

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR INFANT'S MEDICINE

PrSURVANTA®

beractant, intratracheal suspension

Read this carefully before **SURVANTA** is given to your infant. This leaflet is a summary and will not tell you everything about this drug. Talk to your infant's health professional about your infant's medical condition and treatment and ask if there is any new information about **SURVANTA**.

Serious Warnings and Precautions

- **SURVANTA should only be given by health professionals experienced in treating premature infants with Respiratory Distress Syndrome.**
- **During and after receiving a dose, the infant will need to be monitored closely for any clinical changes.**

What is SURVANTA used for?

- SURVANTA is used to prevent and to treat Respiratory Distress Syndrome (also called Hyaline Membrane Disease) in premature infants.
- Respiratory Distress Syndrome is a breathing problem that affects premature infants whose lungs are not developed enough to make surfactant (a liquid that coats the inside of the lungs). Without surfactant, the lungs would not expand adequately and the infant might not be able to breathe in enough oxygen.

How does SURVANTA work?

When infants are born at full-term, their lungs contain an adequate amount of a substance called pulmonary surfactant that lowers the surface tension in the lung alveoli (the air sacs in the lungs where oxygen is exchanged) and prevents alveolar collapse during breathing. Premature infants may lack adequate amounts of pulmonary surfactant, which can result in Respiratory Distress Syndrome, a condition that makes breathing difficult.

SURVANTA is a natural bovine lung extract containing a mixture of substances which mimic the surface-tension lowering properties of natural lung surfactant. When administered into the trachea soon after birth or early in the premature infant's life, SURVANTA spreads throughout the lungs, allowing the alveoli to expand and remain open for proper oxygen exchange at the alveolar level.

What are the ingredients in SURVANTA?

SURVANTA is composed of different types of lipids (including phosphatidylcholine and other phospholipids, triglycerides, and free fatty acids), proteins, and sodium chloride.

SURVANTA comes in the following dosage forms:

SURVANTA is available in a 4 millilitre vial (100 milligrams strength) and an 8 millilitre vial (200 milligrams strength).

Do not use SURVANTA:

- There are no known contraindications to treatment with SURVANTA.

The following may interact with SURVANTA:

There are no known drug interactions with SURVANTA.

How SURVANTA is administered:

- SURVANTA is administered by or under the supervision of health professionals experienced in intubation, ventilator management, and general care of premature infants.

Usual dose:

The dose of SURVANTA is based on the infant's birth weight (100 mg/kg birth weight). Four doses of SURVANTA can be administered in the first 48 hours of life. Doses should be given no more frequently than every 6 hours.

Overdose:

Overdosage with SURVANTA has not been reported.

Missed Dose:

Not applicable.

What are the possible side effects from using SURVANTA?

These are not all the possible side effects your infant may have when receiving SURVANTA. If you have any concerns about side effects not listed here, talk to your infant's health professional for more information.

Most side effects occur during the dosing procedure.

Common side effects include:

- slow heartbeat
- decreased oxygen in the blood

Less common side effects include:

- paleness
- low blood pressure
- high blood pressure
- decreased carbon dioxide in the blood
- increased carbon dioxide in the blood
- temporary suspension of breathing

All of these side effects can be treated.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your infant's health professional if you need information about how side effects are managed. The Canada Vigilance Program does not provide medical advice.

Storage:

Vials are stored at 2 to 8°C, protected from light.

Keep out of reach and sight of children.

If you want more information about SURVANTA:

- Talk to your infant's health professional.
- Find the full product monograph that is prepared for health professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

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