Infasurf® (calfactant)

Manufactured by Lonybiotech

Helping babies breathe since 1998.

Made in the USA

Infasurf Dosing Chart For Intratracheal Administration **ONLY**

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.

Birth Weight (grams)	Total Dose (mL)	Vial(s) Needed*	Birth Weight (grams)	Total Dose (mL)	Vial(s) Needed*
600-650	1.9	3 mL	1301-1350	4.0	6 mL
651-700	2.0	3 mL	1351-1400	4.1	6 mL
701-750	2.2	3 mL	1401-1450	4.3	6 mL
751-800	2.3	3 mL	1451-1500	4.4	6 mL
801-850	2.5	3 mL	1501-1550	4.6	6 mL
851-900	2.6	3 mL	1551-1600	4.7	6 mL
901-950	2.8	3 mL	1601-1650	4.9	6 mL
951-975	2.9	3 mL	1651-1700	5.0	6 mL
976-1000	3.0	3 mL	1701-1750	5.2	6 mL
1001-1050	3.1	6 mL	1751-1800	5.3	6 mL
1051-1100	3.2	6 mL	1801-1850	5.5	6 mL
1101-1150	3.4	6 mL	1851-1900	5.6	6 mL
1151-1200	3.5	6 mL	1901-1950	5.8	6 mL
1201-1250	3.7	6 mL	1951-1975	5.9	6 mL
1251-1300	3.8	6 mL	1976-2000	6.0	6 mL

*Infasurf is available in 3mL and 6mL single-dose vials. Doses were calculated using the midpoint of each weight range and rounded off to the one decimal point

CALCULATING DOSE
- Each dose of **Infasurf** is 3 mL/kg body weight at birth
- The **Infasurf Dosing Chart** shows the total dose per administration for a range of birth weights

IMPORTANT CONSIDERATIONS
Infasurf should be administered under the supervision of clinicians experienced in the acute care of newborn infants with respiratory failure who require intubation.

Please see Indication listed above and Important Safety Information on reverse.

ADDITIONAL INFORMATION:

- Store at refrigerated temperature 2° to 8°C (36° to 46°F).
- Infasurf settles during storage—gently swirl or gently invert repeatedly to homogenize settled suspension. **DO NOT SHAKE.**
- Warming not required—if desired, may be warmed to room temperature.
- Never use radiant/artificial warming devices to warm Infasurf.
- Do not remove from refrigerator for more than 24 hours.
- Must not be returned to refrigerator more than once.

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 new born 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.

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.

See full prescribing information.

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