

VEDOLIZUMAB

BRAND NAME	ENTYVIO
DRUG CLASS	Non-cytotoxic monoclonal antibody (humanised)
AVAILABILITY	Vial contains 300 mg of vedolizumab. Also contains histidine, histidine hydrochloride monohydrate, arginine hydrochloride, sucrose and polysorbate-80. ¹ Prefilled syringe and pen contain 108 mg/0.68 mL of vedolizumab. Also contain citric acid monohydrate, sodium citrate dihydrate, histidine, histidine hydrochloride monohydrate, arginine hydrochloride and polysorbate-80. ¹ The solution is clear and colourless to yellow. ¹
WARNINGS	The occupational hazard of intermittent low dose exposure to vedolizumab is not known. Wear a mask and gloves when reconstituting the vial and preparing the infusion solution to minimise exposure. Anaphylactic reactions may occur. Resuscitation facilities must be readily available. ¹
pH	Vial: 6.3 when reconstituted ¹ Prefilled syringe and pen: 6.5 ¹
PREPARATION	For IV infusion: allow the vial to come to room temperature. Slowly add 4.8 mL of water for injections down the wall of the vial. Do not add directly onto the powder to avoid foaming. Gently swirl the vial for at least 15 seconds. Do not shake or invert. Stand the vial for up to 20 minutes. Allow another 10 minutes if still not dissolved. ¹ The concentration is 60 mg/mL. ¹ The solution is clear or opalescent and colourless to light yellow. ¹ For SUBCUT injection: the prefilled syringe and pen are ready to use. Allow to reach room temperature before use.
STABILITY	Vial: store at 2 to 8 °C. ¹ Do not freeze. Protect from light. ¹ Reconstituted solution: stable in the vial for 8 hours at 2 to 8 °C. ¹ Infusion solution: solutions in sodium chloride 0.9% are stable for 12 hours at 25 °C or 24 hours at 2 to 8 °C. Solutions in Hartmann's: are stable for 8 hours at 2 to 8 °C. ¹ Stability of the infusion solution includes (not additional to) hold time in the vial. Prefilled syringe and pen: store at 2 to 8 °C. ¹ Do not freeze. Protect from light. ¹ Stable for 7 days below 25 °C. Do not return to the fridge. ¹
ADMINISTRATION	
IM injection	Not recommended
SUBCUT injection	Suitable for patients who have previously tolerated at least 2 IV infusions. ¹ Use the prefilled syringe or pen. Inject into the front thigh, abdomen or upper arm. Rotate the site of injection. ² Suitable for self-administration after appropriate patient education. ¹
IV injection	Not recommended ¹
IV infusion	Gently invert the vial 3 times. Dilute 5 mL (300 mg) in 250 mL of a compatible fluid. Gently invert the bag to mix. Do not shake. ¹ Infuse over 30 minutes. ¹
COMPATIBILITY	
Fluids	Hartmann's ¹ , sodium chloride 0.9% ¹
Y-site	Do not mix with other medicines
INCOMPATIBILITY	No information
SPECIAL NOTES	Monitor for possible anaphylactic and infusion reactions during and for some time after the infusion. Infusion reactions are usually mild and include headache, dizziness, pruritis, hypotension, hypertension, nausea, vomiting and pyrexia. If necessary stop or slow the rate of infusion and treat with an antihistamine, paracetamol and/or a corticosteroid. ¹ Most infusion reactions occur during the infusion or within the first two hours however delayed reactions can occur. ¹ Anaphylactic reactions are rare but are a medical emergency. Stop the infusion and commence treatment immediately. ¹

REFERENCES

1. Product information. Available from www.tga.gov.au. Accessed 30/03/2022.
2. Consumer medicine information. Available from www.tga.gov.au. Accessed 30/03/2022.