

EXOGENOUS SURFACTANT INFORMATION

Infasurf® (calfactant)	
INDICATION / ORIGIN	
Indication	Prophylaxis and treatment of Respiratory Distress Syndrome (RDS)
Origin	Lavage of natural calf lung surfactant with no lung tissue ¹
Composition	
Phospholipid Concentration	35 mg/ml ¹
Disaturated phosphatidylcholine	46% of phospholipids ^{1,4}
Surfactant-specific apoproteins	
SP-B	0.74% of phospholipids
SP-C	1.26% of phospholipids
Biophysical Properties	
Time to reach minimum surface tension	2 min ⁵
Minimum dynamic surface tension	0 mN/m ⁷
Minimum concentration needed	1 mg/ml ⁷
How Supplied	
(Please see each product's approved product labeling for full dosing and administration information.)	3 ml (105 mg of phospholipids) ¹ 6 ml (210 mg of phospholipids) ¹

Curosurf® (poractant alfa)	Survanta® (beractant)
Treatment of RDS ²	Prophylaxis and treatment of RDS ³
Extract of minced porcine lung tissue ²	Extract of minced bovine lung tissue fortified with synthetic lipids ³
76 mg/ml ²	25 mg/ml ³
39% of phospholipids ^{2,4}	44-62% of phospholipids ^{3,4}
0.59% of phospholipids ^{2,4} 0.72% of phospholipids ^{2,4}	Not in Package Insert Not in Package Insert
10 min ⁶	15 min ⁵
0 mN/m ⁷	4 mN/m ⁷
2 mg/ml ⁷	2 mg/ml ⁷
1.5 ml (114 mg of phospholipids) ² 3 ml (228 mg of phospholipids) ²	4 ml (100 mg of phospholipids) ³ 8 ml (200 mg of phospholipids) ³

INFASURF is indicated for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS and for the treatment (“rescue”) of premature infants who develop RDS. INFASURF decreases the incidence of RDS, mortality due to RDS, and air leaks associated with RDS.

- Prophylaxis therapy at birth with INFASURF is indicated for premature infants < 29 weeks of gestational age at significant risk of RDS. INFASURF prophylaxis should be administered as soon as possible, preferably within 30 minutes after birth.
- INFASURF therapy is indicated for infants ≤ 72 hours of age with RDS (confirmed by clinical and radiologic findings) and requiring endotracheal intubation.

IMPORTANT SAFETY INFORMATION

INFASURF is intended for intratracheal use only. Administration of exogenous surfactants, including INFASURF, often rapidly improve oxygenation and lung compliance. Following INFASURF administration, patients should be monitored so that oxygen and ventilatory support can be modified in response to changes in respiratory status. INFASURF is not a substitute for neonatal intensive care. Optimal care of premature infants at risk for RDS and newborn infants with RDS require an acute care unit. During dosing with INFASURF, the most common adverse reactions reported in clinical trials were cyanosis (65%), airway obstruction (39%), bradycardia (34%), and reflux into the endotracheal tube (21%). These events were generally transient, and not associated with serious complications. If any of these events occur, administration should be interrupted and the infant's condition stabilized. After the patient is stable, dosing can proceed with appropriate monitoring.

No data are available on the use of INFASURF with experimental therapies of RDS. Data from controlled trials on the efficacy of INFASURF are limited to doses of approximately 100 mg phospholipid/kg body weight and up to a total of 4 doses.

1. Infasurf® (calfactant) intratracheal suspension package insert. 2. Curosurf® (poractant alfa) intratracheal suspension package insert. 3. Survanta (beractant) intratracheal suspension package insert. 4. Data on file at ONY, Inc. 5. Hall et al. Am Rev Resp Dis. 1992;145: 24-30. 6. Robertson et al. Prog Resp Res. 1990;25: 237-246. 7. Seeger et al. Eur Respir J 1993;6: 971-977.