PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SURVANTA 25 mg/ml sterile dispersion

Phospholipids (Beractant)

Sugar free

Read all of this leaflet carefully before SURVANTA is given

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your baby's doctor, pharmacist, nurse or other health care provider.

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.

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

Warnings and precautions

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.

Other medicines and SURVANTA

No interactions known.

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.

You will not be expected to give your baby SURVANTA. It will be given to your baby by a person who is qualified to do so.

If too much SURVANTA is used

Since a health care provider will administer SURVANTA, he / she will control the dosage. However, in the event of overdosage your baby's doctor will manage the overdosage.

If a SURVANTA dose is missed

Since a health care provider will administer SURVANTA, it is unlikely that the dose will be missed.

4. Possible side effects

SURVANTA can have side effects.

Not all side effects reported for SURVANTA are included in this leaflet. Should your baby's general health worsen or if your baby experiences any untoward effects while taking SURVANTA, please consult your baby's health care provider for advice.

The following side effects with SURVANTA are serious and will be managed by your baby's health care provider as necessary during dosing.

Frequent:

- 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.
- Cases of bleeding in the lungs.

Other Side effects:

Less frequent:

- 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 notice any side effects not mentioned in this leaflet, please inform your baby's doctor.

Reporting of side effects

If your baby gets side effects, talk to your baby's doctor or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SURVANTA.

5. How to store SURVANTA

Store all medicines out of reach of children.

- Store at or between 2 - 8 ºC (in a refrigerator) protected from light; however, before it is given to your baby it will be warmed to room temperature.
- Do not freeze. Any product that has been frozen by mistake should be thrown away.
- Do not use after the expiry date stated on the label / carton / bottle.
- Each vial of SURVANTA is for single use only. Used vials with medicine left in them should be thrown away.

- Unopened, unused vials of Survanta that have been warmed to room temperature may be returned to the refrigerator within 24 hours of warming and stored for future use. Survanta should not be warmed and re-refrigerated more than once.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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 – 0,4 mg/ml).
- The other ingredients are sodium chloride, sodium hydroxide, hydrochloric acid, palmitic acid, dipalmitoyl phosphatidylcholine, tripalmitin and water.

What SURVANTA looks like and contents of the pack

SURVANTA is an off-white to light brown liquid.

SURVANTA is supplied as a single glass vial containing 4 ml or 8 ml of liquid.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com