




		EMLc	ATC codes: R07AA02
Indication	Respiratory distress syndrome of newborn	ICD11 code: KB33.0Z	
Medicine type	Biological agent		
List type	Complementary (EML) (EMLc)		
Formulations	Respiratory > Suspension: 80 mg per mL for intratracheal instillation (EMLc) ; 25 mg per mL for intratracheal instillation (EMLc)		
EML status history	First added in 2009 (TRS 958)		
Sex	All		
Age	Newborn (< 1 month)		
Therapeutic alternatives	The recommendation is for this specific medicine		
Patent information	Patents have expired in most jurisdictions Read more about patents . 		
Tags	Biological		
Wikipedia	Surfactant 		
DrugBank	Surfactant (Beractant) 		

Summary of evidence and Expert Committee recommendations

The EMLc Subcommittee reviewed the application for the inclusion of surfactant on the EMLc for the prophylaxis and management of primary respiratory distress syndrome in preterm infants, and secondary surfactant deficiency in infants. High quality evidence demonstrating that both prophylactic and rescue surfactant improve clinical outcome in premature neonates was identified in the application. This included a Cochrane systematic review (1) of seven randomized controlled trials in which clinical outcomes were assessed following prophylactic administration of synthetic surfactant to premature infants aged between 25 to 34 weeks gestation, and with birth weights between 500 and 1350 grams. The meta-analysis showed a statistically significant decrease in the risk of pneumothorax, a decrease in the risk of pulmonary interstitial emphysema, and a decrease in risk of neonatal mortality. However an increased risk of developing patent ductus arteriosus and pulmonary haemorrhage was demonstrated. The Subcommittee noted that the European Consensus Guidelines recommend the use of natural over synthetic surfactant as a prophylactic approach in infants of less than 27 weeks gestation, and for those between 26 and 30 weeks gestation if intubation is required in the delivery room or if no prenatal corticosteroids have been received. The American Academy of Pediatrics guidelines suggest that surfactant should be given to infants with respiratory distress syndrome as soon as possible after intubation, regardless of gestational age or exposure to prenatal corticosteroids. A systematic review (2) which included 11 trials showed that although the use of natural rather than synthetic surfactant resulted in a significant reduction in the risk of pneumothorax and mortality, there was a trend towards an increase in overall intraventricular haemorrhage following the use of natural surfactant. The Subcommittee noted that limited evidence is available to determine the optimal method of surfactant administration and that high-quality evidence is lacking for the use of surfactant in other conditions such as persistent pulmonary hypertension of the newborn, congenital diaphragmatic hernia, neonatal pulmonary haemorrhage and meconium aspiration syndrome. Despite evidence for an increased risk of patent ductus arteriosus, pulmonary haemorrhage and intraventricular haemorrhage following treatment with surfactant therapy, the benefits of use in management of respiratory distress syndrome in the neonatal population clearly

outweigh the risks. Costs of surfactant were noted to be high. The Subcommittee concluded that the application had identified high quality evidence for the use of surfactant in the management of respiratory distress syndrome in premature infants. It was added to the EMLc and placed in a new section devoted to neonatal medicines and categorized as a Complementary medicine given the nature of its use. References: 1. Soll RF. Prophylactic synthetic surfactant for preventing morbidity and mortality in preterm infants. Cochrane Database of Systematic Reviews, 1998, Issue 2. Art No: CD001079. DOI:10.1002/14651858.CD001079. 2. Soll R et al. Natural surfactant extract versus synthetic surfactant for neonatal respiratory distress syndrome. Cochrane Database of Systematic Reviews, 2001, Issue 2. Art No.: CD000144. DOI:10.1002/14651858.CD000144.

