Vedolizumab

Reduce direct handling to a minimum and wear appropriate protective clothing		
CAUTION: High Administration Risk Rating		
Form & Storage	Powder for concentrate for solution for infusion	Store in a refrigerator (2°C - 8°C) in the original package to protect from light.
Reconstitution	• Allow vial to reach room temperature. • Add 4.8mL water for injections, using a syringe with a 21-25 gauge needle, directing the liquid down the wall of the vial to avoid excessive foaming. • Gently swirl the vial for at least 15 seconds. Do not shake vigorously or invert. • Leave for 20 minutes to allow foam to settle; the vial can be gently swirled occasionally during this time. • If not fully dissolved, leave for another 10 minutes. The solution should be clear or opalescent and colourless to light yellow. **Must be diluted further before administration**	
Compatibility & Stability	Sodium Chloride 0.9% ONLY	
Administration	**IV Infusion** Invert the vial gently three times before withdrawing 5mL (300mg) of the reconstituted solution with a 21-25 gauge needle. Add to a 250mL infusion bag of sodium chloride 0.9%. Gently mix the contents of the bag. Administer by IV infusion over 30 minutes. See ***PPG-CUH-CUH-243** Policy Procedure and Guidelines for Management of Patients Attending CUH Infusion Unit for Intravenous Therapy CUH for more information	
Monitoring	• Vital signs pre and post infusion • All patients should be observed continuously during each infusion • Patients are observed for one hour after the first two infusions for signs and symptoms of acute hypersensitivity reactions • Observation is not required for subsequent infusions unless clinically indicated (These are directives given by Gastroenterology Consultants) • Before the first three infusions, Full Blood Count, Renal/Liver/Bone profile, C Reactive Protein are taken by phlebotomy/GP • Bloods for subsequent infusions are taken on cannulation and are used as a baseline for the next infusion if the patient is well. • If after the induction phase (week 14), the patient's bloods fall within the established parameters outlined in 7.8, it is acceptable with the Gastroenterology team for blood testing on cannulation up to every 8 weeks (retrospective)	

	• If the patient presents to the unit and meets the criteria in 7.7*, medical review may be required prior to reconstituting medication for infusion • Monitor for signs and symptoms of a hypersensitivity reaction (bronchospasm, dyspnoea, hypertension, rash, chest tightness, urticaria, wheezing) during the infusion and after completion • Assess neurologic status frequently, withhold treatment if PML is suspected • Monitor for signs and symptoms of liver injury (elevated bilirubin, elevated liver function tests, and jaundice). Discontinue in patients with jaundice or other evidence of significant liver injury • Monitor for signs and symptoms of infection
Documentation Requirements	Document batch numbers and expiry dates of vials in medical notes.
Adverse Drug Reactions	Medicinal products for the treatment of hypersensitivity reactions, e.g. adrenaline, oxygen, antihistamines and corticosteroids should be available for immediate use in the event of an allergic reaction during administration of all infusions.
Disposal	Dispose of infusion bag and administration set in purple-lidded bin.

Information provided relates to Entyvio® (Takeda)