CUROSURF (poractant alfa)

# USER'S GUIDE

## A surfactant with both multiple- and single-bolus dosing options

**Please see Important Safety Information on page 7.**

CUROSURF®
(poractant alfa)
Intratracheal Suspension

# STORAGE AND PREPARATION

## How Supplied

CUROSURF® (poractant alfa) intratracheal suspension is a white to creamy white suspension available in sterile, rubber-stoppered, clear glass vials (1 per carton) containing:

- 1.5 mL [120 mg poractant alfa (surfactant extract)] of suspension
- 3.0 mL [240 mg poractant alfa (surfactant extract)] of suspension

NDC Numbers:
10122-510-01 [1.5 mL]

10122-510-03 [3.0 mL]

Each vial has a color-coded cap that corresponds with the volume of surfactant supplied in each vial:

- Green – 1.5 mL [120 mg surfactant extract]
- Blue – 3.0 mL [240 mg surfactant extract]

## Storage and Handling

- Store CUROSURF in a refrigerator at +2 to +8°C (36°F to 46°F)
- PROTECT FROM LIGHT
- Do not shake
- Unopened, unused vials of CUROSURF suspension that have warmed to room temperature can be returned to refrigerated storage within 24 hours for future use
- CUROSURF should not be warmed to room temperature and returned to the refrigerator more than once
- Vials are for single-dose use only
- After opening the vial, discard the unused portion

## Preparation

- Remove the vial of CUROSURF from a refrigerator at +2 to +8°C (36°F to 46°F) and slowly warm the vial to room temperature before use
- Visually inspect suspension for discoloration prior to administration. Suspension should be white to creamy white. Discard if suspension is discolored
- Before use, the vial should be slowly warmed to room temperature and gently turned upside down in order to obtain a uniform suspension. DO NOT SHAKE



# DOSING

## Initial Dose

The recommended initial dose of CUROSURF® (poractant alfa) is 2.5 mL/kg birth weight administered as 1 or 2 aliquots, depending on the instillation procedure. This dose may be determined from the CUROSURF dosing chart on the back of this booklet.

## Repeat Doses

Up to 2 repeat doses of 1.25 mL/kg birth weight each may be administered. Repeat doses should be administered, at approximately 12-hour intervals, in infants in whom RDS is considered responsible for their persisting or deteriorating respiratory status. The maximum recommended total dose (sum of the initial and up to 2 repeat doses) is 5 mL/kg birth weight.

## Dosing Precautions

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.

## Overdosage

There have been no reports of overdosage following the administration of CUROSURF. In the event of accidental overdosage, and if there are clear clinical effects on the infant's respiration, ventilation, or oxygenation, aspirate as much of the suspension as possible and provide the infant with supportive treatment, with particular attention to fluid and electrolyte balance.

**Please see Important Safety Information on page 7.**

# OPENING VIALS

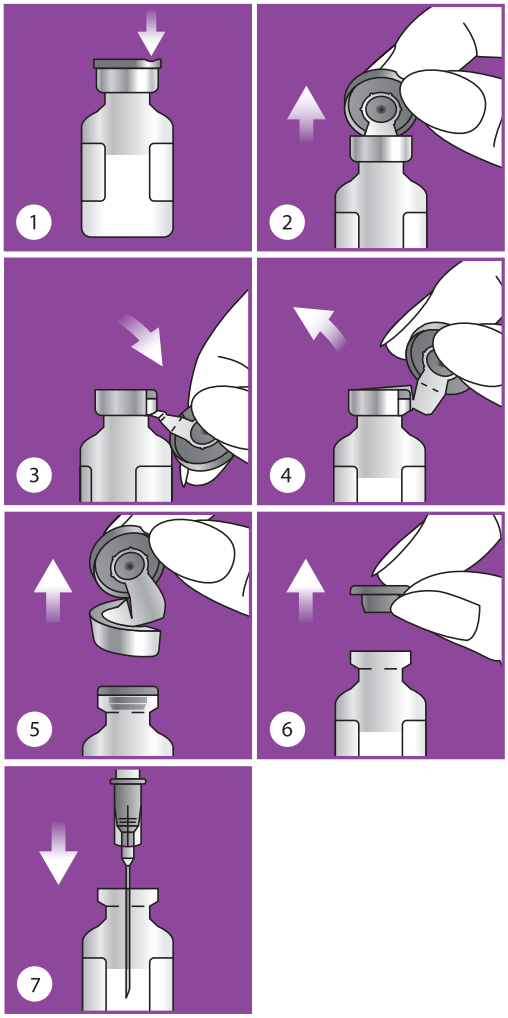
**1)** Locate the notch (FLIP UP) on the colored plastic cap.

**2)** Lift the notch and pull upwards.

**3)** Pull the plastic cap with the aluminum portion downwards.

**4-5)** Remove the whole ring by pulling off the aluminum wrapper.

**6-7)** Remove the rubber stopper to extract content.




# ADMINISTRATION

## General

Before administering CUROSURF® (poractant alfa), assure proper placement and patency of the endotracheal tube. At the discretion of the clinician, the endotracheal tube may be suctioned before administering CUROSURF. The infant should be allowed to stabilize before proceeding with dosing.

CUROSURF can be administered intratracheally by 2 different methods.

## Multiple Bolus Option

*For endotracheal tube instillation using a 5 French end-hole catheter**

1. Slowly withdraw the entire contents of the vial of CUROSURF suspension into a 3- or 5-mL plastic syringe through a large-gauge needle (eg, at least 20 gauge). Enter each single-use vial only once.

2. Attach the 5 French catheter of the appropriate length to the syringe and advance the catheter into the endotracheal tube without going past the premeasured depth. Fill the catheter with CUROSURF suspension. Discard excess CUROSURF through the catheter so that only the dose to be given remains in the syringe.
   - For the first dose: 1.25 mL/kg (birth weight) per aliquot
   - For each repeated dose: 0.625 mL/kg (birth weight) per aliquot

3. First aliquot of CUROSURF suspension:
   a. Position the infant in a neutral position (head and body in alignment without inclination), with either the right or left side dependent.
   b. Immediately before CUROSURF administration, ventilate the infant with supplemental oxygen sufficient to maintain $SaO_2 > 92\%$.
   c. Insert the catheter into the endotracheal tube and instill the first aliquot of CUROSURF suspension.
   d. After the first aliquot is instilled, remove the catheter from the endotracheal tube and resume ventilation of the infant with supplemental oxygen until clinically stable.

4. Second aliquot of CUROSURF suspension:
   a. When the infant is stable, reposition the infant such that the other side is dependent.
   b. Administer the remaining aliquot using the same procedures as the first aliquot.

5. After completion of the dosing procedure, do not suction airways for 1 hour after surfactant instillation unless signs of significant airway obstruction occur [see *Clinical Studies (14.1)* in Full Prescribing Information].

**Please see Important Safety Information on page 7.**

# ADMINISTRATION (cont.)

## Single Bolus Option

*For endotracheal tube instillation using the secondary lumen of a dual-lumen endotracheal tube (medication administration lumen)**

1. Slowly withdraw the entire contents of the vial of CUROSURF suspension into a 3- or 5-mL plastic syringe through a large-gauge needle (eg, at least 20 gauge).

   Do not attach 5 French catheter. Remove the needle and discard excess CUROSURF so that only the dose to be given remains in the syringe.

2. Keep the infant in a neutral position (head and body in alignment without inclination).

3. Administer CUROSURF suspension through the medication administration lumen of the dual-lumen endotracheal tube as a single dose, given over 1 minute, and without interrupting mechanical ventilation.

4. After completion of this dosing procedure, resume management and adjust ventilator as needed. Do not suction airways for 1 hour after surfactant instillation unless signs of significant airway obstruction occur.

*Methods are not interchangeable.

**Please see accompanying Full Prescribing Information.**

While these administration instructions should be followed, clinical judgment should be used for individual scenarios.



**Please see Important Safety Information on page 7.**

# IMPORTANT SAFETY INFORMATION

## 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.

## Important Safety Information

CUROSURF 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.

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%).

**Please see accompanying Full Prescribing Information.**

# DOSING CHART[a]

| Weight (grams) | Initial Dose—2.5 mL/kg (200 mg/kg) | | Repeat Dose—1.25 mL/kg (100 mg/kg) | |
|---|---|---|---|---|
| | Each Dose (mL) | Each Dose (mg) | Each Dose (mL) | Each Dose (mg) |
| 600-650 | 1.60 | 128 | 0.80 | 64 |
| 651-700 | 1.70 | 136 | 0.85 | 68 |
| 701-750 | 1.80 | 144 | 0.90 | 72 |
| 751-800 | 2.00 | 160 | 1.00 | 80 |
| 801-850 | 2.10 | 168 | 1.05 | 84 |
| 851-900 | 2.20 | 176 | 1.10 | 88 |
| 901-950 | 2.30 | 184 | 1.15 | 92 |
| 951-1000 | 2.50 | 200 | 1.25 | 100 |
| 1001-1050 | 2.60 | 208 | 1.30 | 104 |
| 1051-1100 | 2.70 | 216 | 1.35 | 108 |
| 1101-1150 | 2.80 | 224 | 1.40 | 112 |
| 1151-1200 | 3.00 | 240 | 1.50 | 120 |
| 1201-1250 | 3.10 | 248 | 1.55 | 124 |
| 1251-1300 | 3.20 | 256 | 1.60 | 128 |
| 1301-1350 | 3.30 | 264 | 1.65 | 132 |
| 1351-1400 | 3.50 | 280 | 1.75 | 140 |
| 1401-1450 | 3.60 | 288 | 1.80 | 144 |
| 1451-1500 | 3.70 | 296 | 1.85 | 148 |
| 1501-1550 | 3.80 | 304 | 1.90 | 152 |
| 1551-1600 | 4.00 | 320 | 2.00 | 160 |
| 1601-1650 | 4.10 | 328 | 2.05 | 164 |
| 1651-1700 | 4.20 | 336 | 2.10 | 168 |
| 1701-1750 | 4.30 | 344 | 2.15 | 172 |
| 1751-1800 | 4.50 | 360 | 2.25 | 180 |
| 1801-1850 | 4.60 | 368 | 2.30 | 184 |
| 1851-1900 | 4.70 | 376 | 2.35 | 188 |
| 1901-1950 | 4.80 | 384 | 2.40 | 192 |
| 1951-2000 | 5.00 | 400 | 2.50 | 200 |

[a]Adapted from CUROSURF® (poractant alfa) Intratracheal Suspension prescribing information, Chiesi USA, Inc., December 2014.

# ET TUBE REFERENCE CHART

| Weight (grams) | DEPTH OF INSERTION[b] AT LIPS (cm) |
|---|---|
| 500-600 | 5.5 |
| 700-800 | 6.0 |
| 900-1000 | 6.5 |
| 1100-1400 | 7.0 |
| 1500-1800 | 7.5 |
| 1900-2400 | 8.0 |
| 2500-3100 | 8.5 |
| 3200-4200 | 9.0 |

| Weight (grams) | ET TUBE SIZE[c] (ID, mm) |
|---|---|
| <1000 g or <28 weeks | 2.5 |
| 1000-2000 g or 28-34 weeks | 3.0 |
| >2000 g or >34 weeks | 3.5 |

[b]Adapted with permission from Kempley ST, Moreiras JW, Petrone FL. Endotracheal tube length for neonatal intubation. *Resuscitation.* 2008;77(3):369-373.

[c]Adapted from American Academy of Pediatrics. Neonatal Resuscitation Program®; Reference Chart.

**Please see Important Safety Information on page 7.**

For more information about CUROSURF, please call (888) 661-9260 or contact your CUROSURF sales representative.

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