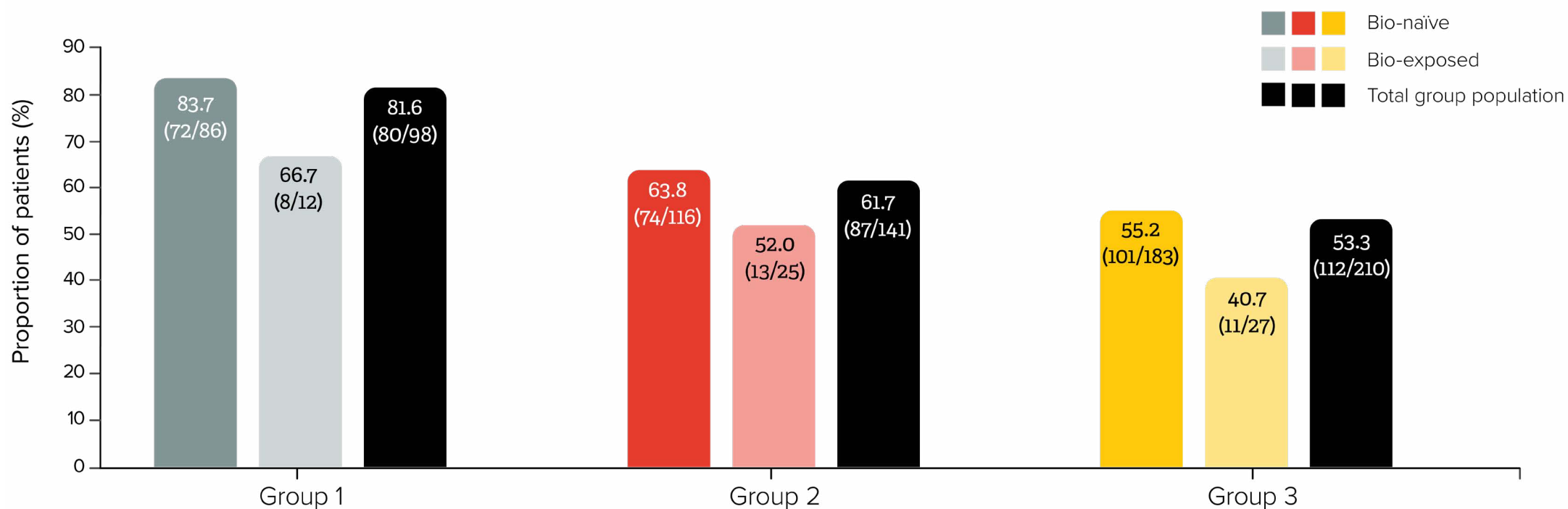


Adapted from Jairath V, et al. UEGW 2024¹¹



A higher proportion of bio-naïve patients achieved disease clearance targets with Entyvio compared with bio-exposed patients¹¹

Achievement of disease clearance target by Week 32:



Adapted from Jairath V, et al. UEGW 2024¹¹





The safety of Entyvio has been measured across several clinical trials²



Very common adverse events ($\geq 1/10$) include nasopharyngitis, headache, and arthralgia. Common adverse events ($\geq 1/100$ to $\leq 1/10$) include, but are not limited to injection site reactions (in subcutaneous formulation only), pneumonia, clostridium difficile infection, bronchitis, gastroenteritis, upper respiratory tract infection, influenza, and sinusitis.²



Infusion-related reactions (which may result in symptoms such as dyspnoea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate) have also been reported in patients treated with Entyvio.²

Hypersensitivity reactions have also been observed in patients switching from subcutaneous to intravenous administration.²



Entyvio is contraindicated in the case of active severe infections (such as tuberculosis, sepsis, cytomegalovirus, and listeriosis) and opportunistic infections (such as progressive multifocal leukoencephalopathy).² Warnings are also given regarding infusion-related reactions, hypersensitivity, infections, malignancies, and live and oral vaccines.²

For the full safety profile, please refer to the Summary of Product Characteristics by visiting www.medicines.ie or scanning the QR code²





References & abbreviations

1. Jairath V, et al. *BMJ Open Gastroenterol* 2024;11:e001218; 2. Entyvio Summary of Product Characteristics. Available at www.medicines.ie; 3. Danese S, et al. *Nat Rev Gastroenterol Hepatol* 2020;17:1-2; 4. Peyrin-Biroulet L, et al. *Clin Gastroenterol Hepatol* 2014;12:929-934; 5. Sandborn W, et al. *AJG* 2011;106:S456; 6. Matsuoka K, et al. *J Gastroenterol* 2023;58:751-765; 7. Shah S, et al. *Clin Gastroenterol Hepatol* 2016;14:1245-1255; 8. Komatsu A, et al. *Scientific Reports* 2024;14:303-308; 9. Kim K. *Clin Endosc* 2022;55:480-488; 10. Pai R, et al. *Exp Rev Gastroenterol Hepatol* 2024;18:73-87; 11. Jairath V, et al. Poster PP0556 presented at UEGW 2024.

CS, corticosteroid; UC, ulcerative colitis.

ENTYVIO® (vedolizumab) PRESCRIBING INFORMATION for REPUBLIC OF IRELAND

Refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Entyvio intravenous (IV): 300 mg powder for concentrate for solution for infusion. Each Entyvio 300 mg vial contains 3.31 mg of polysorbate 80. **Entyvio subcutaneous (S/C):** 108 mg solution for injection in pre-filled pen. Each 108mg pre-filled pen contains 1.48 mg of polysorbate 80. **Indication: Entyvio IV and Entyvio S/C:** Adult patients with moderately to severely active ulcerative colitis (UC)/Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. **Entyvio IV only:** Adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for UC, and have had an inadequate response with or lost response to antibiotic therapy. **Dosage and administration:** Treatment should be initiated and supervised by a specialist healthcare professional experienced in diagnosis and treatment of UC, CD or pouchitis. **Entyvio IV:** Patients should be monitored during and after infusion in a setting equipped to manage anaphylaxis. **UC:** Recommended dose regimen 300 mg administered by IV infusion over 30 minutes at 0, 2, 6 weeks and every 8 weeks thereafter. Discontinue treatment if no evidence of therapeutic benefit by week 10. If patients experience a decrease in response, they may benefit from increased dosage frequency to 300 mg every 4 weeks. Corticosteroids may be reduced/discontinued in patients who respond to treatment with Entyvio. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. **CD:** Recommended dose regimen is 300 mg administered by IV infusion over 30 minutes at 0, 2, 6 weeks and every 8 weeks thereafter. Patients who have not shown evidence of therapeutic benefit may benefit from a dose at week 10. Continue therapy every 8 weeks from week 14 in responding patients. Therapy should be discontinued if no evidence of therapeutic benefit is observed by week 14. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. **Pouchitis:** Recommended dose regimen is 300 mg administered by IV infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter. Treatment should be initiated in parallel with standard of care antibiotic (e.g., four-week of ciprofloxacin). Therapy discontinuation should be considered if no evidence of therapeutic benefit is observed by week 14. There are no retreatment data available if therapy is interrupted and needs to be restarted. **Entyvio S/C:** UC and CD: Recommended dose regimen, following at least two IV infusions, is 108mg administered by subcutaneous injection once every 2 weeks. The first S/C dose should be administered in place of the next scheduled IV dose and every 2 weeks thereafter. Insufficient data to determine if patients who experience a decrease in response on maintenance treatment with Entyvio S/C would benefit from an increase in dosing frequency. No data on transition of

patients from Entyvio S/C to Entyvio IV during maintenance therapy. **Paediatric populations:** No data available in children aged 0-17 years. Not recommended. **Elderly patients:** No dosage adjustment required. **Renal or hepatic impairment:** Entyvio has not been studied in these populations. No dose recommendation can be given. **Contraindications:** Hypersensitivity to Entyvio or any of the excipients. **Excipients list IV:** L histidine, L histidine monohydrochloride, L arginine hydrochloride, Sucrose, Polysorbate 80 (E 433). **Excipient list S/C:** Citric acid monohydrate (E 330), sodium citrate dihydrate (E 331), L histidine, L histidine monohydrochloride, L arginine hydrochloride, polysorbate 80 (E 433), water for injections. Active severe infections such as tuberculosis (TB), sepsis, cytomegalovirus, listeriosis and opportunistic infections such as Progressive Multifocal Leukoencephalopathy (PML). **Warnings and precautions: Entyvio IV:** Patients should be observed continuously during infusions for signs/symptoms of hypersensitivity reactions. Patients should continue to be observed for two hours following infusion completion for the first two infusions and one hour for subsequent infusions. **Infusion-related reactions (IRR):** Hypersensitivity reactions have been reported, the majority were of mild to moderate severity. Hypersensitivity reactions also reported in patients switching from subcutaneous to intravenous formulation. Discontinue treatment if anaphylaxis or other serious allergic reactions occur and initiate appropriate treatment. In mild to moderate IRR, slow or interrupt infusion. Consideration for pre-treatment with antihistamine, hydrocortisone and/or paracetamol should be given prior to next infusion, for patients with history of mild/moderate IRR to Entyvio. **Entyvio IV and Entyvio S/C: Infections:** Not recommended in patients with active, severe infections until infections are controlled. Consider withholding in patients who develop severe infection while on treatment with Entyvio. Before initiating treatment, patients must be screened for TB. If latent TB is diagnosed, anti-tuberculosis appropriate treatment must be initiated prior to Entyvio treatment. **Progressive Multifocal Leukoencephalopathy (PML):** John Cunningham (JC) virus infection resulting in PML and death has occurred in patients treated with other integrin receptor antagonists and systemic immunosuppressive agents. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs/symptoms. **Malignancy:** Underlying increased risk of malignancy in UC and CD. Immunomodulatory products may increase risk. **Prior and concurrent use of biological products:** No clinical data available for Entyvio use in patients previously treated with natalizumab or rituximab. Patients previously exposed to natalizumab should wait at least 12 weeks prior to initiating Entyvio therapy. Entyvio not recommended for concomitant use with biologic immunosuppressants as no clinical data available. **Live and oral vaccines:** Patients may continue to receive

non-live vaccines. Patients recommended to be up-to-date with all appropriate immunisations prior to initiating Entyvio. Live vaccines may be administered concurrently only if benefit clearly outweighs risk. **Interactions:** No interaction studies performed. **UC and CD:** Concomitant administration of corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, and methotrexate) and aminosalicylates did not have a clinically meaningful effect on Entyvio pharmacokinetics. **Pouchitis:** Concomitant administration of antibiotics have been observed. The effect on the pharmacokinetics of commonly co-administered medicinal compounds has not been studied. **Fertility, pregnancy and lactation:** There are no data on the effects of vedolizumab on human fertility. Women of childbearing potential should use adequate contraception and continue for at least 18 weeks after last Entyvio treatment. Preferable to avoid use of Entyvio during pregnancy unless benefits clearly outweigh potential risk to both the mother and foetus. Entyvio has been detected in human milk. The effects on breast-fed infants and milk production are unknown. Use of Entyvio in lactating women should consider the benefit of therapy against potential risks to the infant. **Undesirable effects:** No clinically relevant differences in overall safety profile and adverse reactions observed in patients who received Entyvio S/C compared with Entyvio IV except for injection site reactions (with S/C administration). **Very Common (≥1/10):** nasopharyngitis, headache, arthralgia. **Common (≥1/100, <1/10):** injection site reactions (S/C only), pneumonia, Clostridium difficile infection, bronchitis, gastroenteritis, upper respiratory tract infection, influenza, sinusitis, pharyngitis, herpes zoster, paraesthesia, hypertension, oropharyngeal pain, nasal congestion, cough, anal abscess, anal fissure, nausea, dyspepsia, constipation, abdominal distension, flatulence, haemorrhoids, rectal haemorrhage*, liver enzyme increased, rash, pruritus, eczema, erythema, night sweats, acne, muscle spasm, back pain, muscular weakness, fatigue, pain in extremity, pyrexia, infusion related reaction (IV only) (asthenia* and chest discomfort*), infusion site reaction (IV only) (including: infusion site pain and infusion site irritation). *Reported in the EARNEST pouchitis study. **Uncommon (≥ 1/1,000 to < 1/100) includes:** respiratory tract infection, blurred vision, vulvovaginal candidiasis, oral candidiasis, folliculitis. **Very rare (< 1/10,000):** anaphylactic reaction, anaphylactic shock, hepatitis. Not known: interstitial lung disease. **Refer to the SmPC for details on full side effect profile and interactions. Legal Classification:** POM. **Marketing authorisation (MA): Entyvio IV:** EU/1/14/923/001. **Entyvio S/C:** EU/1/14/923/005. **Name and Address of MA holder:** Takeda Pharma A/S, Delta Park 45, 2665 Vallensbaek Strand, Denmark. Additional information is available on request at: medinfo@takeda.com. **PI Approval Code:** pi-03975. **Date of revision:** Feb 2026.

Adverse Events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority.
Reporting forms and information can be found at: www.hpra.ie.
Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com.