

GEMTUZUMAB OZOGAMICIN

BRAND NAME	MYLOTARG
DRUG CLASS	Cytotoxic antineoplastic, monoclonal antibody (humanised)
AVAILABILITY	Vial contains 5 mg of gemtuzumab ozogamicin. Also contains dextran 40, dibasic sodium phosphate, monobasic sodium phosphate monohydrate, sodium chloride and sucrose. ¹
WARNING	Cytotoxic. Strict handling precautions are required. Doses less than 3.9 mg are prepared in a syringe – check the order and label carefully, to be given by IV infusion over 2 hours.
pH	No information
PREPARATION	In a cytotoxic drug safety cabinet: Reconstitute the vial with 5 mL of water for injections. Swirl gently to dissolve. Do not shake. The solution may contain some small translucent to opaque particles. The concentration is 1 mg/mL and the extractable volume is 4.5 mL. ¹ Dilute the dose with sodium chloride 0.9% to make a concentration between 0.075 mg/mL and 0.234 mg/mL. ¹ If the dose is less than 3.9 mg, prepare the solution in a syringe. For doses of 3.9 mg or more prepare the solution in a syringe or IV bag. ¹ Gently invert to mix. Do not shake. Protect the final product from light. ¹
STABILITY	Vial: store at 2 to 8 °C. Protect from light. ¹ Reconstituted solution: stable for 6 hours at 2 to 8 °C including up to 3 hours below 25 °C. Protect from light. Do not freeze. ¹ Infusion solution: stable for 18 hours at 2 to 8 °C including up to 6 hours below 25 °C. Protect from light. ¹ Administration must be completed within 18 hours of reconstitution with not more than 6 hours below 25 °C. ¹
ADMINISTRATION	
IM injection	Not recommended
SUBCUT injection	Not recommended
IV injection	Not recommended
IV infusion	Infuse over 2 hours. Use a low protein-binding 0.2 micrometre PES inline filter. ¹ Protect the syringe or infusion bag from light. It is not necessary to cover the IV tubing. ¹
COMPATIBILITY	Sodium chloride 0.9% ¹
INCOMPATIBILITY	No information
SPECIAL NOTES	Infusion reactions are common and include fever, chills, hypotension, tachycardia and dyspnoea. ¹ Monitor pulse, blood pressure and temperature during the infusion. ¹ Severe hypersensitivity and anaphylaxis are less common but are a medical emergency. Stop the infusion and commence treatment immediately. ¹ Premedication with a corticosteroid, antihistamine and paracetamol one hour before the infusion is recommended. ¹

REFERENCES

1. Product information, Available from www.tga.gov.au, Accessed 22/10/2020.