Poractant alfa
Newborn use only

2020

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 trans pulmonary pressures.
Drug type	Pulmonary surfactant
Trade name	Curosurf
Presentation	Suspension for intra-tracheal use 120mg/1.5mL or 240mg/3mL vials
Dose	**Respiratory distress syndrome** Loading dose of 200mg/kg Repeat dose of 100mg/kg when required every 6–12 hours. Maximum of 3 doses. **Meconium aspiration syndrome** Single dose: 200mg/kg Further doses can be given as below if required: 2nd dose: 200mg/kg 3rd dose: 100mg/kg 4th dose: 100mg/kg These doses can be administered at 6 hour interval.
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – Not applicable Renal impairment – No dose adjustment. Hepatic impairment – No dose adjustment.
Maximum dose	
Total cumulative dose	
Route	Intra-tracheal
Preparation	Not applicable
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 creamy white). Before use, the vial should be slowly warmed to room temperature (can be warmed in hand or stood at room temperature) and gently turned upside down in order to obtain a uniform suspension. DO NOT SHAKE. Poractant alfa is administered via the endotracheal route using an endotracheal tube (ETT) or thin catheter. **ETT administration:** Assess patency and position of ETT prior to administration. Clear the trachea of secretions if required. Shorten a 5 French end-hole catheter so that the length of the catheter is 1 cm shorter than the ET tube. Slowly withdraw entire contents of vial(s) into a syringe through a needle (≥ 20 gauge). Do not shake. Attach shortened catheter to syringe. Fill catheter with surfactant. May 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 ET tube without interrupting ventilation by passing the catheter through a neonatal suction valve attached to the ET tube. This is especially useful in high-frequency ventilation to minimise de-recruitment. Alternatively, surfactant can be instilled through the catheter by briefly disconnecting the ETT from the ventilator. Approximately 2 mL of air may be used to push any remaining surfactant in the catheter into the lungs. **Thin catheter administration:** Use a 4 French end-hole catheter marked approximately 1.5 cm above one end. Connect a syringe and catheter prefilled with surfactant preparation. While the infant is breathing via nasal CPAP, introduce laryngoscope and insert catheter using Magill forceps up to the mark on the catheter. Secure tube position and remove laryngoscope. With the infant's mouth closed, instil surfactant

	during 30 to 120 seconds by mini-boluses. In cases of apnoea or bradycardia, perform positive pressure ventilation until recovery.
Monitoring	Continuous oxygen saturation and cardiorespiratory monitoring.
Contraindications	None known
Precautions	Correction of acidosis, hypotension, anaemia, hypoglycaemia and hypothermia is recommended by the manufacturer prior to poractant alfa administration but this is not always possible in practice.
Drug interactions	Not applicable
Adverse reactions	Transient: Bradycardia, hypotension, endotracheal tube blockage and oxygen desaturation. These events require stopping poractant alfa 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	Should not be mixed with any other medications or fluids.
Incompatibility	Not applicable
Stability	Vials are for single use only. DO NOT SHAKE. Unopened, unused vials that have warmed to room temperature can be returned to refrigerated storage within 24 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	**Early versus delayed surfactant treatment** Early selective surfactant administration given to infants with RDS requiring assisted ventilation leads to a decreased risk of acute pulmonary injury (decreased risk of pneumothorax and pulmonary interstitial emphysema) and a decreased risk of neonatal mortality and chronic lung disease compared to delaying treatment of such infants until they develop worsening RDS [4, 5] (LOE I, A). **Prophylaxis versus rescue treatment** There does not appear to be additional benefit from prophylactic surfactant compared to nasal CPAP and early rescue surfactant [4, 6] (LOE I, GOR B). **Method of administration** Post-ventilatory surfactant (after resuscitation) reduces mortality and chronic lung disease 36-40 weeks [7] (LOE II, GOR B). Nasal continuous positive airway pressure (nCPAP) with rescue thin catheter surfactant versus nCPAP with rescue intubation and surfactant reduces the risk of intubation and pneumothorax and reduces the incidence of chronic lung disease [8-12] (LOE I, GOR B). Nasal CPAP with rescue thin catheter surfactant is better tolerated than nCPAP with rescue intubation and surfactant and immediate extubation (InSurE) with no difference in other clinical outcomes [10-12] (LOE I, GOR B). **Dose** Higher first dose poractant (200 mg/kg compared to 100 mg/kg) reduces need for re-dosing without proven clinical benefit [13,14] (LOE 1, GOR B). Higher dose poractant 200 mg/kg compared to lower dose beractant 100 mg/kg reduces mortality and need for re-dosing [15-17] (LOE 1, GOR B). Multiple doses of surfactant (up to 4) given to infants with ongoing respiratory insufficiency leads to improved clinical outcomes [18] (LOE 1, GOR A). Meconium aspiration syndrome: Surfactant replacement therapy for meconium aspiration syndrome reduces the incidence of respiratory failure [19] (LOE 1, GOR B). Trials used surfactant 100−200 mg/kg every 6

	hours up to a maximum 4 doses. Trials reported response from earlier (before 6 hours) and frequent surfactant replacement (every 6 hours for 3−4 doses) [20, 21].
Practice points	
References	1. Thomson Reuters, Neofax 2011, Poractant Alfa Monograph, page 308-309. 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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