Eptinezumab (Vyepti®)

Reduce direct handling to a minimum and wear appropriate personal protective equipment		
CAUTION: High Administration Risk Rating		
Form	100mg concentrate for infusion (100mg/mL) 300mg concentrate for infusion (300mg/3mL)	Store in a refrigerator (2°C - 8°C) in the original package to protect from light.
Reconstitution	Already in solution **MUST be further diluted before administration** Prior to dilution, the medicinal product (concentrate in the vials) should be inspected visually; do not use if the concentrate contains visible particulate matter or is cloudy or discoloured (other than clear to slightly opalescent, colourless to brownish-yellow).	
Compatibility & Stability	Sodium Chloride 0.9% **ONLY**	
Administration	**IV Infusion only**	
	100mg dose • Withdraw 1.0 mL from one single-use 100 mg vial using a sterile needle and syringe. • Inject the 1.0 mL (100 mg) content into a 100 mL bag of 0.9% sodium chloride for injection **300mg dose** • Withdraw 1.0 mL from 3 x single-use 100 mg vials or 3.0 mL of Vyepti® from one single-use 300 mg vial using a sterile needle and syringe. • Inject the resulting 3.0 mL (300 mg) content into a 100 mL bag of 0.9% sodium chloride. Infuse over approximately 30 minutes. • Use an intravenous infusion set with a **0.2 µ in-line filter**. This filter **B Braun Sterifix® 0.2µ Ref 4099303** is available to order from stores. • After the infusion is complete, flush the line with 20 mL of 0.9% sodium chloride for injection.	
Documentation Requirements	Document batch numbers and expiry dates of vials in medical notes.	
Adverse Drug Reactions	The most common adverse reactions were nasopharyngitis and hypersensitivity. Most hypersensitivity reactions occurred during infusion and were not serious. Fatigue was most frequent on the day of the first infusion. Following the first week and with subsequent infusions, fatigue was reported in lower incidences and the incidences were comparable to placebo. Serious hypersensitivity reactions, including anaphylactic reactions, have been reported and may develop within minutes of the infusion. Most hypersensitivity reactions occurred during infusion and were not serious. If a serious hypersensitivity reaction occurs, administration of VYEPTI should be discontinued immediately and appropriate therapy initiated. If the hypersensitivity reaction is not serious, continuation of further treatment with VYEPTI is up to the discretion of the treating physician, taking into account the benefit-risk for the individual patient.	

	Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: **Ireland** HPRA Pharmacovigilance Website: www.hpra.ie
Disposal	Dispose of infusion bag and administration set in purple-lidded bin.
Additional Information	This medicinal product contains 40.5 mg of sorbitol in each mL. Patients with hereditary fructose intolerance (HFI) must not be given this medicinal product unless strictly necessary

Information provided relates to Vyepti® (Lundbeck)