

USTEKINUMAB

BRAND NAME	STELARA
DRUG CLASS	Immunosuppressant, cytokine modulator, monoclonal antibody (human)
AVAILABILITY	Vial for subcutaneous use contains 45 mg/0.5 mL of ustekinumab. ¹ Prefilled syringe for subcutaneous use contains 90 mg/mL of ustekinumab. Vial and prefilled syringe for subcutaneous use also contain histidine/histidine hydrochloride, sucrose and polysorbate-80. ¹ The solution is clear to slightly opalescent and colourless to light yellow. ¹ Vial for intravenous use contains 130 mg/26 mL of ustekinumab. Also contains histidine, histidine hydrochloride, sucrose, polysorbate-80, L-methionine and disodium edetate. ¹ The solution is clear and colourless to light yellow. ¹
WARNING	The occupational hazard of intermittent low dose exposure to ustekinumab is not known. Wear a mask and gloves when reconstituting the vial and preparing the infusion solution to minimise exposure.
pH	6 ¹
PREPARATION	Do not shake the vial or prefilled syringe. ¹ Subcutaneous formulations are ready to use. For IV infusion, dilute the dose to 250 mL with sodium chloride 0.9% and mix gently. Do not shake. ¹
STABILITY	Vial and prefilled syringe: store at 2 to 8 °C. Do not freeze. Protect from light. ¹ Prefilled syringe is stable for 30 days below 30 °C. Do not return to the fridge. ¹ Infusion solution: stable for 8 hours below 25 °C. ¹
ADMINISTRATION	
IM injection	Not recommended
SUBCUT injection	Inject into the thigh, abdomen or upper arm. Suitable for self-administration after appropriate patient education. ^{1,2}
IV injection	Not recommended
IV infusion	Infuse over at least 1 hour. Use a low protein-binding 0.2 micrometre filter. ¹
COMPATIBILITY	
Fluids	Sodium chloride 0.9% ¹
Drugs	No information
INCOMPATIBILITY	No information
SPECIAL NOTES	Hypersensitivity reactions including rash and urticaria may occur. ¹ Anaphylactic reactions have been reported. ¹ For Crohn's disease, the first dose is given by IV infusion, then subsequent doses are given by subcutaneous injection. ¹ Given by subcutaneous injection for plaque psoriasis and psoriatic arthritis. ¹

REFERENCES

1. Product information. Available from www.tga.gov.au. Accessed 05/07/2022.
2. Consumer medicine information. Available from www.tga.gov.au. Accessed 05/07/2022.