Belimumab (Benlysta®)

Reduce direct handling to a minimum and wear appropriate personal protective equipment

Belimumab dosing is weight based; ensure accuracy of documented weight before administration

CAUTION: High Administration Risk Rating

Form	Vials containing belimumab powder for reconstitution – 120mg and 400mg	Store in a refrigerator (2°C - 8°C) in original carton to protect from light

Reconstitution	• Allow **10 to 15 minutes** for the vial to warm to room temperature (15°C to 25°C).
	• It is recommended that a 21–25-gauge needle be used when piercing the vial stopper for reconstitution and dilution.
	• Reconstitute with **water for injection**,
	  ○ **1.5mL per 120mg** vial or
	  ○ **4.8mL per 400mg** vial, to obtain a concentration of 80mg/mL
	• The stream of water for injections should be directed toward the side of the vial to minimize foaming. Gently swirl the vial for 60 seconds. Allow the vial to sit at room temperature (15°C to 25°C) during reconstitution, gently swirling the vial for 60 seconds every 5 minutes until the powder is dissolved.
	• Do not shake.
	• Reconstitution is typically complete within **10 to 15 minutes** after the water has been added, but it may take up to 30 minutes. Once reconstitution is complete, the solution should be opalescent and colourless to pale yellow, and without particles. Small air bubbles, however, are expected and acceptable.
	• A volume of 1.5mL (120mg belimumab) can be withdrawn from the 120mg vial
	A volume of 5mL (400mg belimumab) can be withdrawn from the 400mg vial
	• Protect the reconstituted solution from sunlight.
	• **MUST be further diluted before administration**	

Compatibility & Stability	Sodium chloride 0.9% **ONLY**	
Administration	**IV Infusion**	
	• Dilute **to 250mL** with sodium chloride 0.9% • Withdraw and discard a volume equal to the volume of the reconstituted Benlysta solution required for the patient's dose. • Then add the required volume of the reconstituted Benlysta solution into the infusion bag. • Gently invert the bag or bottle to mix the solution. • Infuse over 1 hour	
Premedication	• Paracetamol 1g IV if >50kg (15mg/kg if <50kg) • Chlorphenamine 10mg IV	
Monitoring	• The infusion rate may be slowed or interrupted if the patient develops an infusion reaction. • Monitor blood pressure, pulse, respiratory rate and temperature frequently (e.g., every 15 minutes initially then every 30-60 minutes if previous observations stable) during and for several hours post-	

	infusion (e.g., for 5 hours after first two infusions, but follow local guidance). • Warn patient that hypersensitivity reactions may occur/reoccur on the day of, or the day after, infusion and to seek immediate medical help if symptoms develop.
Documentation Requirements	Document batch numbers and expiry dates of vials in medical notes.
Adverse Drug Reactions	• Severe or life-threatening hypersensitivity reactions and infusion reactions. • Patients with a history of multiple drug allergies or significant hypersensitivity reactions may be at increased risk • Patients should remain under clinical supervision for a prolonged period of time (for several hours), following at least the first 2 infusions, taking into account the possibility of a late onset reaction. • Clinical trials show an increased risk of depression, suicidal ideation or behavior, or self-injury in patients with systemic lupus erythematosus on belimumab. Healthcare professionals should assess patients for these risks before starting treatment, monitor for new or worsening signs of these risks during treatment, and advise patients to seek immediate medical attention if new or worsening symptoms occur. • Monitor for symptoms suggestive of PML (e.g., cognitive, neurological or psychiatric symptoms or signs) during the course of treatment therapy • See **PPG-CUH-CUH-243** Policy Procedure and Guidelines for Management of Patients Attending CUH Infusion Unit for Intravenous Therapy CUH for more information

Information provided relates to Benlysta® (GlaxoSmithKlineUK)