Package leaflet: Information for the Parent/Guardian

Survanta® 25 mg/ml Suspension
Beractant

IMPORTANT INFORMATION

Read all of this leaflet carefully before this medicine is given because it contains important information for you.

- Keep this leaflet; you may need to read it again.
- If you have any questions, please ask your doctor or nurse.

What is in this leaflet

1. What Survanta is and what it is used for

Survanta contains the active substance beractant which is a natural surfactant extracted from cow's lungs (see section 6) to help your child breathe.

Your baby will be/has been given Survanta because he or she is at risk of developing, or is suffering from, a condition called Respiratory Distress Syndrome (hyaline membrane disease) which may cause severe breathing difficulties.

Survanta is used for the treatment of Respiratory Distress Syndrome (RDS) in newborn premature infants with a birth weight of 700 g or greater.

Survanta is also used for the treatment of premature babies, when the pregnancy has lasted for less than 32 weeks, at risk of developing RDS who require a tube to be inserted into their windpipe for stabilisation or with evidence of surfactant deficiency.

Respiratory Distress Syndrome occurs in some babies, particularly premature babies, who lack a substance usually produced in the lungs known as surfactant. This surfactant lines the inside of the lungs, stopping them from sticking together, so that the baby can breathe normally.

Survanta as a natural surfactant acts in a similar way to your baby's own surfactant helping your baby to breathe normally.

2. What you need to know before Survanta is used

Your baby will only be given Survanta if the equipment for ventilation and monitoring babies with Respiratory Distress Syndrome is available.

After being given Survanta, your baby will continue to be monitored by the doctor or nurse to ensure that the right amount of oxygen is being given.

During the dosing procedure, occasional episodes of slow heartbeat (bradycardia) and/ or oxygen reduction in the circulation have been reported. If these occur, dosing will be stopped and appropriate measures to relieve the condition will be started. After stabilisation, the dosing procedure will be resumed.

3. How Survanta is used

The dosage of Survanta varies for each child depending on their body weight. The usual dose is 100 mg Survanta per kg body weight. The doctor will calculate the right dose. Usually the first dose will be given as soon as possible after birth (usually within 15 minutes) or as soon as possible after Respiratory Distress Syndrome has been diagnosed.

The dose of Survanta will be administered to your baby via a tube or a small diameter catheter into the baby's windpipe. Do not be concerned if your baby is disconnected from its ventilator while Survanta is being administered.

The dose may be repeated up to three times at six hourly intervals within 48 hours. Survanta will be warmed to room temperature before administration to your baby.

4. Possible side effects

Like all medicines, Survanta can be associated with side effects although not everybody gets them.

The following side effects with Survanta are serious and will be managed by your baby's Doctor as necessary during dosing.

Very common: affecting more than 1 in 10:

• Bleeding in the brain. The occurrence of this side effect is no different to what would be expected in untreated babies of the same age.

Common: affecting less than 1 in 10

• Cases of bleeding in the lungs.

Other Side effects:

Uncommon: affecting less than 1 in 100

• Blockage of the breathing tube that has been inserted into your baby's windpipe.

During the administration of Survanta with a small diameter catheter, the following additional side effects have been seen: 'slow heart rate' and 'below normal levels of oxygen in the blood'.

If you have any questions about your baby's treatment which are not answered by this leaflet, ask the doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Survanta

Keep out of the sight and reach of children.
• Survanta should not be used after the expiry date shown on the label.
• Survanta should have been stored in a refrigerator and protected from light; however before it is given to your baby it will be warmed to room temperature.
• Survanta must not be frozen. Any product that has been frozen by mistake should be thrown away.
• Each vial of Survanta is for single use only. Used vials with medicine left in them should be thrown away.
• If any vial is not used within 8 hours of re-warming to room temperature it should be thrown away. Vials should not be returned to the refrigerator once warmed.

Medicines should not be disposed of via wastewater or household waste.

6. Contents of the pack and other information

What Survanta contains

-The active substance is beractant which is a mixture containing phospholipids (25 mg/ml), free fatty acids (1.4 -3.5 mg/ml), triglycerides (0.5 -1.75 mg/ml) and protein (0.1 -1.0 mg/ml).

-The other excipients are sodium chloride, sodium hydroxide, hydrochloric acid, palmitic acid, dipalmitoyl phosphatidylcholine, tripalmitin and water.

What Survanta looks like

-It is a sterile off-white to light brown suspension and is supplied in a single use glass vial containing 8 ml (200 mg phospholipids). Packs of 1, 3, and 10 vials are available*.

*Not all pack sizes may be marketed.

Marketing Authorisation Holder:
AbbVie Ltd.,
Maidenhead, SL6 4UB. UK

Manufacturer:
AbbVie Logistics B.V.
Zuiderzeelaan 53
8017 JV Zwolle
The Netherlands

This leaflet was last revised in June 2020

For information in large print, tape, CD or Braille, phone 01628 561090 (UK).

INSTRUCTION FOR USE
Survanta® Beractant

Description and Composition
Survanta is a sterile, non-pyrogenic pulmonary surfactant intended for intratracheal use only.
It is a bovine lung extract containing phospholipids, neutral lipids, fatty acids and surfactant associated proteins to which have been added dipalmitoyl phosphatidylcholine, palmitic acid and tripalmitin.

The resulting composition provides:

phospholipids 25 mg/ml (including
11.0 - 15.5 mg/ml disaturated
phosphatidylcholine)
triglycerides 0.5 - 1.75 mg/ml
free fatty acids 1.4 - 3.5 mg/ml
protein less than 1.0 mg/ml

It is suspended in 0.9% sodium chloride (Ph Eur) solution. It also contains sodium hydroxide and hydrochloric acid.
Each milliliter of Survanta contains 25 mg phospholipids. It is an off-white to light brown liquid supplied in single-use glass vials containing 8 ml (200 mg phospholipids).

Properties
Endogenous pulmonary surfactant lowers surface tension on alveolar surfaces during respiration and stabilises the alveoli against collapse at resting transpulmonary pressures. Deficiency of pulmonary surfactant causes Respiratory Distress Syndrome (RDS) in premature infants. Survanta replenishes surfactant and restores surface activity to lungs of these infants.

Therapeutic Indications
Survanta is indicated for the treatment of Respiratory Distress Syndrome (RDS) in newborn premature infants with birth weight of 700 g or greater.

Survanta is also indicated for the prophylactic treatment of premature infants <32 weeks gestational age at risk of developing RDS who require intubation for stabilisation or with evidence of surfactant deficiency.

Contraindications
No specific contraindications for Survanta have been defined by the clinical studies.

Warnings and Precautions
Special Precautions for Use:
Survanta should only be administered with adequate facilities for ventilation and monitoring of babies with RDS. Marked improvements in oxygenation may occur within minutes of the administration of Survanta. Therefore, frequent and careful monitoring of systemic oxygenation is essential to avoid hyperoxia. Following Survanta administration, monitoring of the arterial blood gases, the fraction of inspired oxygen and ventilatory change is required to ensure appropriate adjustments.

During the dosing procedure, transient episodes of bradycardia and/or oxygen desaturation have been reported. If these occur, dosing should be stopped and appropriate measures to alleviate the condition should be initiated. After stabilisation the dosing procedure should be resumed.

Survanta is stored refrigerated (2-8°C). Before administration, Survanta should be warmed by standing at room temperature for 20 minutes or warmed in the hand for 8 minutes. ARTIFICIAL WARMING METHODS SHOULD NOT BE USED.

Discard each vial if not used within 8 hours of warming to room temperature. Vials should not be returned to the refrigerator once warmed.

Each vial of Survanta is for single use. Used vials with residual drug should be discarded. Survanta should be inspected visually for discolouration prior to administration. The colour of Survanta is off-white to light brown. Some settling may occur during storage.
If this occurs, gently invert the vial several times (DO NOT SHAKE) to redisperse.

Interactions with Other Medications
None known to date.

Dosage Instructions
Unless otherwise prescribed, 4 ml suspension per kg birth weight is the normal dose to be administered via the trachea (intratracheal administration).
Higher doses should not be used.

The dosing chart below shows the total dosage for a range of birth weights.

Weight (grammes)	**Total Dosage (ml)**	**Weight (grammes)**	**Total Dosage (ml)**
701 - 750	3.0	1351-1400	5.6
751 - 800	3.2	1401-1450	5.8
801-850	3.4	1451-1500	6.0
851-900	3.6	1501-1550	6.2
901-950	3.8	1551-1600	6.4
951-1000	4.0	1601-1650	6.6
1001-1050	4.2	1651-1700	6.8
1051-1100	4.4	1701-1750	7.0
1101-1150	4.6	1751-1800	7.2
1151-1200	4.8	1801-1850	7.4
1201-1250	5.0	1851-1900	7.6
1251-1300	5.2	1901-1950	7.8
1301-1350	5.4	1951-2000	8.0

Method of Administration
Survanta should be administered via the endotracheopulmonary route.

The dosing procedure is facilitated if one person administers the dose while another person positions and monitors the infant.

Survanta should be warmed to room temperature before administration (see section 6.3).

Instillation in Mechanically Ventilated Infants

Before administering Survanta to infants on mechanical ventilation, suggested settings include respiratory frequency at 60/minute, inspiration time 0.5s, and Fi02 at 1.0. Inspiratory pressure needs no change at this point.

There are 2 alternative methods of administration for mechanically ventilated infants:

i. The dose is administered by disconnecting the endotracheal tube from the ventilator, inserting a small diameter catheter and administering the dose with the infant in a neutral position. The tip of the catheter should lie at the end of the endotracheal tube.

Alternatively:

ii. The dose can be administered by inserting a small diameter catheter through a suction port connector without disconnection from the ventilator with the infant in a neutral position. The tip of the catheter should lie at the end of the endotracheal tube.

After the dose is administered, the catheter is then withdrawn completely, and the ventilator is reconnected if necessary.

Instillation in Spontaneously Breathing Infants

Intubation Surfactant Extubation (INSURE)
Following intubation and insertion of the catheter as described above, place the infant in a neutral position and gently inject the dose as a single bolus over 1 to 3 minutes in the delivery room or later after admission to the neonatal unit. After instillation, use a bagging technique and proceed to extubation and CPAP as clinically indicated.

Less Invasive Surfactant Administration (LISA)
A small diameter catheter may be used to administer the dose without intubation. In such cases, place the catheter directly into the trachea of infants on CPAP with direct visualization of the vocal cords by laryngoscopy and gently inject the dose as a single bolus over 1 to 3 minutes. After instillation, immediately remove the catheter. Ensure continuous spontaneous breathing and continue CPAP treatment during the entire procedure.

Control arterial blood gas values and the inspiratory oxygen concentration, and check for changes in ventilatory parameters immediately after finishing the dosing with Survanta.

The dosage for repeat doses of Survanta is also 100 mg phospholipids per kg and is based on the infant's birth weight. The need for additional doses of Survanta should be determined by evidence of continuing respiratory distress. Dose no sooner than 6 hours after the previous dose. Up to 3 additional doses may be given in the first 48 hours.

Undesirable Effects

Mechanically Ventilated Infants
Intracranial haemorrhage has been observed in patients who received either beractant or placebo. The incidence of intracranial haemorrhage in all patients is similar to that reported in the literature in this patient population. Pulmonary haemorrhage has also been reported. Blockage of the endotracheal tube by mucous secretions has been reported. No other serious adverse reactions have been reported.

INSURE and LISA Techniques
Safety results with the INSURE and LISA techniques were comparable to those of the control groups, although bradycardia and hypoxemia were reported more frequently in some cases with LISA.

The following adverse reactions were identified in patients treated with Survanta. The adverse reactions are listed below by body system organ class and frequency. Frequencies are defined as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) or not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Reactions
Vascular disorders	Very common	Intracranial haemorrhage
Respiratory	Common	Pulmonary haemorrhage
Surgical and Medical Procedures	Uncommon	Blockage of endotracheal tube by mucous secretions

No antibody production to Survanta proteins has been observed.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions direct to:

United Kingdom
Yellow Card Scheme:
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Overdose
If an excessively large dose of Survanta is given, observe the infant for signs of acute airway obstruction. Treatment should be symptomatic and supportive. Rales and moist breath sounds can transiently occur after Survanta is given, and do not indicate overdosage. Endo-tracheal suctioning or other remedial action is not required unless clear-cut signs of airway obstruction are present.

Pharmaceutical Precautions
This drug should not be used after the expiry date falls due (see vial label for expiry date). Remaining amounts of Survanta should be disposed of.

Survanta must be protected from light and stored under refrigeration at 2 - 8 °C. DO NOT FREEZE. Any inadvertently frozen product should be discarded.

Survanta should be inspected visually for discolouration prior to administration. The colour of Survanta is off-white to light brown.

Legal Category: POM

Product Licence Number (UK): PL 41042/0003

Marketing Authorisation Holder: AbbVie Ltd.,
Maidenhead,
SL6 4UB.
UK

This leaflet was last revised in June 2020.