DARATUMUMAB

BRAND NAME	DARZALEX, DARZALEX SC
DRUG CLASS	Non-cytotoxic antineoplastic, monoclonal antibody (human)
AVAILABILITY	**Darzalex** vial contains 100 mg/5 mL and 400 mg/20 mL of daratumumab. Also contains glacial acetic acid, mannitol, polysorbate-20, sodium acetate trihydrate and sodium chloride. The solution is clear and colourless to yellow.[1] **Darzalex SC** vial contains 1800 mg/15 mL of daratumumab. Also contains recombinant human hyaluronidase, histidine, histidine hydrochloride, sorbitol, methionine and polysorbate-20. The solution is clear to opalescent and colourless to yellow.[1]
WARNING	The occupational hazard of intermittent low dose exposure to daratumumab is not known. Wear a mask and gloves when preparing the infusion solution to minimise exposure. Daratumumab is not cytotoxic. Severe infusion reactions may occur. Resuscitation facilities must be readily available.
pH	Darzalex: 5.5[2]
PREPARATION	**Darzalex**: dilute the dose to a final volume of 1000 mL with sodium chloride 0.9%. Invert the bag and mix gently. **Do not shake**.[1] A few small translucent particles may be present.[1] **Darzalex SC**: ready to use for subcutaneous injection only. Allow to reach room temperature before use. **Do not shake**.[1]
STABILITY	Vial: store at 2 to 8 °C. Do not freeze. Protect from light.[1] Darzalex SC vial is stable for 24 hours below 30 °C.[1] Darzalex SC solution is stable in a syringe for 24 hours at 2 to 8 °C protected from light followed by up to 12 hours at 15 to 25 °C and ambient light.[1] Infusion solution: stable for 24 hours at 2 to 8 °C protected from light and for 15 hours at 15 to 25 °C. Do not freeze.[1]
ADMINISTRATION	
IM injection	Not recommended[1]
SUBCUT injection	**Darzalex SC only**: inject slowly into the abdomen over 3 to 5 minutes.[1] Slow the injection if it is painful. Use a second site on the opposite side if required.[1]
IV injection	Not recommended[1]
IV infusion	**Darzalex only**: infuse the diluted solution at a rate of 50 mL/hour. If no infusion reactions occur increase the rate by 50 mL/hour every hour to a maximum rate of 200 mL/hour.[1] Use a low protein-binding, 0.22 or 0.2 micrometer inline PES filter.[1] If the first infusion is well-tolerated, a volume of 500 mL can be used for the second infusion.[1] If the first and second infusions are well-tolerated, a volume of 500 mL can be used and subsequent infusions can be started at 100 mL/hour.[1]
COMPATIBILITY	Sodium chloride 0.9%[1]
INCOMPATIBILITY	No information
SPECIAL NOTES	Infusion reactions are common with the first dose regardless of the route of administration and may be severe, including bronchospasm, hypoxia, dyspnoea, hypertension and pulmonary oedema. Delayed reactions can occur. Monitor during and after the infusion or injection.[1] For mild or moderate infusion reactions stop the infusion. When symptoms have resolved, restart the infusion at half the rate at which the reaction occurred.[1] For severe infusion reactions stop the infusion and treat accordingly.[1] Give a corticosteroid, antihistamine and paracetamol before the infusion or SUBCUT injection and a corticosteroid for 2 days after.[1] Check your local guidelines.

REFERENCES
1. Product information. Available from www.tga.gov.au. Accessed 21/06/2022.
2. Medical information. Daratumumab pH. [Phone call]. Macquarie Park, NSW: Janssen-Cilag Pty Ltd; 20/03/2019.