Beractant

Alert	This medication should only be administered by a medical officer or nurse practitioner.	
Indication	Treatment and prophylaxis of respiratory distress syndrome (RDS). Treatment of meconium aspiration syndrome (MAS).	
Action	Lowers surface tension on alveolar surfaces during respiration and stabilises the alveoli against collapse at resting transpulmonary pressures.	
Drug Type	Pulmonary surfactant	
Trade Name	Survanta	
Presentation	Suspension for intra-tracheal use 200 mg/8 mL	
Dosage/Interval	Respiratory distress syndrome Single dose of 100 mg/kg Dose may be repeated every 6 hours if required Maximum 4 doses in first 48 hours of life	
	Meconium aspiration syndrome Single dose of 150 mg/kg Dose may be repeated every 6 hours if required Maximum of 4 doses Studies have used doses in the range 100–150 mg/kg/dose.	
Maximum daily dose	RDS: 400 mg/kg/day MAS: 600 mg/kg/day	
Total cumulative	RDS: 4 doses in first 48 hours of life	
dose	MAS: 4 doses	
	Intra-tracheal	
Route		
Preparation/Dilution	Nil	
Administration	This medication should only be administered by a medical officer or nurse practitioner.	
	Inspect product visually for discolouration prior to administration (suspension should be white to light brown). Before use, the vial should be slowly warmed to room temperature (can be warmed in hand for at least 8 minutes or stood at room temperature for at least 20 minutes) and gently turned upside down in order to obtain a uniform suspension. DO NOT SHAKE. Assess patency and position of endotracheal tube (ETT) prior to administration. Clear the trachea of secretions. Shorten a 5 French end-hole catheter so that the length of the catheter is 1 cm shorter than the ETT tube. Slowly withdraw the contents of the vial(s) into a syringe through a needle (≥ 20 gauge). Do not shake. Attach shortened catheter to syringe. Fill catheter with surfactant. Administer in 1 to 2 aliquots as tolerated with the neonate in neutral supine position. If the infant is on a ventilator, the catheter can be inserted into the infant's ETT without interrupting ventilation by passing the catheter through a neonatal suction valve attached to the ETT. This is especially useful in high-frequency ventilation when it potentially minimises de-recruitment. Alternatively, surfactant can be instilled through the catheter by briefly disconnecting the ETT from the ventilator. Approximately 2 mL of air should be used to push any remaining surfactant in the catheter into the lungs. Please note: there are other administration methods available which are beyond the scope of this protocol.	
Monitoring	Continuous oxygen saturation and cardiorespiratory monitoring.	

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Contraindications	None known
Precautions	Beractant can rapidly affect oxygenation and lung compliance. Therefore, its use should be restricted to a highly supervised clinical setting with immediate availability of clinicians experienced with intubation, ventilator management and general care of premature infants.
Drug Interactions	N/A
Adverse Reactions	Transient: Bradycardia, hypotension, endotracheal tube blockage and oxygen desaturation (these events require stopping beractant administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring). Ventilator settings may need to be adjusted post-surfactant to accommodate increased lung compliance.
Compatibility	Beractant should not be mixed with any other medications or fluids.
Incompatibility	N/A
Stability	Vials are for single use only. DO NOT SHAKE. Unopened, unused vials of beractant that have warmed to room temperature can be returned to refrigerated storage within 8 hours for future use. Document on the packaging the date and time the product was removed from the fridge. Notify Pharmacy Department/NICU Pharmacist if this occurs. Do not warm to room temperature and return to refrigerated storage more than once.
Storage	Store at 2–8°C. Protect from light.
Special Comments	Surfactant may alter amplitude-integrated electroencephalography (aEEG) recordings after administration.
Evidence summary	Prophylaxis versus rescue treatment: A number of trials have previously demonstrated prophylactic administration of surfactant reduced mortality, rate of pneumothorax and interstitial emphysema over rescue treatment ⁵ (Grade A). Conversely, some recent trials suggest early initiation of CPAP and selective surfactant administration is associated with decreased chronic lung disease and mortality rates compared to prophylactic surfactant use. However, it is thought that the recruited populations may not be applicable to all babies ⁸ (Level I, Grade C). Therefore, the general consensus appears to favour early rescue treatment. However, if an extremely preterm infant requires immediate intubation for stabilisation or if the mother has not had antenatal steroids, then surfactant should be administered before a formal diagnosis of RDS ^{4,6} (Grade A).
	 High versus low initial dose: Two randomised studies involving poractant comparing initial dose of 200 mg/kg versus 100 mg/kg found no significant differences in long-term outcomes, although the higher dose offered short-term benefits in terms of early weaning of oxygen and ventilation ^{13,14} (Grade B, level II). A meta-analysis comparing poractant 200 mg/kg, 100 mg/kg, and beractant 100 mg/kg suggests a reduction in mortality favouring the higher dose of poractant ⁷ (Grade A). Number of doses: Randomised trials suggest multiple doses are beneficial compared to a single dose⁹ (Grade A). Two of the trials used up to 3 doses ^{10,12} (Grade B) and one trial used 4 doses ¹¹ (Level II). Meconium aspiration syndrome: A review of 4 randomised controlled trials found that surfactant administration (3 studies used
	 beractant, 1 used poractant) in infants with MAS may reduce the severity of respiratory illness and reduce the need for extracorporeal membrane oxygenation (ECMO) ¹⁵⁻¹⁸ (Grade A). A review of 3 randomised trials found lung lavage with diluted surfactant in infants with MAS may be beneficial (2 studies comparing diluted surfactant versus standard treatment found a significant decrease in the combined outcome of death and use of ECMO in the treatment group; 1 study compared surfactant lavage followed by surfactant bolus therapy versus surfactant bolus alone and observed no differences in mortality, pneumothorax, duration of mechanical ventilation, or duration of hospitalisation), but more evidence is needed ¹⁹.

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References	1. Thomson Reuters, Neofax 2011, Poractant Alfa Monograph, page 308–309.
Neiciciices	2. Hey E. Neonatal Formulary 6, 2011, Surfactants, page 248–249.
	3. MIMS, Curosurf Product Information, 2010, Ascent Pharma.
	4. Sweet et al. European Consensus Guidelines on the Management of Neonatal Respiratory
	Distress Syndrome in Preterm Infants – 2013 Update, Neonatology 2013;103:353–368.
	5. Soll R, Özek E. Prophylactic animal derived surfactant extract for preventing morbidity and
	mortality in preterm infants. Cochrane Database of Systematic Reviews 1997, Issue 4. Art. No.:
	CD000511. DOI: 10.1002/14651858.CD000511.
	6. Bahadue FL, Soll R. Early versus delayed selective surfactant treatment for neonatal respiratory distress syndrome. Cochrane Database of Systematic Reviews 2012, Issue 11. Art. No.: CD001456. DOI: 10.1002/14651858.CD001456.pub2.
	7. Singh N, Hawley KL, Viswanathan K: Efficacy of porcine versus bovine surfactants for preterm
	newborns with respiratory distress syndrome: systematic review and meta-analysis. Pediatrics 2011; 128:e1588–e1595.
	8. Rojas-Reyes MX, Morley CJ, Soll R: Prophylactic versus selective use of surfactant in preventing morbidity and mortality in preterm infants. Cochrane Database of Systematic Reviews 2012:CD000510.
	9. Soll R, Ozek E: Multiple versus single doses of exogenous surfactant for the prevention or
	treatment of neonatal respiratory distress syndrome. Cochrane Database of Systematic Reviews 2009:CD000141.
	10. Corbet A et al. Double-blind randomized trial of one versus three prophylactic doses of
	synthetic surfactant in 826 neonates weighing 700 to 1000 grams: effects on mortality rate.
	Journal of Pediatrics 1995;126:969–78.
	11. Dunn MS, Shennan AT, Possmayer F. Single- vs multiple-dose surfactant replacement therapy in neonates of 30 to 36 weeks' gestation with respiratory distress syndrome. Pediatrics 1990;86:564–71.
	12. Speer CP et al: Randomized European multicenter trial of surfactant replacement therapy for
	severe neonatal respiratory distress syndrome: single versus multiple doses of Curosurf. Pediatrics 1992; 89: 13–20.
	13. Halliday HL et al. (1993) Multicentre randomised trial comparing high and low dose surfactant
	regimens for the treatment of respiratory distress syndrome (the Curosurf 4 trial), Archives of Disease in Childhood; 69: 276-280.
	14. Figueras-Aloy J et al. Early administration of the second dose of surfactant (beractant) in the
	treatment of severe hyaline membrane disease. Acta Paediatr 2001;90:296–301.
	15. El Shahed AI, Dargaville PA, Ohlsson A, Soll R, Surfactant for meconium aspiration syndrome in
	full term/near term infants (Review), Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD002054.
	16. Findlay RD et al. Surfactant Replacement Therapy for Meconium Aspiration Syndrome, Pediatrics 1996, 97(1):48–52.
	17. Lotze et al. Multicenter study of surfactant (beractant) use in the treatment of term infants
	with severe respiratory failure, The Journal of Pediatrics 1998, 132(1):40–47.
	18. Chinese Collaborative Study Group for Neonatal Respiratory Diseases, Treatment of severe
	meconium aspiration syndrome with porcine surfactant: A multicentre, randomized, controlled trial, Acta Pædiatrica, 2005; 94: 896–902.
	19. Hahn S, Choi HJ, Soll R, Dargaville PA, Lung lavage for meconium aspiration syndrome in
	newborn infants (Review), Cochrane Database of Systematic Reviews 2013, Issue 4. Art. No.: CD003486.

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