Infasurf®
(calfactant)

Manufactured by ONY Biotech

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 and Important Safety Information on reverse.

See full prescribing information.

Made in the USA

Infasurf Dosing Chart

For Intratracheal Administration **ONLY**

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

Doses were calculated using the midpoint of each weight range and rounded off to one decimal point

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INDICATIONS AND USAGE

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 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. 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 associated with serious risks. Warnings regarding intratracheal use include rapid improvement in oxygenation and lung compliance which necessitate careful monitoring, neonatal intensive care requirements. 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, and equipped, and experienced with intubation, ventilator management, and general care of these patients. Transient episodes of endotracheal tube reflux, cyanosis, bradycardia, and airway obstruction have occurred which require stopping Infasurf administration and taking appropriate measures to alleviate the condition.

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. The incidence of common complications of prematurity and RDS with Infasurf treatment in four active-controlled clinical trials (a prophylaxis and a treatment trial vs Exosurf®, and a prophylaxis and a treatment trial vs Survanta®) was combined for prophylaxis and treatment study results (N=1001 Infasurf patients, N=553 Infasurf patients, respectively) and included: apnea (61%, 76%), patent ductus arteriosus (47%, 45%), intracranial hemorrhage (29%, 36%), severe intracranial hemorrhage (12%, 9%), patients with both intraventricular hemorrhage and periventricular leukomalacia (7%, 5%), sepsis (20%, 28%), pulmonary air leaks (12%, 15%), pulmonary interstitial emphysema (7%, 10%), pulmonary hemorrhage (7%, 7%), and necrotizing enterocolitis (5%, 17%).

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%).