

USTEKINUMAB

BRAND NAME	STELARA																				
DRUG CLASS	Immunosuppressant, cytokine modulator, monoclonal antibody (human)																				
AVAILABILITY	<p>Vial for subcutaneous use contains 45 mg/0.5 mL of ustekinumab.</p> <p>Prefilled syringe for subcutaneous use contains 90 mg/mL of ustekinumab.</p> <p>Vial and prefilled syringe for subcutaneous use also contain histidine, histidine hydrochloride, sucrose and polysorbate-80. The solution is clear to slightly opalescent and colourless to light yellow.¹</p> <p>Vial for intravenous use contains 130 mg/26 mL of ustekinumab.</p> <p>Also contains histidine, histidine hydrochloride, sucrose, polysorbate-80, L-methionine and disodium edetate. The solution is clear and colourless to light yellow.¹</p>																				
WARNING	<p>The occupational hazard of intermittent low dose exposure to ustekinumab is not known. Wear a mask (N95/P2) and gloves when reconstituting the vial and preparing the infusion solution to minimise exposure.</p>																				
pH	6 ¹																				
PREPARATION	<p>Subcutaneous formulations are ready to use. Do not shake the vial or prefilled syringe.¹</p> <p>For IV infusion – dilute the dose to 250 mL with sodium chloride 0.9% and mix gently. Do not shake.¹</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Dose</th> <th>Number of vials</th> <th>Volume of sodium chloride 0.9% to remove from a 250 mL bag</th> <th>Final volume</th> </tr> </thead> <tbody> <tr> <td>130 mg</td> <td>1</td> <td>26 mL</td> <td>250 mL</td> </tr> <tr> <td>260 mg</td> <td>2</td> <td>52 mL</td> <td>250 mL</td> </tr> <tr> <td>390 mg</td> <td>3</td> <td>78 mL</td> <td>250 mL</td> </tr> <tr> <td>520 mg</td> <td>4</td> <td>104 mL</td> <td>250 mL</td> </tr> </tbody> </table>	Dose	Number of vials	Volume of sodium chloride 0.9% to remove from a 250 mL bag	Final volume	130 mg	1	26 mL	250 mL	260 mg	2	52 mL	250 mL	390 mg	3	78 mL	250 mL	520 mg	4	104 mL	250 mL
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STABILITY	<p>Vial and prefilled syringe: store at 2 to 8 °C. Do not freeze. Protect from light.¹</p> <p>Prefilled syringe is stable for 30 days below 30 °C. Do not return to the fridge.¹</p> <p>Infusion solution: stable for 8 hours below 25 °C.¹</p>																				
ADMINISTRATION	<p>IM injection Not recommended</p> <p>SUBCUT injection Inject into the thigh, abdomen or upper arm. May be suitable for self-administration after appropriate patient education.^{1,2}</p> <p>IV injection Not recommended</p> <p>IV infusion See PREPARATION. Infuse over at least 1 hour. Use a low protein-binding 0.2 micrometre filter.¹</p>																				
COMPATIBILITY	Sodium chloride 0.9% ¹																				
INCOMPATIBILITY	No information																				
SPECIAL NOTES	<p>Hypersensitivity reactions including anaphylaxis, angioedema, rash and urticaria have been reported.¹</p> <p>For Crohn's disease, the first dose is given by IV infusion, then subsequent doses are given by subcutaneous injection.¹</p> <p>Given by subcutaneous injection for plaque psoriasis and psoriatic arthritis.¹</p>																				

REFERENCES

1. Product information. Available from www.tga.gov.au. Accessed 15/07/2024.
2. Consumer medicine information. Available from www.tga.gov.au. Accessed 15/07/2024.