Infasurf® (calfactant) is cost effective.

A key factor affecting cost is the surfactant's first-dose regimen, based on weight, combined with vial sizes available.

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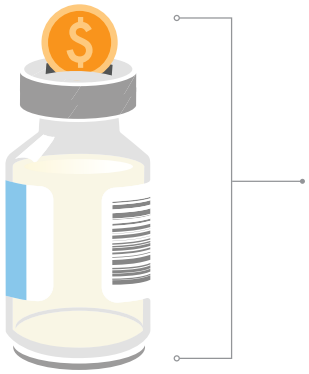


29%

29% fewer vials of Infasurf® (calfactant) needed on the initial dose than Curosurf® (poractant alfa).

Infasurf® (calfactant) - Each Dose[1]

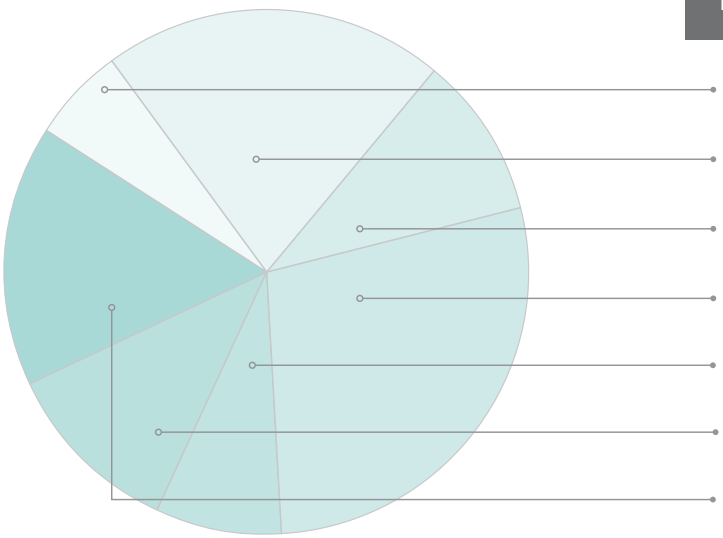
Small **3 mL**	Treats up to **1000 g**	Large **6 mL**	Treats up to **2000 g**

Curosurf® (poractant alfa) - Initial Dose[2]

Small **1.5 mL**	Treats up to **600 g**	Large **3 mL**	Treats up to **1200 g**

Cost: $_____ **Cost: $**_____ **Cost: $**_____ **Cost: $**_____

Patient Demographics of Treated Infants 2005-2010* - Birth weight determines the dose required.



Birth Weight Distribution*		Vials Needed[1,2] Infasurf®	Vials Needed[1,2] Curosurf®
6%	≤ 600g		
21%	601 - 1000g		
10%	1001 - 1200g		
28%	1201 - 1800g		
8%	1801 - 2000g		
11%	2001 - 2400g		
16%	2401 - 3000g		
		3 mL - 54 6 mL - 73 **127**	1.5 mL - 50 3 mL - 129 **179**

Number of vials required to treat a 100-patient population with an initial dose:

- All patients receive an initial dose
- Fewer vials have shown to lower total surfactant costs[3]

*Calculation of cohorts is based upon a large national sample which described birth weight distribution of 51,282 surfactant-treated patients from 322 neonatal intensive care units over six years.[4] Birth weight cohorts were defined where a change in vial size or vial count is required by each drug's respective prescribing information.

There are no prospective, randomized clinical trials comparing Infasurf® and Curosurf® with respect to safety or efficacy.

INDICATION

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

Prophylaxis
Prophylaxis therapy at birth with Infasurf is indicated for premature infants <29 weeks of gestational age at significant risk for RDS. Infasurf prophylaxis should be administered as soon as possible, preferably within 30 minutes after birth.

Treatment
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. THE ADMINISTRATION OF EXOGENOUS SURFACTANTS, INCLUDING INFASURF, OFTEN RAPIDLY IMPROVES OXYGENATION AND LUNG COMPLIANCE. Following administration of Infasurf, patients should be carefully monitored so that oxygen therapy and ventilatory support can be modified in response to changes in respiratory status.

Infasurf therapy is not a substitute for neonatal intensive care. Optimal care of premature infants at risk for RDS and newborn infants with RDS who need endotracheal intubation requires an acute care unit organized, staffed, equipped, and experienced with intubation, ventilator management, and general care of these patients.

TRANSIENT EPISODES OF REFLUX OF INFASURF INTO THE ENDOTRACHEAL TUBE, CYANOSIS, BRADYCARDIA, OR AIRWAY OBSTRUCTION HAVE OCCURRED DURING THE DOSING PROCEDURES that required stopping Infasurf and taking appropriate measures to alleviate the condition. After the patient is stable, dosing can proceed with appropriate monitoring.

An increased proportion of patients with both intraventricular hemorrhage (IVH) and periventricular leukomalacia (PVL) was observed in Infasurf-treated infants in the Infasurf-Exosurf Neonatal controlled trials. These observations were not associated with increased mortality.

The most common adverse reactions associated with Infasurf dosing procedures in the controlled trials were cyanosis (65%), airway obstruction (39%), bradycardia (34%), reflux of surfactant into the endotracheal tube (21%), requirement for manual ventilation (16%), and reintubation (3%). These events were generally transient and not associated with serious complications or death.

The incidence of common complications of prematurity and RDS in the four controlled Infasurf trials are presented in the Table. Prophylaxis and treatment study results for each surfactant are combined.

Please see accompanying full prescribing information and refer to list of Re-Dose Rate Publications included in pocket.

Common Complications of Prematurity and RDS in Controlled Trials	Infasurf® (n=1001), %	Exosurf Neonatal® (n=978), %	Infasurf® (n=553), %	Survanta® (n=566), %
Apnea	61	61	76	76
Patent ductus arteriosus	47	48	45	48
Intracranial hemorrhage	29	31	36	36
Severe intracranial hemorrhage[a]	12	10	9	7
IVH and PVL[b]	7	3	5	5
Sepsis	20	22	28	27
Pulmonary air leaks	12	22	15	15
Pulmonary interstitial emphysema	7	17	10	10
Pulmonary hemorrhage	7	7	7	6
Necrotizing enterocolitis	5	5	17	18

[a] Grade III and IV by the method of Papile.
[b] Patients with both intraventricular hemorrhage and periventricular leukomalacia.

To receive additional information about product specifics, cost benefits and education, please contact:

References:

1. Infasurf® (calfactant) Intratracheal Suspension Prescribing Information, ONY Biotech, March 2018. **2.** Curosurf® (poractant alfa) Intratracheal Suspension Prescribing Information, Chiesi USA, Inc. December 2014. **3.** Zayek MM, Eyal FG, Smith RC. Comparison of the pharmacoeconomics of calfactant and poractant alfa in surfactant replacement therapy. JPPT. 2018;23(2):146-151. **4.** Trembath A, Hornik CP, Clark R, et al. Comparative effectiveness of surfactant preparations in premature infants. J Pediatr. 2013;163(4):955-960.

ONY Biotech is a leader in the creation of critically important products for the treatment of premature infants. Since 1998, ONY Biotech has made tomorrow possible for so many premature babies and their families, thanks to Infasurf® (calfactant).

onybiotech

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Please see additional information in pocket.