

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
Dose	<p>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</p> <p>Meconium aspiration syndrome Single dose of 150 mg/kg Dose may be repeated every 6 hours if required Maximum of 4 doses</p> <p>Studies have used doses in the range 100–150 mg/kg/dose.</p>
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – Not applicable Renal impairment – No dose adjustment. Hepatic impairment – No dose adjustment.
Maximum dose	RDS: 400 mg/kg/day MAS: 600 mg/kg/day
Total cumulative dose	
Route	Intra-tracheal
Preparation	Not applicable
Administration	<p>This medication should only be administered by a medical officer or nurse practitioner.</p> <p>Inspect product visually for discolouration prior to administration (suspension should be white to light brown).</p> <p>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.</p> <p>Assess patency and position of endotracheal tube (ETT) prior to administration.</p> <p>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 (\geq 20 gauge). Do not shake.</p> <p>Attach shortened catheter to syringe. Fill catheter with surfactant.</p> <p>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.</p> <p>Alternatively, surfactant can be instilled through the catheter by briefly disconnecting the ETT from the ventilator.</p> <p>Approximately 2 mL of air should be used to push any remaining surfactant in the catheter into the lungs.</p> <p>Please note: there are other administration methods available which are beyond the scope of this protocol.</p>
Monitoring	Continuous oxygen saturation and cardiorespiratory monitoring.
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	Not applicable
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	No information.
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.
Excipients	
Special comments	Surfactant may alter amplitude-integrated electroencephalography (aEEG) recordings after administration.
Evidence	<p>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 treatment⁵ (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 babies⁸ (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).</p> <p>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 poractant⁷ (Grade A).</p> <p>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 doses¹¹ (Level II).</p> <p>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 needed¹⁹.</p>
Practice points	
References	<ol style="list-style-type: none"> Thomson Reuters, Neofax 2011, Poractant Alfa Monograph, page 308–309. Hey E. Neonatal Formulary 6, 2011, Surfactants, page 248–249. MIMS, Curosurf Product Information, 2010, Ascent Pharma. Sweet et al. European Consensus Guidelines on the Management of Neonatal Respiratory Distress Syndrome in Preterm Infants – 2013 Update, Neonatology 2013;103:353–368. Soll R, Özkan E. Prophylactic animal derived surfactant extract for preventing morbidity and mortality in preterm infants. Cochrane Database of Systematic Reviews 1997, Issue 4. Art. No.:

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Survanta (Beractant)

Newborn use only

2020

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