

For premature infants with
respiratory distress syndrome (RDS)

#1
MOST USED SURFACTANT
in the U.S.*

DELIVER FAST RDS SUCCESS

with an initial dose containing
UP TO 2X MORE SURFACTANT^{2-4†}



**FAST
ONSET^{5-7†}**



**SINGLE-DOSE
SUCCESS^{7-12‡}**



**LOWEST
VOLUME^{2-4‡}**



Important Safety Information

CUROSURF® (poractant alfa) is intended for intratracheal use only. The administration of exogenous surfactants, including CUROSURF, can rapidly affect oxygenation and lung compliance. Therefore, infants receiving CUROSURF should receive frequent clinical and laboratory assessments so that oxygen and ventilatory support can be modified to respond to respiratory changes.

Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

*Please note that this metric only provides insight into the surfactant selected by NICUs and does not imply equivalence or superiority between or among the products for any given clinical end point.

†Not proven to impact clinical outcomes such as mortality.

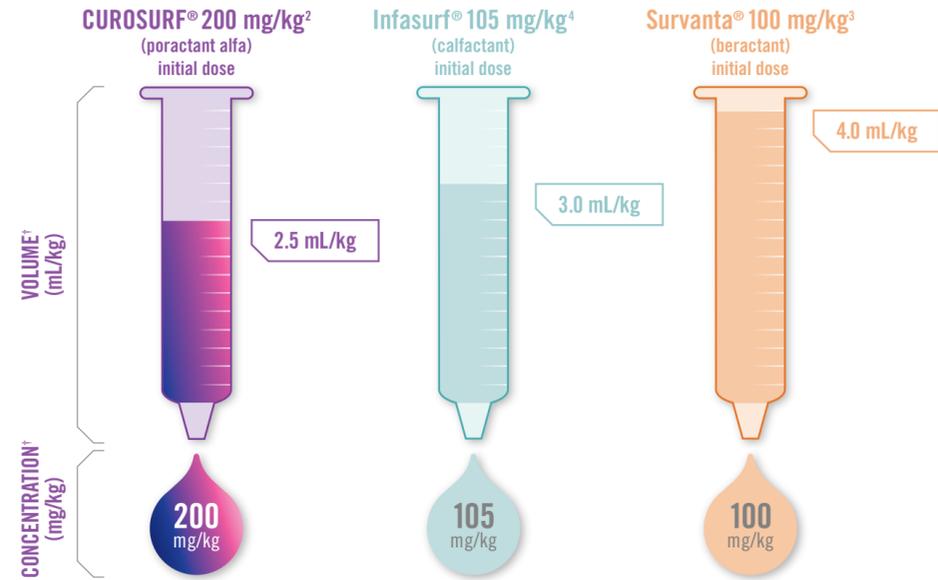
‡Not established to result in superior safety or efficacy.

 **Chiesi**
in Neonatology for Life

CUROSURF® 
(poractant alfa)
Intratracheal Suspension

CUROSURF (poractant alfa) 200 mg/kg*

UP TO 2X MORE SURFACTANT AND THE LOWEST VOLUME²⁻⁴



Clinical studies have not established that lower volume, fewer doses, or longer dosing intervals result in superior efficacy or safety based on clinically relevant end points.

The initial dose of CUROSURF 200 mg/kg provides a longer half-life than poractant alfa 100 mg/kg^{13*}



Physiologic and pharmacokinetic end points (e.g., longer DSPC half-life) have not been proven to impact key clinical outcomes such as mortality due to RDS. A small amount of radiolabeled dipalmitoylphosphatidylcholine (DPPC) was added to facilitate this study.

*CUROSURF is FDA approved for an initial dose of 200 mg/kg (2.5 mL/kg). The 100 mg/kg (1.25 mL/kg) dose of CUROSURF is approved for repeat dosing only.
 †Based on a 1000-g infant and manufacturer's dosing schedule. Volume of surfactant is measured in milliliters per kilogram of body weight at birth.

Indication

CUROSURF® (poractant alfa) Intratracheal Suspension is indicated for the rescue treatment of Respiratory Distress Syndrome (RDS) in premature infants. CUROSURF reduces mortality and pneumothoraces associated with RDS.

Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

The long half-life seen with CUROSURF 200 mg/kg can lead to a long duration of clinical effect, which may impact the need for supplemental oxygen and redosing.¹³

CUROSURF (poractant alfa) 200 mg/kg*

THE ONLY SURFACTANT FDA-APPROVED FOR A 200 mg/kg INITIAL DOSE²⁻⁴

	CUROSURF 200 mg/kg ^{2,16} initial dose	Infasurf 105 mg/kg ^{4,16} initial dose	Survanta 100 mg/kg ^{3,16} initial dose
Source	Porcine	Bovine	Bovine
Phospholipid concentration (mg/mL)	76	35	25
Dipalmitoylphosphatidylcholine (mg/mL)	30	16	11.0-15.5
SP-B (mg/mL)	0.45	0.26	Not Specified
SP-C (µg protein/µmol · L ⁻¹ phospholipid)	5.0-11.6	8.1	1.0-20.0
Additives	No	No	Yes

- An initial dose of CUROSURF delivers more than twice the phospholipid concentration vs other exogenous surfactants²⁻⁴
 - And 44% more SP-B than Infasurf²⁻⁴
- There is no therapeutic or pharmaceutical equivalent to CUROSURF^{2-4,16}

While clinical studies have demonstrated that SP-B, SP-C, and phospholipids are essential elements, they have not established the quantity required for optimal surfactant efficacy.

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Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

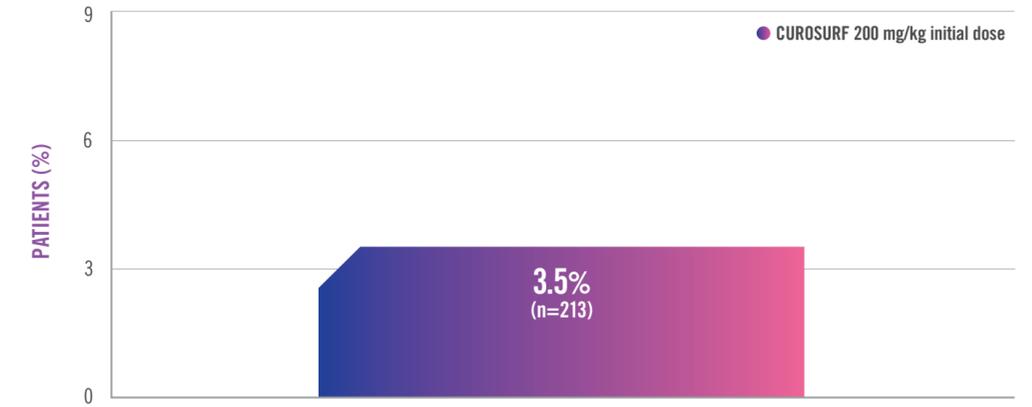
There is no therapeutic equivalent to CUROSURF.^{2-4,16}

CUROSURF (poractant alfa) 200 mg/kg*

LOW REFLUX RATES¹⁷

Low reflux rate 5 to 15 minutes after administration¹⁷

It has been suggested that the thin suspension may help to minimize airway and endotracheal tube obstruction and associated complications such as transient hypercapnia.^{17,18}



Administration traits or end points (eg, faster reduction in FiO₂, reflux or bradycardia rates, or oxygen desaturation) have not been proven to impact key clinical outcomes such as mortality or BPD due to RDS.

Gerdes JS, et al. *J Pediatr Pharmacol Ther.* 2006;11:92-100.

An open-label, observational study of 277 (CUROSURF 200 mg/kg, n=213; calfactant 100 mg/kg, n=64) infants compared the two surfactants with respect to their technical aspects of administration, short-term clinical observations, and the implications of any differences observed. The study was not randomized or blinded. Birth weight averaged 1410 ± 676 grams for CUROSURF and 1649 ± 87 grams for Infasurf. The gestational age was 29.4 ± 3.5 weeks for CUROSURF and 30.2 ± 4.2 weeks for Infasurf. Data for calfactant 100 mg/kg is not shown. The study was not powered to determine statistically significant differences between the short-term clinical outcomes, including reflux rate.¹⁷

Important Safety Information

Pulmonary hemorrhage, a known complication of premature birth and very low birth-weight, has been reported with CUROSURF. The rates of common complications of prematurity observed in a multicenter single-dose study that enrolled infants 700–2000 g birth weight with RDS requiring mechanical ventilation and FiO₂ ≥ 0.60 are as follows for CUROSURF 2.5 mL/kg (200 mg/kg) (n=78) and control (n=66; no surfactant) respectively: acquired pneumonia (17% vs. 21%), acquired septicemia (14% vs. 18%), bronchopulmonary dysplasia (18% vs. 22%), intracranial hemorrhage (51% vs. 64%), patent ductus arteriosus (60% vs. 48%), pneumothorax (21% vs. 36%) and pulmonary interstitial emphysema (21% vs. 38%).

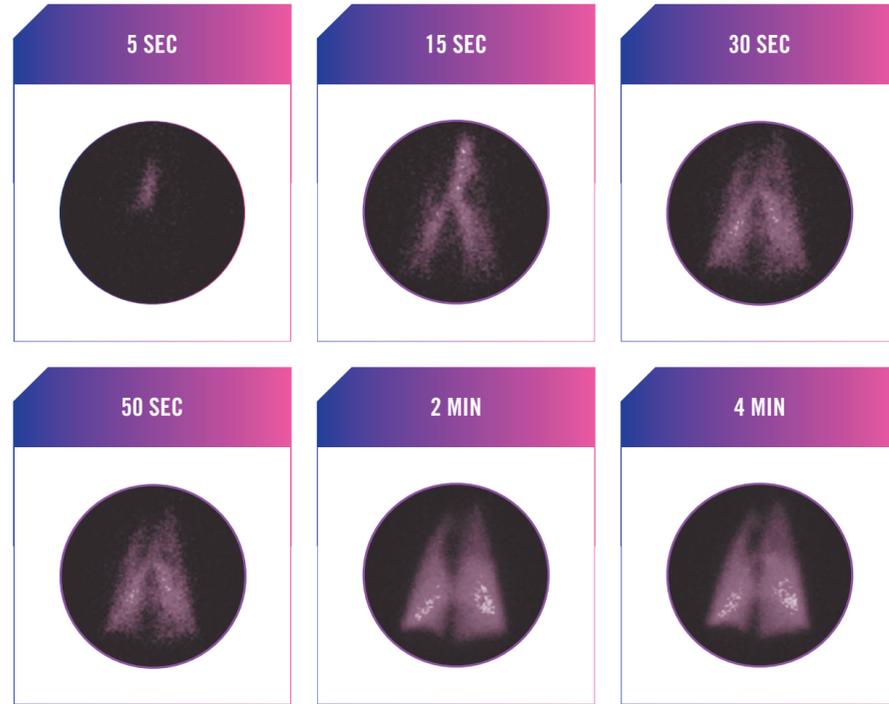
Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

Low reflux rates may improve tolerability and ease of administration.¹⁷



CUROSURF (poractant alfa) 200 mg/kg* SPREADS FAST AND EVENLY¹⁴

CUROSURF distribution in lamb lungs over 4 minutes^{14†‡}



- Quickly forms a stable surfactant monolayer inside alveoli¹⁵
- Suctioning of airways permitted after 1 hour²
- Preclinical data may not be predictive of clinical results

†Unpublished photos presented during the 15th International Workshop on Surfactant Replacement, 2000.
‡It is unknown if CUROSURF was delivered as a single bolus in this study.

Important Safety Information

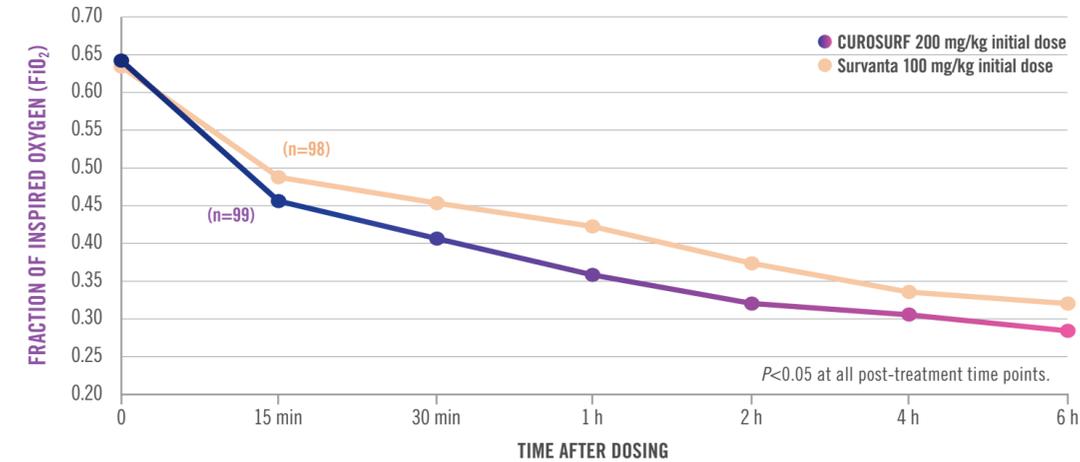
Transient adverse reactions associated with administration of CUROSURF include bradycardia, hypotension, endotracheal tube blockage, and oxygen desaturation. These events require stopping CUROSURF administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring.

Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

CUROSURF is the ONLY surfactant with an FDA-approved single bolus delivery option.^{2,4}



CUROSURF (poractant alfa) 200 mg/kg* FASTER REDUCTIONS IN FiO₂ VS SURVANTA (beractant) 100 mg/kg^{7†}



*CUROSURF is FDA approved for an initial dose of 200 mg/kg (2.5 mL/kg). The 100 mg/kg (1.25 mL/kg) dose of CUROSURF is approved for repeat dosing only.
†Primary end point was FiO₂ AUC₀₋₆ defining onset of clinical response.
FiO₂=Fraction of inspired oxygen.

Physiological end points (eg, faster reduction in FiO₂) have not been proven to impact key clinical outcomes such as mortality due to RDS.

Ramanathan R, et al. *Am J Perinatol.* 2004;21:109-119.

A randomized, multi-center, masked comparison trial of CUROSURF vs Survanta in the treatment of RDS in 293 preterm infants weighing 750 to 1750 grams at birth and < 35 weeks gestation (CUROSURF 200 mg/kg, n=99; poractant alfa 100 mg/kg, n=96; beractant 100 mg/kg, n=98). Randomization was stratified by birth weight and site. The onset of clinical response after the first dose was studied by comparing changes in the FiO₂ between 0 and 6 hours measured using the area under the curve (FiO₂ AUC₀₋₆). Data for poractant alfa 100 mg/kg is not shown.⁷

Important Safety Information

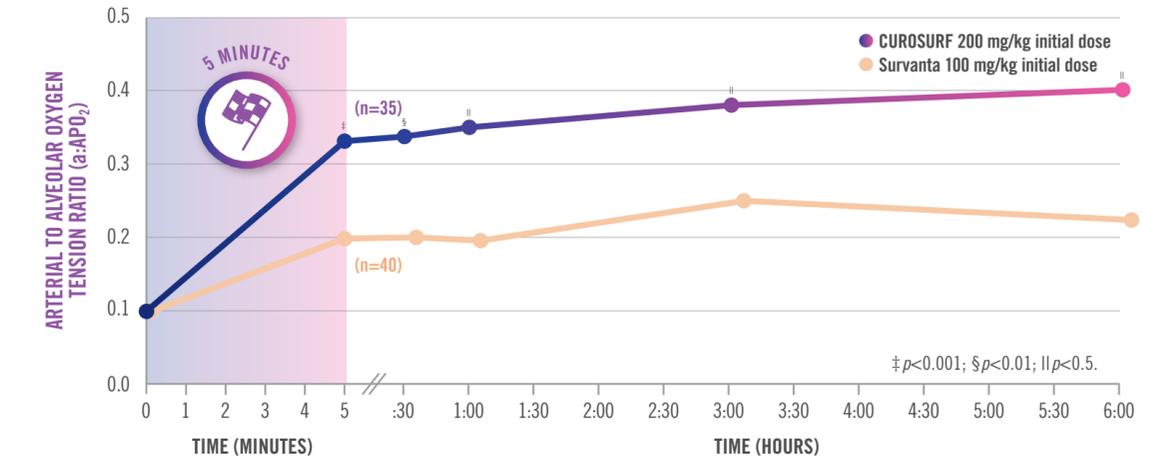
CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of preterm infants.

Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

CUROSURF improves oxygenation within 5 minutes and rapidly reduces FiO₂ requirements over the initial treatment period.^{2,7}

CUROSURF (poractant alfa) 200 mg/kg* AND FASTER IMPROVEMENT IN OXYGENATION⁵

CUROSURF[®]
(poractant alfa)
Intratracheal Suspension



a:APO₂=Arterial to alveolar oxygen tension ratio.

Physiological end points (eg, faster reduction in FiO₂) have not been proven to impact key clinical outcomes such as mortality due to RDS.

Speer CP, et al. *Arch Dis Child.* 1995;72:F8-F13.

A randomized, nonblinded clinical trial of CUROSURF and Survanta in the treatment of RDS in 75 preterm infants requiring artificial ventilation with an FiO₂ ≥ 0.4, weighing 700 to 1500 grams at birth and aged 1–24 hours (CUROSURF 200 mg/kg, n=35; beractant 100 mg/kg, n=40). Randomization was stratified by birth weight. The effects of the two treatment regimens on gas exchange, ventilatory requirements, and 28-day outcome were compared. Study patients received rescue surfactant and mechanical ventilation as primary intervention.⁵

Important Safety Information

Pulmonary hemorrhage, a known complication of premature birth and very low birth-weight, has been reported with CUROSURF. The rates of common complications of prematurity observed in a multicenter single-dose study that enrolled infants 700–2000 g birth weight with RDS requiring mechanical ventilation and FiO₂ ≥ 0.60 are as follows for CUROSURF 2.5 mL/kg (200 mg/kg) (n=78) and control (n=66; no surfactant) respectively: acquired pneumonia (17% vs. 21%), acquired septicemia (14% vs. 18%), bronchopulmonary dysplasia (18% vs. 22%), intracranial hemorrhage (51% vs. 64%), patent ductus arteriosus (60% vs. 48%), pneumothorax (21% vs. 36%) and pulmonary interstitial emphysema (21% vs. 38%).

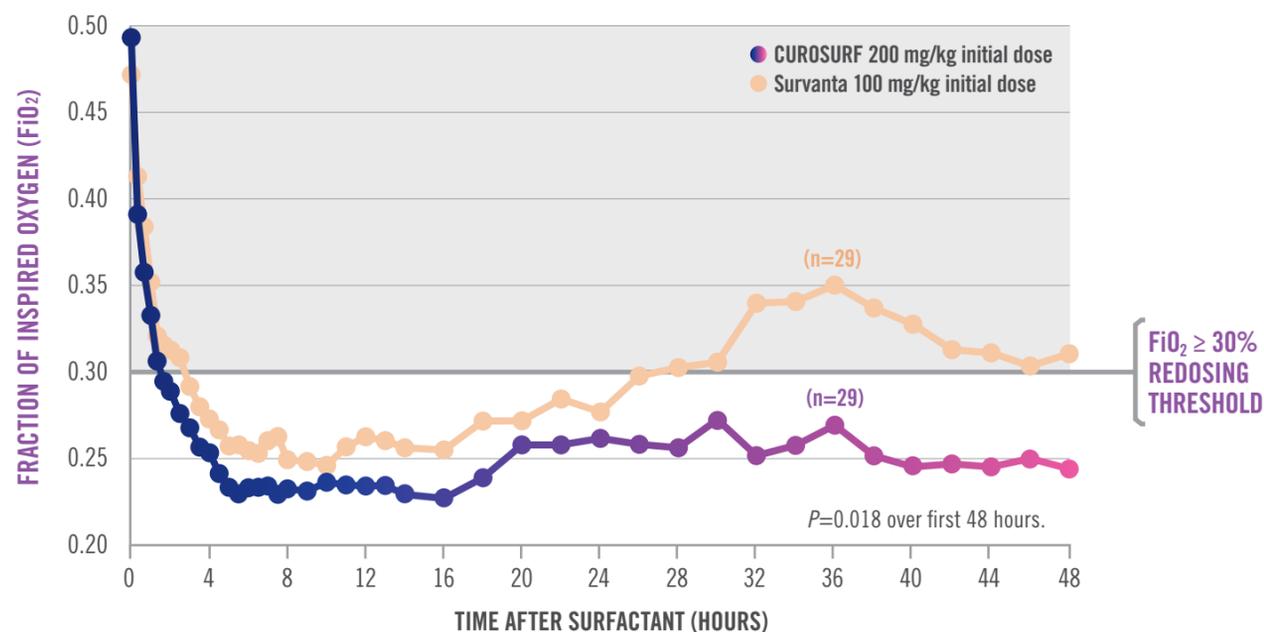
Please see Important Safety Information on page 12 and accompanying Full Prescribing Information.

It has been suggested that faster oxygenation supports the treatment goal of weaning infants from mechanical ventilation (MV) more rapidly.⁷



CUROSURF (poractant alfa) 200 mg/kg*

PROVEN FiO_2 REDUCTIONS SUSTAINED OVER TIME VS SURVANTA (beractant) 100 mg/kg¹⁹



- In a clinical trial, oxygen requirements did not rebound above redosing threshold ($FiO_2 \geq 0.30$) after first dose of CUROSURF during the first 48 hours¹⁹

*CUROSURF is FDA approved for an initial dose of 200 mg/kg (2.5 mL/kg). The 100 mg/kg (1.25 mL/kg) dose of CUROSURF is approved for repeat dosing only.

FiO_2 =Fraction of inspired oxygen.

Shading indicates FiO_2 range in which redosing was required.

Malloy CA, et al. *Acta Paediatr.* 2005;94:779-784.

A randomized trial comparing CUROSURF and Survanta treatment in neonatal RDS. The primary outcome measure was FiO_2 requirement in the first 48 hours after surfactant therapy. A total of 58 infants completed the study and were included in the analysis (CUROSURF 200 mg/kg, n=29; beractant 100 mg/kg, n=29). The mean gestational ages for the CUROSURF and Survanta groups were 29.6 ± 3.6 and 29.3 ± 2.9 weeks, with average birth weights of 1394 ± 699 and 1408 ± 534 grams, respectively.¹⁹

Important Safety Information

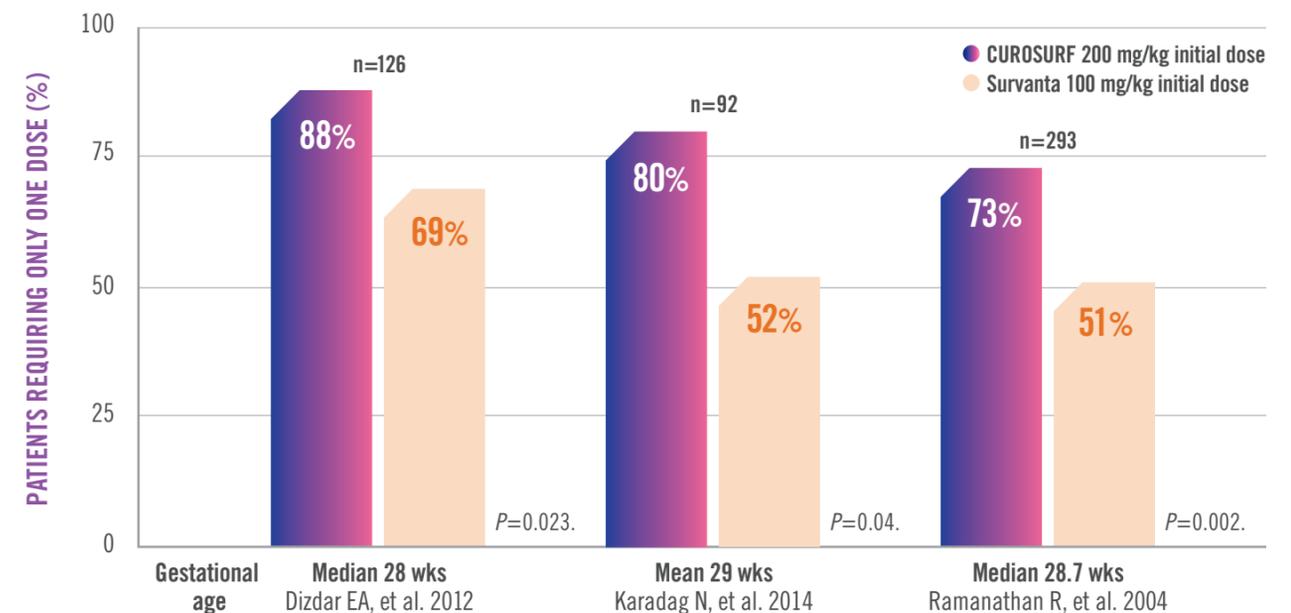
CUROSURF® (poractant alfa) is intended for intratracheal use only. The administration of exogenous surfactants, including CUROSURF, can rapidly affect oxygenation and lung compliance. Therefore, infants receiving CUROSURF should receive frequent clinical and laboratory assessments so that oxygen and ventilatory support can be modified to respond to respiratory changes.

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Sustained reduction of FiO_2 levels over 48 hours may reduce the need for redosing.¹⁹

CUROSURF (poractant alfa) 200 mg/kg*

HIGH RATES OF SINGLE-DOSE SUCCESS ACROSS MULTIPLE STUDIES⁷⁻⁹



Clinical studies have not established that fewer doses or longer dosing intervals result in superior safety or efficacy based on clinically relevant end points.

Dizdar EA, et al. *Am J Perinatol.* 2012;29:95-100.

A randomized, controlled trial of CUROSURF vs Survanta in the treatment of RDS in 126 preterm infants (CUROSURF 200 mg/kg, n=61; beractant 100 mg/kg, n=65). FiO_2 after surfactant treatment, need for repeat doses, and duration of respiratory support and hospitalization were evaluated between groups. Differences in baseline patient demographics between the two treatment groups were reported for antenatal steroid use and gender distribution.⁸

Karadag N, et al. *Am J Perinatol.* 2014;31:1015-1022.

A prospective study on 92 preterm infants with RDS, randomized to receive CUROSURF or Survanta (CUROSURF 200 mg/kg, n=46; beractant 100 mg/kg, n=46). The study compared the effects of the two treatment regimens on perfusion index and oxygenation.⁹

Ramanathan R, et al. *Am J Perinatol.* 2004;21:109-119.

A randomized, multi-center, masked comparison trial of CUROSURF vs Survanta in the treatment of RDS in 293 preterm infants weighing 750 to 1750 grams at birth and < 35 weeks gestation (CUROSURF 200 mg/kg, n=99; poractant alfa 100 mg/kg, n=96; beractant 100 mg/kg, n=98). Randomization was stratified by birth weight and site. The onset of clinical response after the first dose was studied by comparing changes in the FiO_2 between 0 and 6 hours measured using the area under the curve (FiO_2 AUC₀₋₆). Total number of doses of surfactant and duration of respiratory support were also evaluated between groups. Data for poractant alfa 100 mg/kg is not shown.⁷

Important Safety Information

Transient adverse reactions associated with administration of CUROSURF include bradycardia, hypotension, endotracheal tube blockage, and oxygen desaturation. These events require stopping CUROSURF administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring.

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In clinical studies, most infants required only one dose of CUROSURF, which may reduce complications associated with reintubation and subsequent MV.^{7,12}



CUROSURF (poractant alfa) 200 mg/kg* SUPPORTS THE GOALS OF RAPID EXTUBATION AND LESS INVASIVE VENTILATION^{10-12,20}

In some clinical studies, infants treated with CUROSURF using the INSURE strategy were generally extubated within approximately 5 to 10 minutes following administration.^{10-12,20}

RAPID EXTUBATION
following surfactant
administration



The INSURE strategy provides the benefits of surfactant while avoiding prolonged MV²¹



- Extubation should be performed when the infant is stable at the discretion of the clinician
- Rapid extubation after surfactant administration may not be achievable or desirable in the most immature infants, and decisions to extubate should be individualized

It is important to note that the INSURE strategy may not be appropriate for all infants. Infants with RDS may vary markedly in the severity of respiratory disease, maturity, and presence of other complications, and thus it is necessary to individualize patient care.

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In clinical studies, early rescue INSURE strategy ($FiO_2 \leq 0.45$) was associated with improved outcomes vs late selective therapy ($FiO_2 > 0.45$)²¹

Important Safety Information

CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of preterm infants.

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Early rescue INSURE strategy may help avoid potential for respiratory insufficiency and the need for subsequent MV.²¹

FiO_2 IS THE STRONGEST PREDICTOR OF CPAP FAILURE IN EARLY LIFE²²

Predicting CPAP failure earlier using an FiO_2 that is $\geq 30\%$ may help optimize the timing of surfactant treatment and improve outcomes for preterm infants.²²

Gestational age: 25–28 weeks^{22†}



†Data from ROC curves showed that FiO_2 in early life appeared to be a good predictor of CPAP failure (OR 1.19, 95% CI 1.06, 1.33; $P=0.002$), with an AUC of at least 0.8 in both GA ranges. A threshold of $FiO_2 \geq 0.3$ provided a balance between adequate sensitivity and an acceptable false-positive rate on ROC analysis.

Dargaville PA, et al. *Neonatology*. 2013;104(1):8-14.

A retrospective and observational study of data collected from June 2006 to June 2009 at the Royal Hobart Hospital and from May 2009 to April 2010 at the Royal Women's Hospital, Melbourne. Preterm infants (25–32 weeks' gestation, n=297) who were admitted to the NICU for respiratory support in the first 24 hours of life and managed initially with CPAP (maximum CPAP pressure of 8 cm H₂O and FiO_2 0.45–0.50) were included. CPAP failure was defined as the need for intubation before 72 hours. Data was separated into two gestation ranges (25–28 weeks and 29–32 weeks) and grouped according to whether the infants were successfully managed on or failed CPAP. Logistic regression models were used to investigate the effects of FiO_2 and CPAP levels in early life in the prediction of CPAP failure. The highest values for FiO_2 and CPAP in the first 2 hours (25–28 weeks) or 6 hours (29–32 weeks) were used.²²

Clinical consequences for infants who failed early on CPAP²²⁻²⁴

- Increased risk of mortality and morbidities, including pneumothorax, bronchopulmonary dysplasia (BPD), and intraventricular hemorrhage (IVH)^{22,23}
- Prolonged duration of respiratory support could lead to serious AEs related to oxygen toxicity²⁴

Important Safety Information

Pulmonary hemorrhage, a known complication of premature birth and very low birth-weight, has been reported with CUROSURF. The rates of common complications of prematurity observed in a multicenter single-dose study that enrolled infants 700–2000 g birth weight with RDS requiring mechanical ventilation and $FiO_2 \geq 0.60$ are as follows for CUROSURF 2.5 mL/kg (200 mg/kg) (n=78) and control (n=66; no surfactant) respectively: acquired pneumonia (17% vs. 21%), acquired septicemia (14% vs. 18%), bronchopulmonary dysplasia (18% vs. 22%), intracranial hemorrhage (51% vs. 64%), patent ductus arteriosus (60% vs. 48%), pneumothorax (21% vs. 36%) and pulmonary interstitial emphysema (21% vs. 38%).

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Predicting CPAP failure using an $FiO_2 \geq 30\%$ may help optimize the timing of surfactant treatment and improve outcomes for preterm infants.²²



IMPORTANT SAFETY INFORMATION

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CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of preterm infants.

Transient adverse reactions associated with administration of CUROSURF include bradycardia, hypotension, endotracheal tube blockage, and oxygen desaturation. These events require stopping CUROSURF administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring.

Pulmonary hemorrhage, a known complication of premature birth and very low birth-weight, has been reported with CUROSURF. The rates of common complications of prematurity observed in a multicenter single-dose study that enrolled infants 700–2000 g birth weight with RDS requiring mechanical ventilation and $FiO_2 \geq 0.60$ are as follows for CUROSURF 2.5 mL/kg (200 mg/kg) (n=78) and control (n=66; no surfactant) respectively: acquired pneumonia (17% vs. 21%), acquired septicemia (14% vs. 18%), bronchopulmonary dysplasia (18% vs. 22%), intracranial hemorrhage (51% vs. 64%), patent ductus arteriosus (60% vs. 48%), pneumothorax (21% vs. 36%) and pulmonary interstitial emphysema (21% vs. 38%).

INDICATION

CUROSURF[®] (poractant alfa) Intratracheal Suspension is indicated for the rescue treatment of Respiratory Distress Syndrome (RDS) in premature infants. CUROSURF reduces mortality and pneumothoraces associated with RDS.

Please see accompanying Full Prescribing Information.

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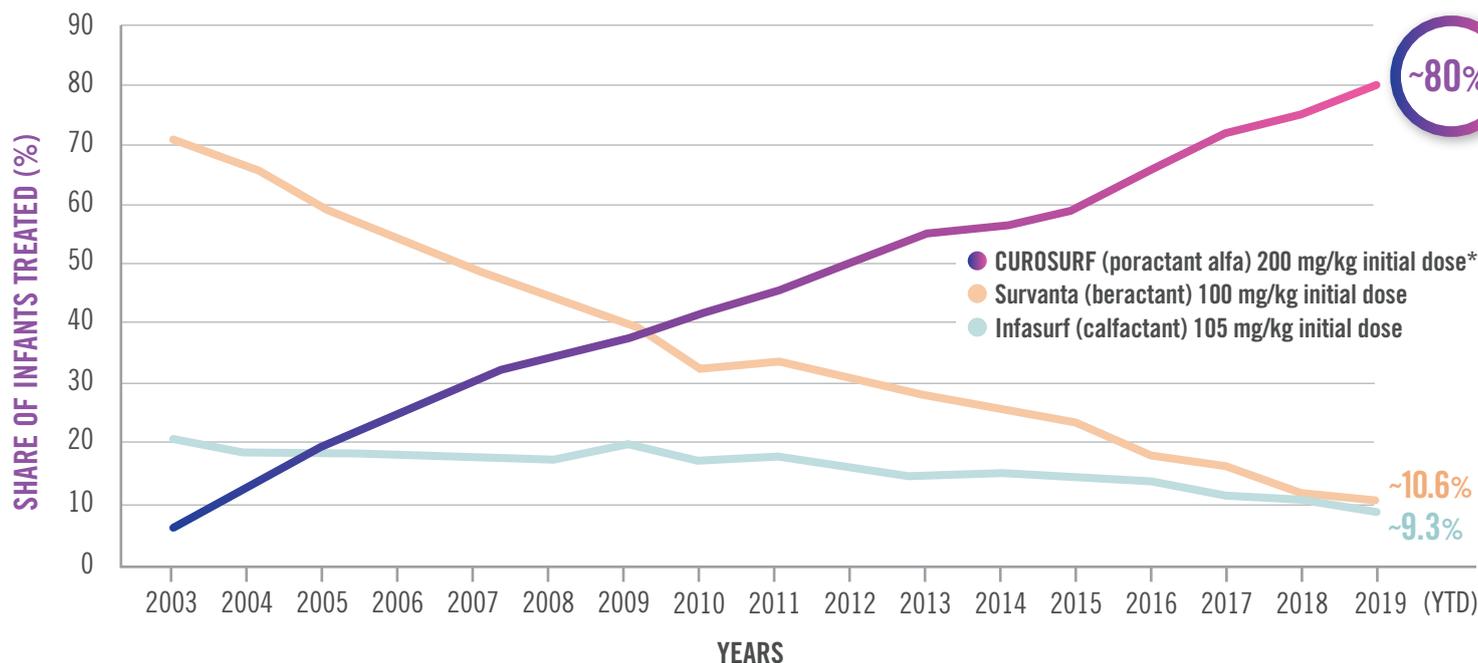


CUROSURF (poractant alfa) 200 mg/kg*

CHOOSE THE MOST USED SURFACTANT IN THE UNITED STATES FOR 10 YEARS AND COUNTING^{1,25}

#1
MOST USED SURFACTANT
in the U.S.[†]

CUROSURF is chosen by more NICUs than all other surfactants combined^{25-27†}



*CUROSURF is FDA approved for an initial dose of 200 mg/kg (2.5 mL/kg). The 100 mg/kg (1.25 mL/kg) dose of CUROSURF is approved for repeat dosing only.

†The number of patients treated with each surfactant is calculated by dividing the total amount of each surfactant sold by the average amount of surfactant each patient receives. Please note that this metric only provides insight into the surfactant selected by NICUs and does not imply equivalence or superiority between or among the products for any given clinical end point.

4.2
MILLION

INFANTS TREATED WITH CUROSURF WORLDWIDE²⁵

80%

CHOSEN BY MORE THAN 80% OF THE MAJORITY OF TOP HOSPITALS THAT USE SURFACTANT^{25,28,29}

- 50 Best Hospitals for Neonatology | US News and World Report[‡]
- U.S. Member Hospitals | Children's Hospital Association[§]



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‡Based on US News and World Report's "50 Best Hospitals for Neonatology" and Data on File, Chiesi Farmaceutici S.p.A. and Chiesi USA, Inc., 2018.

§Based on hospitals listed in the Children's Hospital Association's "Children's Hospital Directory" and Data on File, Chiesi Farmaceutici S.p.A. and Chiesi USA, Inc., 2018.

Chiesi
in Neonatology for Life

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Survanta® is a registered trademark of AbbVie Inc.
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6/19 PP-C-0095 V4.0

CUROSURF® 
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Intratracheal Suspension