

<b>Alert</b>	This medication should only be administered by a medical officer or nurse practitioner.
<b>Indication</b>	Treatment and prophylaxis of respiratory distress syndrome (RDS). Treatment of meconium aspiration syndrome (MAS).
<b>Action</b>	Lowers surface tension on alveolar surfaces during respiration and stabilises the alveoli against collapse at resting transpulmonary pressures.
<b>Drug Type</b>	Pulmonary surfactant
<b>Trade Name</b>	Survanta
<b>Presentation</b>	Suspension for intra-tracheal use 200 mg/8 mL
<b>Dosage/Interval</b>	<p><b>Respiratory distress syndrome</b> 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><b>Meconium aspiration syndrome</b> 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>
<b>Maximum daily dose</b>	RDS: 400 mg/kg/day MAS: 600 mg/kg/day
<b>Total cumulative dose</b>	RDS: 4 doses in first 48 hours of life MAS: 4 doses
<b>Route</b>	Intra-tracheal
<b>Preparation/Dilution</b>	Nil
<b>Administration</b>	<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). 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 (<math>\geq 20</math> 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.</p> <p>Please note: there are other administration methods available which are beyond the scope of this protocol.</p>

<b>Monitoring</b>	Continuous oxygen saturation and cardiorespiratory monitoring.
<b>Contraindications</b>	None known
<b>Precautions</b>	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.
<b>Drug Interactions</b>	N/A
<b>Adverse Reactions</b>	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.
<b>Compatibility</b>	Beractant should not be mixed with any other medications or fluids.
<b>Incompatibility</b>	N/A
<b>Stability</b>	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.
<b>Storage</b>	Store at 2–8°C. Protect from light.
<b>Special Comments</b>	Surfactant may alter amplitude-integrated electroencephalography (aEEG) recordings after administration.
<b>Evidence summary</b>	<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 treatment<sup>5</sup> (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<sup>8</sup> (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<sup>4,6</sup> (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<sup>13,14</sup> (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<sup>7</sup> (Grade A).</p> <p>Number of doses: Randomised trials suggest multiple doses are beneficial compared to a single dose<sup>9</sup> (Grade A). Two of the trials used up to 3 doses<sup>10,12</sup> (Grade B) and one trial used 4 doses<sup>11</sup> (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)<sup>15-18</sup> (Grade A). A review of 3 randomised trials found lung lavage with diluted surfactant in infants with MAS may</p>

	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 <sup>19</sup> .
<b>References</b>	<ol style="list-style-type: none"> <li>1. Thomson Reuters, Neofax 2011, Poractant Alfa Monograph, page 308–309.</li> <li>2. Hey E. Neonatal Formulary 6, 2011, Surfactants, page 248–249.</li> <li>3. MIMS, Curosurf Product Information, 2010, Ascent Pharma.</li> <li>4. Sweet et al. European Consensus Guidelines on the Management of Neonatal Respiratory Distress Syndrome in Preterm Infants – 2013 Update, <i>Neonatology</i> 2013;103:353–368.</li> <li>5. Soll R, Özek E. Prophylactic animal derived surfactant extract for preventing morbidity and mortality in preterm infants. <i>Cochrane Database of Systematic Reviews</i> 1997, Issue 4. Art. No.: CD000511. DOI: 10.1002/14651858.CD000511.</li> <li>6. Bahadue FL, Soll R. Early versus delayed selective surfactant treatment for neonatal respiratory distress syndrome. <i>Cochrane Database of Systematic Reviews</i> 2012, Issue 11. Art. No.: CD001456. DOI: 10.1002/14651858.CD001456.pub2.</li> <li>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. <i>Pediatrics</i> 2011; 128:e1588–e1595.</li> <li>8. Rojas-Reyes MX, Morley CJ, Soll R: Prophylactic versus selective use of surfactant in preventing morbidity and mortality in preterm infants. <i>Cochrane Database of Systematic Reviews</i> 2012:CD000510.</li> <li>9. Soll R, Ozek E: Multiple versus single doses of exogenous surfactant for the prevention or treatment of neonatal respiratory distress syndrome. <i>Cochrane Database of Systematic Reviews</i> 2009:CD000141.</li> <li>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. <i>Journal of Pediatrics</i> 1995;126:969–78.</li> <li>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. <i>Pediatrics</i> 1990;86:564–71.</li> <li>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. <i>Pediatrics</i> 1992; 89: 13–20.</li> <li>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), <i>Archives of Disease in Childhood</i>; 69: 276-280.</li> <li>14. Figueras-Aloy J et al. Early administration of the second dose of surfactant (beractant) in the treatment of severe hyaline membrane disease. <i>Acta Paediatr</i> 2001;90:296–301.</li> <li>15. El Shahed AI, Dargaville PA, Ohlsson A, Soll R, Surfactant for meconium aspiration syndrome in full term/near term infants (Review), <i>Cochrane Database of Systematic Reviews</i> 2007, Issue 3. Art. No.: CD002054.</li> <li>16. Findlay RD et al. Surfactant Replacement Therapy for Meconium Aspiration Syndrome, <i>Pediatrics</i> 1996, 97(1):48–52.</li> <li>17. Lotze et al. Multicenter study of surfactant (beractant) use in the treatment of term infants with severe respiratory failure, <i>The Journal of Pediatrics</i> 1998, 132(1):40–47.</li> <li>18. Chinese Collaborative Study Group for Neonatal Respiratory Diseases, Treatment of severe meconium aspiration syndrome with porcine surfactant: A multicentre, randomized, controlled trial, <i>Acta Pædiatrica</i>, 2005; 94: 896–902.</li> <li>19. Hahn S, Choi HJ, Soll R, Dargaville PA, Lung lavage for meconium aspiration syndrome in newborn infants (Review), <i>Cochrane Database of Systematic Reviews</i> 2013, Issue 4. Art. No.: CD003486.</li> </ol>

<b>Original version Date: 27/10/2015</b>	<b>Author: NeoMed Consensus Group</b>
<b>Current Version number: 1</b>	<b>Current Version Date: 27/10/2015</b>

---

Risk Rating: Medium	Due for Review: 27/10/2018
Approval by: As per Local policy	Approval Date: