



Quick Reference Administration Guide

Infasurf[®]
(calfactant)

Infasurf is indicated for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants.



Helping babies breathe since 1998

PRE-INSTILLATION (1)

Prepare Infasurf®

1. Calculate total dose as 3mL/kg body weight at birth.
2. Warming not required. If desired, Infasurf can be warmed to room temperature.
3. **NEVER** use radiant/artificial warming devices to warm Infasurf.
4. Repeatedly invert the vial(s) to homogenize settled suspension - **DO NOT SHAKE**.
5. Draw each aliquot through a 20 gauge needle into separate syringes with care taken to avoid excessive foaming*.
6. Each syringe should contain an amount of air **EQUAL** to the liquid volume.
7. Unopened, unused vials of Infasurf that have warmed to room temperature can be returned to refrigerated storage within 24 hours for future use.
8. Infasurf should not be removed from the refrigerator more than once.

*The welfare of the patient is always the primary consideration during Infasurf instillation. In the tiniest and most fragile patients, dividing the dose into 4 aliquots may minimize the stress of administration.

[See additional information on reverse]

Infasurf®
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Additional Information on Preparing Infasurf®

- Infasurf is intended for Intratracheal use only.
- 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.
- See Indication and additional Important Safety Information on card #7.
- See Full Prescribing Information.



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PRE-INSTILLATION (2)

Prepare Infant

1. Position infant supine with the head midline.

ET Tube **MUST BE:**

IN PROPER POSITION – confirm presence of expired CO₂, bilateral chest rise and equal bilateral breath sounds.

UNOBSTRUCTED – suction as needed.

SECURELY FIXED IN PLACE – use extra care if only manual retention is used during instillation.

2. **INFANT MUST BE CLINICALLY STABLE** – Confirm SpO₂, Expired CO₂, HR, and BP are at acceptable levels.

[See additional information on reverse]

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Additional Information on Preparing the Infant

- Infasurf should be administered under the supervision of clinicians experienced in the acute care of newborn infants with respiratory failure who require intubation.
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INSTILLATION (1)

Instill Infasurf®

1. Attach a syringe to instillation catheter.
2. Advance catheter to the distal tip of ET Tube.
3. **DO NOT** advance catheter beyond the carina into either main stem bronchus.
4. During instillation hold the plunger up and the outlet down – air must be above liquid during instillation.
5. Instill surfactant suspension quickly and smoothly over 1-2 seconds followed immediately by the air. (Air will clear surfactant out of catheter.)
6. **DO NOT** pause in between the liquid and air instillation.

[See additional information on reverse]

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Additional Information on Instilling Infasurf®

- Never hesitate to suction the ET Tube and airway whenever airway obstruction is suspected. Suctioning is not contraindicated after surfactant instillation.
- During administration of Infasurf liquid suspension into the airway, infants often experience bradycardia, reflux of Infasurf into the endotracheal tube, airway obstruction, cyanosis, dislodgement of the endotracheal tube, or hypoventilation. If any of these events occur, the administration should be interrupted and the infant's condition should be stabilized using appropriate interventions before the administration of Infasurf is resumed.
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INSTILLATION (2)

Initiate Ventilation

1. Withdraw instillation catheter rapidly and gently turn infant to left or right side to optimize surfactant distribution.
2. Initiate ventilation with a flow inflating bag or a T piece resuscitation device (i.e. Neopuff™, Neo-Tee®, ventilator).
3. Effective gas exchange will require the use of effective peak inspiratory pressure (PIP), inspiratory time (IT), inspiratory plateau pressures, and positive end expiratory pressure (PEEP).

[See additional information on reverse]

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Additional Information on Initiating Ventilation

- Rapid and substantial increases in blood oxygenation and improved lung compliance often follow Infasurf® instillation.
- Close clinical monitoring and surveillance following administration may be needed to adjust oxygen therapy and ventilator pressures appropriately.
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- See Full Prescribing Information.



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POST INSTILLATION (1)

Ventilation

Continue manual ventilation for 1-2 minutes or until adequate ventilation is established.

Use:

- Initial peak inspiratory pressure sufficient enough to overcome high inertia and flow resistance of liquid in the airway – this will propel surfactant to distal lung*
- Initial inspiratory time sufficient to create a plateau pressure (proximal airway pressure is equilibrated throughout the lung)*
 - This promotes uniform ventilation and rapid surfactant distribution to distal lung.
- Maintain positive end expiratory pressure*

* Hospitals should determine settings based upon their individual protocols and patient assessment.

[See additional information on reverse]

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Additional Information on Ventilation

- Close clinical monitoring and surveillance following administration may be needed to adjust oxygen therapy and ventilator pressures appropriately.
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POST INSTILLATION (2)

Infant Assessment

1. Look for signs that instillation has been completed successfully: normal chest rise, color, SpO₂, HR and BP.
2. Listen for clear breath sounds – **MINIMAL REFLUX AND ABSENCE OF RHONCHI ARE PHYSICAL SIGNS** that surfactant is out of airways and absorbed into the alveoli.
3. Adjust ventilatory support up or down as needed.
4. Subsequent aliquot instillations are given once cardiopulmonary stability is established.

[See additional information on reverse]

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Additional Information on Infant Assessment

- Close clinical monitoring and surveillance following administration may be needed to adjust oxygen therapy and ventilator pressures appropriately.
- Please refer to the AARC guidelines.¹
- See Indication and additional Important Safety Information on card #7.
- See Full Prescribing Information.

¹ Walsh, Brian K. In et al., AARC Clinical Practice Guideline. Surfactant Replacement Therapy 2013. Respiratory Care, February 2013, Vol. 58, no 2, pp 367-375.



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Infasurf Dosing Chart

For Intratracheal Administration ONLY

7

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 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 and Important Safety Information on reverse.

See full prescribing information.

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 Surfactant) was combined for prophylaxis and treatment study results (N=1001 Infasurf patients, N=553 Exosurf 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%).

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