PART III: CONSUMER INFORMATION
SURVANTA®
beractant, intratracheal suspension

This leaflet is Part III of a three-part "Product Monograph" published when SURVANTA was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about SURVANTA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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 babies 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 baby might not be able to breathe in enough oxygen.

What it does:
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 (RDS), 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.

When it should not be used:
There are no known contraindications to treatment with SURVANTA.

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

What dosage forms it comes in:
SURVANTA is available in a 4 mL vial (100 mg strength) and an 8 mL vial (200 mg strength).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- SURVANTA® should only be given by Health Professionals experienced in treating premature babies with Respiratory Distress Syndrome.
- During and after receiving a dose, the baby will need to be monitored closely for any clinical changes.

INTERACTIONS WITH THIS MEDICATION

There are no known drug interactions with SURVANTA.

PROPER USE OF THIS MEDICATION

SURVANTA is administered by or under the supervision of clinicians 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 six hours.

Overdose:
Overdosage with SURVANTA has not been reported.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most side effects occur during the dosing procedure. Common side effects include slow heartbeat and 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, and temporary suspension of breathing. All of these side effects can be treated.

HOW TO STORE IT

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

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- **Report on line at:** www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - Fax toll-free to 1-866-678-6789
  - Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 1908C
  Ottawa, ON K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at: www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

Note: Should you require information related to the management of side effects, contact your healthcare professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full product monograph, prepared for healthcare professionals can be found at www.abbvie.com or by contacting the sponsor, AbbVie Corporation, St-Laurent QC, H4S 1Z1 at 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last revised: January 05, 2018