

NIRSEVIMAB

Indication	<ul style="list-style-type: none"> • Prevention of RSV¹⁻⁴ <ul style="list-style-type: none"> ○ Neonates born during RSV season^{1,5,6} ○ Infants entering their first RSV season^{1,5,6} ○ If indicated by infant's condition^{7,8}, as per ATAGI recommendations ○ If maternal vaccine status is unknown or administered less than 14 days before birth^{7,8} 			
INTRAMUSCULAR	Presentation	<ul style="list-style-type: none"> • Prefilled syringe: 50 mg • Prefilled syringe: 100 mg 		
	Dosage ^{1,6}	*Current gestational age	Weight	
		Less than 8 months	Less than 5 kg	50 mg single dose
			5 kg or more	100 mg single dose
	*Current gestational age is the same as postmenstrual age (PMA)			
Preparation	<ul style="list-style-type: none"> • Visually inspect solution (clear to opalescent and colourless to yellow^{1,6,9}) <ul style="list-style-type: none"> ○ Discard if cloudy, discoloured or contains particulate matter^{1,6} 			
Administration	<ul style="list-style-type: none"> • IM injection into thickest part of the vastus lateralis in the anterolateral thigh (maximum 0.5 mL per site)^{1,6,9} <ul style="list-style-type: none"> ○ If multiple injections into same thigh are necessary, separate injection sites by at least 2.5 cm⁵ 			
Special considerations	<ul style="list-style-type: none"> • Consider implementing a local protocol to aid identification of IM injection sites, such as <ul style="list-style-type: none"> ○ Left thigh—vitamin K₁ and HBIG ○ Right thigh—hepatitis B vaccine and nirsevimab • Precautions <ul style="list-style-type: none"> ○ Anticoagulation therapy or bleeding disorders (e.g. haemophilia, thrombocytopenia)^{1,9}, increased risk of injection site haematoma • If 100 mg single dose unavailable, administer 2 x 50 mg single dose 			
Timing of administration	<ul style="list-style-type: none"> • If available, refer to current QH RSV prevention clinical guidance • Aim to maximise protection during peak RSV season—usually April to September in most temperate climates of Australia⁵ <ul style="list-style-type: none"> ○ Single dose provides protection for at least 5 months^{1,3,5,6} • Term neonates <ul style="list-style-type: none"> ○ If born before or during RSV season, offer as soon as possible after birth ○ If born after RSV season, offer before the start of infant's first RSV season • If inpatient in neonatal unit <ul style="list-style-type: none"> ○ Individualise assessment⁷ ○ If prolonged admission, recommend administration prior to discharge⁷ • If confirmed RSV infection <ul style="list-style-type: none"> ○ Defer until asymptomatic⁷ 			
Documentation	<ul style="list-style-type: none"> • Consent and patient information as per local protocols • Personal Health Record (immunisation section) <ul style="list-style-type: none"> ○ Affix adhesive batch label from prefilled syringe • Australian Immunisation Register 			
Monitoring	<ul style="list-style-type: none"> • Post-immunisation observations (as per local protocol)⁹ <ul style="list-style-type: none"> ○ Injection site for redness and swelling^{1,9} 			
Compatibility	<ul style="list-style-type: none"> • No information^{6,9} 			
Incompatibility	<ul style="list-style-type: none"> • Do not mix other vaccines in same syringe^{1,9} 			



Interactions	<ul style="list-style-type: none"> • Other immunoglobulins (e.g. HBIG)⁹ <ul style="list-style-type: none"> ○ If administered at the same time, give in alternate thigh⁹ • Palivizumab <ul style="list-style-type: none"> ○ Do not administer if nirsevimab administered in same season^{1,6,7} ○ If palivizumab previously administered, nirsevimab can be administered after 28 days⁷
Stability ^{1,6,9}	<ul style="list-style-type: none"> • Refrigerate 2–8 °C <ul style="list-style-type: none"> ○ Do not freeze. Protect from light. Do not shake before use ○ Can be stored at room temperature for a maximum of 8 hours. Discard if not administered within this time
Side effects	<ul style="list-style-type: none"> • Integumentary: redness or swelling (injection site)^{1,9}, rash¹ • Nervous system: fever^{9,10} • Rare: hypersensitivity reaction (i.e. anaphylaxis)^{1,5,9}
Actions	<ul style="list-style-type: none"> • Recombinant human IgG long-acting monoclonal antibody against RSV^{1,3,4,11} • Provides passive immunity by targeting and altering the RSV surface protein¹¹ • Prevents fusion of viral and cellular membranes and viral entry into the host cell¹¹
Abbreviations	<ul style="list-style-type: none"> • Current gestational age is the same as <i>postmenstrual age</i> (PMA) <p>ATAGI: Australian Technical Advisory Group on Immunisation, HBIG: hepatitis B immunoglobulin, IgG: immunoglobulin G, IM: intramuscular, QH: Queensland Health, RSV: respiratory syncytial virus</p>
Keywords	human IgG, IgG, neonatal medicine, neonatal monograph, nirsevimab, passive immunity, respiratory syncytial virus, RSV

The Queensland Clinical Guideline *Neonatal Medicines* is integral to and should be read in conjunction with this monograph. Refer to the disclaimer. Destroy all printed copies of this monograph after use.

References

1. IBM Micromedex®/Neofax®. Nirsevimab. [Internet]. Colorado USA: Truven Health Analytics; 2024 [cited 2024 June 3]. Available from: <https://www.micromedexsolutions.com/neofax>.
2. Turalde-Mapili MWR, Mapili JAL, Turalde CWR, Pagcatipunan MR. The efficacy and safety of nirsevimab for the prevention of RSV infection among infants: a systematic review and meta-analysis. *Frontiers in Pediatrics* 2023;11:1-9. doi:10.3389/fped.2023.1132740.
3. Griffin MP, Yuan Y, Takas T, Domachowske JB, Madhi SA, Manzoni P, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. *The New England Journal of Medicine* 2020;383(5):415-25. doi:10.1056/NEJMoa1913556.
4. Hammitt LL, Dagan R, Yuan Y, Baca Cots M, Bosheva M, Madhi SA, et al. Nirsevimab for prevention of RSV in healthy late-preterm and term infants. *The New England Journal of Medicine* 2022;386(9):837-46. doi:10.1056/NEJMoa2110275.
5. Australian Government Department of Health and Aged Care. Australian Technical Advisory Group on Immunisation (ATAGI). [Internet]. March 2024 [cited 2024 June 4]:1-6. Available from: <https://www.health.gov.au/committees-and-groups/atagi>.
6. Therapeutic Goods Administration (TGA). Hydroxocobalamin (Hydroxo-B12). [Internet]. Canberra: Australian Government; October 2022 [cited 2024 August 26]. Available from: <https://www.tga.gov.au>.
7. Queensland Health. The Queensland Paediatric Respiratory Syncytial Virus Prevention Program. Clinical guidance for immunisation service providers 2024. Version 1.5. 2024. p. 1-17.
8. Australian Government Department of Health and Aged Care. Australian Immunisation Handbook. [Internet]. June 2024 [cited 2024 July 3]:1-37. Available from: <https://www.health.gov.au/resources/publications/the-australian-immunisation-handbook>.
9. Australian Injectable Drugs Handbook. Nirsevimab. 9th ed. [Internet]. New South Wales: Society of Hospital Pharmacists of Australia (SHPA); May 2024 [cited 2024 June 3]. Available from: <https://aidh.hcn.com.au>.
10. Drysdale SB, Cathie K, Flamein F, Knuf M, Collins AM, Hill HC, et al. Nirsevimab for prevention of hospitalizations due to RSV in infants. *The New England Journal of Medicine* 2023;389(26):2425-35. doi:10.1056/NEJMoa2309189.
11. Zhu Q, McLellan JS, Kallewaard NL, Ulbrandt ND, Palaszynski S, Zhang J, et al. A highly potent extended half-life antibody as a potential RSV vaccine surrogate for all infants. *Science Translational Medicine* 2017;9(388). doi:10.1126/scitranslmed.aaj1928.

Document history

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