Palivizumab
Newborn use only

2020

Alert	Cost effectiveness is unclear. Use of this drug should be done in conjunction with local hospital guidelines. Use should consider the infant's susceptibility to severe RSV disease, RSV prevalence and seasonality, risk of exposure including siblings and social factors, and parental preference.
Indication	Prophylaxis against RSV infection in at risk infants (see practice points section).
Action	Humanised monoclonal antibody that neutralises and inhibits fusion of respiratory syncytial virus (RSV) with the host cell, preventing its replication.
Drug type	Humanised monoclonal antibody
Trade name	Synagis solution for injection. [1]
Presentation	100 mg/mL; 0.5 mL (50 mg), 1 mL (100 mg)
Dose	Administer 15 mg/kg via intra-muscular injection once per month during periods of RSV risk (e.g. May to August in Southern Australia). Preferably administer first dose before RSV season (e.g. April in southern Australia). It may not be cost-effective to use beyond 12 months corrected age.
Dose adjustment	Therapeutic hypothermia: not applicable. ECMO: after cardiopulmonary bypass surgery, give a dose once child is stable (serum concentration markedly reduced after these procedures). Renal: not applicable. Hepatic: not applicable.
Maximum dose	Monthly doses of 15 mg/kg to maximum 5 doses. Infants discharged during RSV season may receive fewer doses.
Total cumulative dose	
Route	IM
Preparation	Do not dilute or mix with any other medications Do not shake the vial
Administration	Administration immediately by IMI into anterolateral thigh. The gluteal muscle should not be used as a routine site of injection due to the risk of damage to the sciatic nerve. Give injection volumes >1 mL as divided doses. To administer, remove the tab portion of the vial cap, clean the stopper with alcohol.
Monitoring	Hypersensitivity including anaphylaxis.
Contraindications	Palivizumab is contraindicated in patients with hypersensitivity to the active substance or other humanized monoclonal antibodies. [1]
Precautions	Keep all equipment needed for the treatment of severe hypersensitivity reactions ready before the administration of palivizumab.
Drug interactions	
Adverse reactions	These did not occur more commonly than in the placebo arm of a trial. [2]. Common (>1%): fever, rash, rhinitis, wheeze, cough, diarrhoea, injection site reaction, cyanosis (in children with congenital heart disease); Infrequent (0.1–1%) anaemia, elevated liver enzymes; Rare (<0.1%) hypersensitivity (including anaphylaxis). [3]
Compatibility	Not applicable. Do not reconstitute palivizumab with any other diluents or medicinal components.
Incompatibility	Do not reconstitute palivizumab with any other diluents or medicinal components.
Stability	Administer immediately.
Storage	Palivizumab vials should be stored in a refrigerator at 2^{O} to $8\,^{O}$C. Do not freeze. [1]
Excipients	Palivizumab contains histidine and glycine and the active ingredient, palivizumab, at a concentration of 100 milligrams per mL. [1]
Special comments	Educate the parents regarding adverse effects such as fever, irritability and diarrhoea.
Evidence	Refer to full version.
Practice points	**Palivizumab for prevention of respiratory syncytial virus infection in children:** Palivizumab prophylaxis is effective in reducing the frequency of hospitalisations including admissions to ICU due to RSV infection in children with chronic lung disease, congenital heart disease, or those born preterm. There is insufficient data to determine if Palivizumab prophylaxis reduces need for mechanical ventilation or mortality. [2] [LOE I GOR B] It is reasonable to consider use in Australia of palivizumab 15 mg/kg/dose from April to August (5 doses) in the following infants:

	• Ex-preterm infants with chronic lung disease (oxygen or respiratory support at 36 weeks post menstrual age); • Preterm infants born ≤26 weeks gestation; • Infants with haemodynamically significant congenital heart disease between 0 to <6 months age; and • Infants at risk of severe RSV bronchiolitis including infants with moderate to severe pulmonary conditions particularly those requiring continued respiratory and/or oxygen support. • Children with severe pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life. • Children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis. • Insufficient data are available to recommend palivizumab prophylaxis for children with cystic fibrosis or Down syndrome. Additional practice points: • Infants born during the RSV season may require fewer doses. [10, 12] • Prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization. [10, 12] • Prophylaxis is not required in congenital heart disease where there is mild cardiomyopathy or surgically corrected disease (unless medication required for heart failure). [3] • After cardiopulmonary bypass surgery, give a dose once child is stable (serum concentration markedly reduced after these procedures); resume doses each month if prophylaxis still required. [3]
References	Refer to full version.

VERSION/NUMBER	**DATE**
Original 1.0	**28/05/2020**
REVIEW (5 years)	28/05/2025

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