

INFLIXIMAB

BRAND NAME	INFLECTRA, REMICADE, REMSIMA, RENFLEXIS
DRUG CLASS	Antirheumatic, immunosuppressant, monoclonal antibody, TNF-alpha antagonist
AVAILABILITY	Inflectra, Remicade, Remsima and Renflexis vials contain 100 mg of infliximab. Also contains monobasic sodium phosphate monohydrate, dibasic sodium phosphate dihydrate, sucrose and polysorbate-80. ¹ Remsima prefilled syringe and pen contain 120 mg/mL of infliximab. Also contain acetic acid, sodium acetate trihydrate, sorbitol and polysorbate-80. ¹ The solution is clear to opalescent and colourless to pale brown. ² INFLECTRA, REMSIMA and RENFLEXIS are biosimilar products to REMICADE. ¹
WARNINGS	The occupational hazard of intermittent low dose exposure to infliximab is not known. Wear a mask and gloves when reconstituting the vial and preparing the infusion solution to minimise exposure. Hypersensitivity and anaphylactic reactions may occur. Resuscitation facilities must be readily available. ¹
pH	6.9–7.5 when reconstituted ³
PREPARATION	Vial: reconstitute the vial with 10 mL of water for injections. Inject the water down the side of the vial and swirl gently to dissolve. Do not shake . Allow the solution to stand for 5 minutes to disperse any foam that forms. The solution is opalescent and colourless to light yellow. ¹ The concentration is 10 mg/mL. ¹ Start the infusion within 3 hours of reconstitution and dilution. ¹ Prefilled syringe and pen: allow to reach room temperature before use. ⁴
STABILITY	Vial: store at 2 to 8 °C. Do not freeze. ¹ Remicade may be stored below 30 °C for up to 12 months. Do not return to the fridge. ¹ Prefilled syringe/pen: store at 2 to 8 °C. Do not freeze. Protect from light. ¹ Stable for 25 °C for up to 28 days. Do not return to the fridge. ^{1,4} Reconstituted solution: stable for 24 hours at 2 to 8 °C ¹ Infusion solution: stable for 24 hours at 2 to 30 °C ¹
ADMINISTRATION	
IM injection	Not recommended ¹
SUBCUT injection	Suitable for maintenance therapy in adults. Use the prefilled syringe or pen. Inject into the abdomen, thigh or upper, outer arm. Rotate the site of injection. Suitable for self-administration after appropriate patient education. ¹
IV injection	Not recommended ¹
IV infusion	Dilute the dose with sodium chloride 0.9% to a final volume of 250 mL and a final concentration of 0.4–4 mg/mL. Infuse over 2 hours through a 1.2 micrometre low protein-binding inline filter. ¹ Patients who tolerate three 2-hour infusions may cautiously receive future infusions over at least 1 hour, if their dose is less than 6 mg/kg. ¹ Check your local guidelines.
IV use for infants and children	Dilute the dose with sodium chloride 0.9% to a final volume of 250 mL and a maximum final concentration of 4 mg/mL. Infuse over 2 hours through a 1.2 micrometre or smaller low protein-binding inline filter. ^{1,5}
COMPATIBILITY	
Fluids	Sodium chloride 0.9% ¹
Y-site	No information
INCOMPATIBILITY	No information

SPECIAL NOTES

Infusion reactions are common and are most likely to occur within a few hours and with the first and second infusion. Monitor the patient during and for at least 2 hours after the infusion for dyspnoea, urticaria, hypotension, flushing and headache. Slow or stop the infusion if necessary.¹

Anaphylactic reactions are a medical emergency. Stop the infusion and commence treatment immediately.

Pretreatment with an antihistamine, paracetamol and corticosteroid may help prevent mild infusion reactions.¹

REFERENCES

1. Product information. Available from www.tga.gov.au. Accessed 10/11/2021.
2. Consumer medicine information. Available from www.tga.gov.au. Accessed 10/11/2021.
3. Medical information. Remicade Infliximab medical information response 00229449-MIR [email]. Macquarie Park: Janssen-Cilag Pty Ltd; 26/06/2019.
4. Remsima subcutaneous. Instructions for self injection. Available from www.remsimate.com.au. July 2021. Accessed 10/11/2021.
5. Phelps SJ, Hageman TM, Lee KR, Thompson AJ. Pediatric injectable drugs. 11th ed. Bethesda, MD: Am Soc Health-System Pharmacists; 2018.