



**Evidence based
approach
to treat RDS**

**Frequently Asked
Questions**
about
SURVANTA

SURVANTA[®]
The Natural Surfactant

What is the composition of Survanta ?

Each vial contains

Total phospholipids	25 mg/ml {Colfosceril palmitate (DPPC)}
Free fatty acid	1.4-3.5 mg/ml
Triglycerides	0.5-1.75 mg/ml
Protein	less than 1.0 mg/ml

The components are suspended in 0.9% sodium chloride solution, and heat sterilized. Contains no preservatives.

Composition of Survanta

Physico-Chemical properties of Survanta ?

What are Physico-Chemical properties of Survanta ?

The physico-chemical properties of beractant, described originally by Fujiwara, can be summarized as follows:⁷

1. Rapid spreading-Less than 10 second to reach an equilibrium surface tension of 24-27 dynes/cm.
2. Rapid absorption-Less than one minute to reach a surface tension of 27-30 dynes/cm (with aa hypo-phase concentration of 50 mcg of phospholipid/ml).
3. Minimum surface tension-Less than 10 dynes/cm with only 20-30% surface compression.
4. Reproducible surface tension area diagram with maximum surface tension 27-30 dynes/cm.
5. Very low surface compressibility (less than 0.02 cm/dyne) at a surface tension of 10 dynes/cm.
6. Increased lung distensibility and deflation stability after tracheal installation of surfacant in the premature rabbit fetus (gestational age: 27 days) with conversion of pressure of volume-characteristics into those of the terms fetus (30 days) i.e. 45-48 ml/ kg of body weight at a deflation pressure of 5cm H₂O.
7. Homogenous alveolar expansion at low intra-pulmonary pressure, similar when administered in the premature rabbit fetus.

What are different dosage for a range of birth weights ?

The Dosing Chart below shows the total dosage for a range of birth weights.

Beractant Dosing Chart

(grams)	DOSE (mL)	(grams)	DOSE (mL)
600-650	2.6	1301-1350	5.4
651-700	2.8	1351-1400	5.6
701-750	3.0	1401-1450	5.8
751-800	3.2	1451-1500	6.0
801-850	3.4	1501-1550	6.2
851-900	3.6	1551-1600	6.4
901-950	3.8	1601-1650	6.6
951-1000	4.0	1651-1700	6.8
1001-1050	4.2	1701-1750	6.8
1051-1100	4.4	1751-1800	7.0
1101-1150	4.6	1801-1850	7.2
1151-1200	4.8	1851-1900	7.4
1201-1250	5.0	1901-1950	7.8
1251-1300	5.2	1951-2000	8.0

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Dosing Chart

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Direction for Use.

What precautions should be taken at the time of administering Survanta

Beractant should be inspected visually for discoloration prior to administration. The color beractant is off-white to light brown. If settling occurs during storage, swirl the vial gently. (DO NOT SHAKE) to redisperse. Some foaming at the surface may occur during handling and is inherent in the nature of the product. Beractant is stored refrigerated (2-8°C). Before administration, beractant should be warmed by standing at room temperature for at least 20 minutes or warmed in the hand for at least 8 minutes. Artificial warming methods should not be used. If a prevention dose is to be given, preparation of beractant should begin before the infant's birth.

Unopened, unused vials of beractant that have been warmed to room temperature may be returned to the refrigerator within 24 hours of warming, and stored for future use. Beractant should not be warmed and returned to the refrigerator more than once.

Each single-use vial of Beractant should be entered only once. Used vials with residual drug should be discarded.

Beractant does not require reconstitution or sonication before use.

If an infant experience bradycardia or oxygen desaturation during the dosing procedure, stop the dosing procedure and initiate appropriate measures to alleviate the condition. After the infant has stabilized, resume the dosing procedure.

Rales and moist breath sounds can occur transiently after administration of beractant. Endotracheal suctioning or other remedial action is unnecessary unless clear-cut signs of airway obstruction are present.

What is the methodology for administrating the first dose of Survanta?

1. Determine the total dose of beractant from the Beractant Dosing Chart based on the infant's birth weight. Slowly withdraw the entire contents of the vial into a plastic syringe through a large-gauge needle (e.g. at least 20 gauge). Do not filter beractant and avoid shaking. Attach the premeasured 5 French end-hole catheter to the syringe. Fill the catheter with beractant. Discard excess beractant through the catheter so that only the total dose to be given remains in the syringe.
2. Before administering beractant, assure proper placement and patency of the endotracheal tube. At the discretion of the clinician, the endotracheal tube may be suctioned before administering beractant. The infant should be allowed to stabilize before proceeding with dosing.
3. In the prevention strategy, weigh intubate and stabilize the infant. Administer the dose as soon as possible after birth, preferably within 15 minutes. Position the infant appropriately and gently inject the first quarter-dose through the catheter over 2-3 seconds.
4. After administration of the first quarter-dose, remove the catheter from the endotracheal tube. Manually ventilate with a handbag with sufficient oxygen to prevent cyanosis, at a rate of 60 breaths/minute, and sufficient positive pressure to provide adequate air exchange and chest wall excursion.
5. In the rescue strategy, the first dose should be given as soon as possible after the infant is placed on a ventilator for management of RDS. In the clinical trials, immediately before instilling the first quarter-dose, the infant's ventilator settings were changed to rate 60/minute, inspiration time 0.5 second, and FiO₂-1.0. Position the infant appropriately and gently inject the first quarter-dose through the catheter over 2-3 seconds. After administration of the first quarter-dose, remove the catheter from the endotracheal tube and continue mechanical ventilation.
6. In the both strategies, ventilate the infant for at least 30 seconds or until stable. Reposition the instillation of the next quarter-dose. Instill the remaining quarter-doses using the same procedures. After instillation of each quarter-dose, remove the catheter and ventilate for at least 30 seconds or until the infant is stabilized. After instillation of the final quarter-dose remove the catheter without flushing it. Do not suction the infant for hour after dosing unless signs of significant airway obstruction occur.
7. After instillation of the final fractional dose through secondary lumen of a double-lumen endotracheal tube, remove the syringe from the secondary lumen, INJECT 0.5 mL of air to flush the secondary lumen and cap it.
8. After completion of the dosing procedure, resume usual ventilator management and clinical care.

What is the methodology for administrating the repeat dose of Survanta ?

1. The dosage of beractant for repeat doses is also 100 mg phospholipids/kg and is based on the infant's birth weight. The infant should not be reweighed for determination of the beractant dosage. Use the Beractant Dosing Chart to determine the total dosage.
2. The need for additional doses of beractant is determined by evidence of continuing respiratory distress. Using the following criteria for redosing, significant reductions in mortality due to RDS were observed in the multiple dose clinical trails with beractant.
3. Dose no sooner than 6 hours after the preceding dose if the infant remains intubated and requires at least 30% inspired oxygen to maintain a PaO₂ less than or equal to 80 torr.
4. Radiographic confirmation of RDS should be obtained before administering additional doses to those who received a prevention dose.
5. Prepare beractant and position the infant for administration of each quarter dose as previously described. After instillation of each quarter -dose, remove the dosing catheter from the endotracheal tube and ventilate the infant for at least 30 seconds or until stable.
6. In the clinical studies, ventilator settings used to administer repeat doses were different than those used for the 1st dose. For repeat doses, the FiO₂ was increased by 0.20 or an amount sufficient to prevent cyanosis. The ventilator delivered a rate of 30/minute with an inspiratory time less than 1.0 second. If the infant's pretreatment rate was 30 or greater, it was left unchanged during bearctant instillation.
7. Manual handbag ventilation should not be used to administer repeat doses.
8. During the dosing procedure, ventilator setting may be adjusted at the discretion of the clinician to maintain appropriate oxygenation and ventilation.
9. After completion of the dosing procedure, resume usual ventilator management and clinical care.

Can more than one dose of Survanta be drawn out of a vial?

Survanta is supplied as a single-use vial, and the product does not contain antimicrobial preservatives, which are required in multiple use containers to inhibit the growth of microorganisms.¹ Preservatives are not included in the Survanta formulation because of their questionable safety in the premature population (e.g., benzyl alcohol). Because Survanta does not contain preservatives, the vial should not be entered more than once.

If, based on an infant's weight, a vial may supply more than one dose, more than one dosing syringe can be filled at the time of vial entry, provided aseptic technique is used. Filled syringes not used immediately may be stored in the refrigerator for a maximum of eight (8) hours before use. Once removed from the refrigerator, the drug in a syringe should be used immediately after being brought to room temperature or discarded.

1. <51> Antimicrobial Preservatives - Effectiveness. USP: 24: NF 19: 1809. United States Pharmacopeial Convention, Inc, Rockville, MD, 1999.



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Color of Survanta

Is there anything wrong with the vials of drug we just received if the color is different from previously received drug?

The color of Survanta is off-white to light brown. There may be variations within this range, from batch to batch. Each Survanta vial is visually inspected and judged to be within our specifications for appearance and color before it is released. Do not use the drug from a vial if it looks markedly discolored relative to your prior experience (e.g., dark brown).

Can a vial of Survanta still be used if it looks foamy when removed from the carton?

A small amount of foaming on the surface (up to 0.5 cm) may occur during routine handling and is inherent to the product. Therefore, if the vial has not been shaken, it is acceptable to use the drug provided that the extent of foaming does not prohibit accurate dosing. A large amount of foaming (more than 0.5 cm) may indicate that the vial has been shaken and the product should not be used. Vigorous shaking will induce foaming and the presence of foam will prohibit accurate measurement of the dose.

How long can a vial of Survanta remain unrefrigerated before it should be discarded?

A vial may remain at room temperature continuously for a maximum of twenty-four (24) hours. In order to ensure stability of the drug, vials left out of the refrigerator for longer than 24 hours should not be used and should be discarded.

Survanta vials can be carried through one cycle of removal and exposure to room temperature for a maximum of 24 hours and subsequent return to the refrigerator. Once a vial is returned to room temperature a second time, it must be used within 24 hours or discarded.

Foaminess

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Refrigeration of Survanta

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Pneumatic Tube System

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Osmolality

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pH of Survanta

What is the impact on stability when a vial of Survanta is sent through the pneumatic tube system of a hospital?

We currently have no data to support the stability of Survanta when the drug is subjected to the forces encountered in a pneumatic tube system. Intuitively, we have no reason to suspect that this practice would be detrimental to the product. Because pneumatic tube conditions may vary greatly from hospital to hospital, it is not possible for us to conduct a study that we could be confident would mimic all potential circumstances. If such practice results in excessive foaming or bubbles, the sending of the drug via pneumatic tube system should be discontinued.

What is the osmolality of Survanta?

The osmolality of Survanta is approximately 310 mosm/kg H₂O.

What is the pH range of Survanta?

The pH range of Survanta is 6.2 - 7.6.

For Medical Profession Only

www.survanta.com

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