CUROSURF (poractant alfa)

USER'S GUIDE

The only surfactant with single bolus administration option

Please see Important Safety Information on page 7.

CUROSURF®
(poractant alfa)
Intratracheal Suspension

STORAGE AND PREPARATION

How Supplied

CUROSURF® (poractant alfa) Intratracheal Suspension is available in sterile, ready-to-use, rubber-stoppered clear glass vials containing (one vial per carton):

- 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 (36-46°F)
- PROTECT FROM LIGHT
- Unopened vials of CUROSURF may be warmed to room temperature for up to 24 hours prior to use
- CUROSURF should not be warmed to room temperature and returned to the refrigerator more than once
- Each single-use vial should be entered only once
- Vials with unused surfactant should be discarded after initial entry

Preparation

- Before use, the vial should be slowly warmed to room temperature and gently turned upside down, in order to obtain a uniform suspension
- Visually inspect suspension for discoloration prior to administration. Suspension should be white to creamy white. Discard if suspension is discolored
- DO NOT SHAKE

DOSING

Initial Dose

The recommended initial dose of CUROSURF® (poractant alfa) is 2.5 mL/kg birth weight. 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 who remain intubated and 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

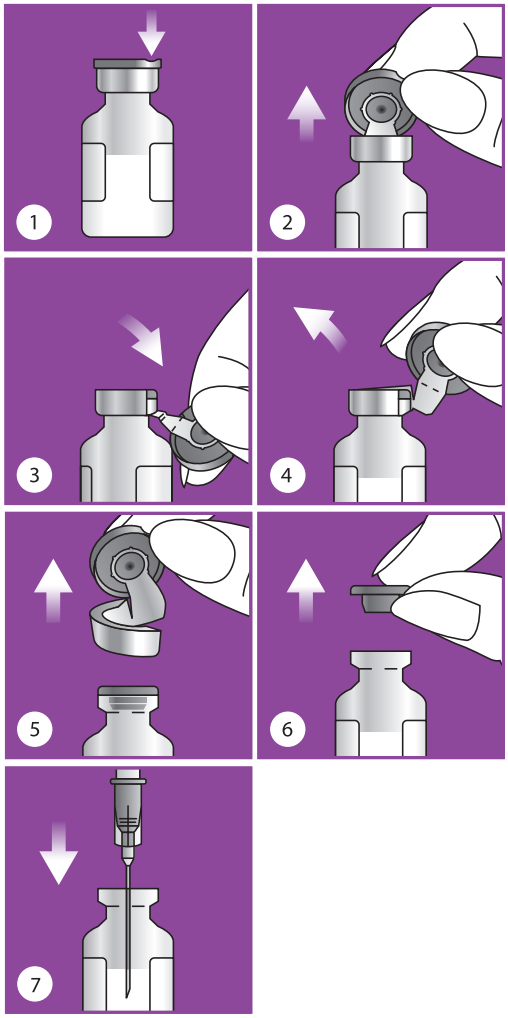
1) Locate the notch (FLIP UP) on the colored plastic cap.

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:

Single Bolus Option

- Single aliquot administered through the secondary lumen of a dual lumen endotracheal tube without interruption of mechanical ventilation

Multiple Bolus Option

- Two divided aliquots administered through a 5 French end-hole catheter after briefly disconnecting the endotracheal tube from the ventilator

Single Bolus Option

If using the secondary lumen of a dual lumen endotracheal tube

- Determine the dose of CUROSURF to be administered based on birth weight
- Slowly withdraw the entire contents of the vial of CUROSURF into a 3 mL or 5 mL plastic syringe through a large-gauge needle (e.g., at least 20 gauge)
- Remove the needle and discard excess CUROSURF so that only the dose to be given remains in the syringe
- Do not attach a pre-cut 8-cm 5 French end-hole catheter to the syringe
- Keep the infant in a neutral position (head and body in alignment without inclination)
- Administer CUROSURF through the proximal end of the secondary lumen of the endotracheal tube as a single dose, given over 1 minute, and without interrupting mechanical ventilation
- After completion of this dosing procedure, ventilator management may require transient increases in FiO_2, ventilator rate, or peak inspiratory pressure. Do not suction airways for 1 hour after surfactant instillation unless signs of significant airway obstruction occur

Please see Important Safety Information on page 7.

ADMINISTRATION (cont.)

Multiple Bolus Option

If using a 5 French end-hole catheter

- Determine the dose of CUROSURF® (poractant alfa) to be administered based on birth weight
- Slowly withdraw the entire contents of the vial of CUROSURF into a 3 mL or 5 mL plastic syringe through a large-gauge needle (e.g., at least 20 gauge)
- Attach a pre-cut 8-cm 5 French end-hole catheter to the syringe
- Fill the catheter with CUROSURF
  - Discard excess CUROSURF through the catheter so that only the total dose to be given remains in the syringe
- Position the infant in a neutral position (head and body in alignment without inclination), with either the right or left side dependent
- Immediately before CUROSURF administration, it is recommended to adjust ventilator settings considering the CUROSURF product labeling and your institution's protocols
- Briefly disconnect the endotracheal tube from the ventilator
- Insert the pre-cut 8-cm 5 French end-hole catheter into the endotracheal tube and instill the first aliquot (1.25 mL/kg birth weight) of CUROSURF
- After the first aliquot is instilled, remove the catheter from the endotracheal tube and manually ventilate the infant for 1 minute
- When the infant is stable, reposition the infant such that the other side is dependent and administer the remaining aliquot using the same procedure
- After completion of the dosing procedure, resume usual ventilator management and clinical care. Do not suction airways for 1 hour after surfactant instillation unless signs of significant airway obstruction occur

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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.

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

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Chiesi

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