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 indicated for treatment of Respiratory Distress Syndrome (RDS) in newborn premature infants with a birth weight of 700 g or greater and who have had tube inserted and are on a mechanical ventilator to help them breathe.

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.

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 (usually within 8 hours of birth).

The dose of Survanta will be administered to your baby via a tube already in place in your baby's windpipe. Do not be concerned if your baby is disconnected from its ventilator while Survanta is being administered. To make sure that Survanta reaches all parts of your baby's lungs, the dose is split into smaller doses and your baby's position altered before each part of the dose is given.

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.

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

Malta
ADR Reporting
www.medicinesauthority.gov.mt/ adrportal

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.

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