

SURVANTA®

beractant

CONSUMER MEDICINE INFORMATION

PLEASE READ THIS INFORMATION CAREFULLY

What is in this leaflet?

This leaflet provides a summary of information about SURVANTA. As it is a summary, it may not answer all your questions.

If anything is not clear or concerns you, please talk to your doctor or hospital pharmacist.

Keep this leaflet in case you have future questions about SURVANTA.

What is SURVANTA?

Medicine brand name:
SURVANTA®

Active ingredient name: beractant

What does it look like?

Glass vial containing a white-brown liquid

Ingredients

SURVANTA is a mixture of natural extracts from young cow's lungs, balanced with other surfactants. These include phospholipid 25 mg in each mL as well as neutral lipids, fatty acids, surfactant-associated proteins, also colfosceril palmitate, palmitic acid, tripalmitin, sodium chloride and water.

These are heat-sterilised.

How might SURVANTA help the baby?

SURVANTA is surfactant from young cows. It is used to replace the natural surfactant produced by babies' lungs which is missing in premature babies. Without this normal surfactant, babies are at great risk of developing problems with breathing. This is called Respiratory Distress Syndrome (or Hyaline Membrane Disease). Respiratory Distress Syndrome may cause death or serious complications.

SURVANTA may be given immediately after birth to prevent this problem. It may also be given to treat babies who have already developed Respiratory Distress Syndrome.

How does it work?

SURVANTA treatment makes it easier for your baby to breathe normally. SURVANTA increases the oxygen in the blood and protects the lungs. This may help reduce some of the complications of Respiratory Distress Syndrome.

Advice before using SURVANTA

All medicines have benefits and risks. Any potential risks must be weighed against the possible good SURVANTA will do. This is a decision you and your doctor will make.

SURVANTA must be given directly into the lungs.

SURVANTA will always be given by a specialist doctor in a hospital where there are appropriate facilities to care for a premature baby with breathing difficulties. Premature babies may need to be transferred from the hospital at which they were born to another hospital which has these facilities. This transfer of the baby should not affect the baby's response to SURVANTA if it is needed.

Some pregnant women who are known to be at risk of having a premature baby may receive treatment with other medicines called 'steroids' during the final weeks of pregnancy. Treatment with steroids will help to mature the baby's lungs to produce their own surfactant. This lessens the chance of the baby developing Respiratory Distress Syndrome (RDS) and needing treatment with SURVANTA.

Possible Unwanted Effects

- Premature babies are at risk of many complications.
- SURVANTA will only be useful to treat their breathing problems and will have no effect on other problems of prematurity.

Serious effects may therefore occur with or without therapy with SURVANTA.

- During the dosing of SURVANTA there may be short term slowing of the baby's heart and a reduction in the oxygen

level in the blood. The doctor will take all necessary steps to minimise this.

- There is an increased chance of hospital acquired infections.
- There may be an increased chance of bleeding in the lungs and brain and also apnoea (a transient failure to breathe).

Side effects aren't known to appear in the longer-term.

How is SURVANTA given?

This liquid is normally given to the baby by a small tube placed in the windpipe (trachea). The doctor will adjust the dose by the weight of the baby and the response to the medicine. The baby may be moved to different positions while the medicine is given to ensure the liquid is spread all through the lungs.

The doctor may wish to give additional doses of SURVANTA. This is normal if the baby does not respond fully to the medicine. SURVANTA is given within the first 48 hours of birth. The baby may continue to be ventilated during and after the dosing of SURVANTA.

Overdosage

- The amount of SURVANTA given is carefully determined by the doctor based on the baby's weight and any previous response to the medication.
- There have been no reports that show a baby to have been given too much SURVANTA. A small excess of SURVANTA is not thought to have major side effects. If a large overdose is given, the doctor can take appropriate steps to remove the medicine from the lungs.

How to store SURVANTA

SURVANTA should be stored in a refrigerator between 2° and 8°C.

For further information

For further information consult your doctor, or the hospital pharmacist will have more detailed information.

Registered in Australia as

SURVANTA -
AUST R 48406

SURVANTA is distributed by:

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Mascot NSW 2020
Australia

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