

# Survanta<sup>®</sup>

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about your baby being given this medicine, speak to your doctor, nurse or pharmacist.

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### 1. Why is the doctor giving Survanta to my baby?

Survanta contains the active ingredient beractant. Survanta is used to replace the natural fluid in a baby's lungs which may be missing if the baby is premature.

For more information, see Section [1. Why is the doctor giving Survanta to my baby?](#) in the full CMI.

### 2. What should I know before my baby is given Survanta?

Talk to the doctor if you have any concerns about your baby being given Survanta.

For more information, see Section [2. What should I know before my baby is given Survanta?](#) in the full CMI.

### 3. What if my baby is receiving other medicines?

Survanta is used in newborn, premature infants; therefore, there is no information on whether it may interfere with other medicines, or that other medicines may interfere with it.

See Section [3. What if my baby is receiving other medicines?](#) in the full CMI.

### 4. How is Survanta given?

- Survanta is given directly into the windpipe.
- It is given by highly specialised doctors in hospitals with the facilities to care for premature babies.

More information can be found in Section [4. How is Survanta given?](#) in the full CMI.

### 5. What should I know about using Survanta?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Make sure you understand the risks and benefits of your baby being given Survanta</li><li>• Tell the baby's doctor if you have taken steroids in the last few weeks of your pregnancy.</li></ul>
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<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Survanta is given by highly specialised doctors and medical teams; therefore, there are no particular instructions for you or your baby during treatment.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Survanta is for premature babies; therefore, there is no information available regarding its use and driving or operating machinery.</li> </ul>
<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>• Survanta is used for premature babies; therefore, there is no information available regarding its use with alcohol.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• The hospital will store Survanta in a refrigerator at 2°C to 8°C.</li> <li>• You may see the medicine sitting out of the refrigerator before it is used. This allows it</li> </ul>

	to warm slightly before use.
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For more information, see Section [5. What should I know about using Survanta?](#) in the full CMI.

## **6. Are there any side effects?**

Slowing of the heart rate, brief episodes of failing to breathe, reduced oxygen levels in the blood, bleeding in the brain, bleeding in the lungs, blockage in the breathing tube, serious infection.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Survanta<sup>®</sup> (ser-van-tah)

**Active ingredients:** *beractant* (ber-ract-ant)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about Survanta. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about Survanta being used for your baby.**

**Where to find information in this leaflet:**

- [1. Why is the doctor giving Survanta to my baby?](#)
- [2. What should I know before my baby is given Survanta?](#)
- [3. What if my baby is receiving other medicines?](#)
- [4. How is Survanta given?](#)
- [5. What should I know about using Survanta?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why is the doctor giving Survanta to my baby?

**Survanta contains the active ingredient beractant.** Survanta is used to replace the natural fluid in a baby's lungs which may be missing if the baby is premature.

Without this natural fluid, babies are at great risk of developing problems with breathing.

## 2. What should I know before my baby is given Survanta?

### Warnings

#### Check with the doctor if you:

- have taken steroids during the last few weeks of your pregnancy
- have any questions or concerns about your baby being given Survanta
- are unsure about other complications your baby may have because he/she is premature.

During treatment, your baby may be at risk of developing certain side effects. It is important you understand these risks. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

You may have been prescribed steroids during the last few weeks of your pregnancy, if your doctor thought you were at risk of having a premature baby. This can help the baby's lungs develop. Make sure to tell your baby's doctor if you have taken steroids.

Talk to your doctor or nurse if you have any concerns or questions about breastfeeding your baby after he/she has received Survanta.

### **3. What if my baby is receiving other medicines?**

Survanta is used in newborn premature infants; therefore, there is no information on whether it may interfere with other medicines, or that other medicines may interfere with it.

### **4. How is Survanta given?**

#### **How much to give**

- The doctor will calculate how much Survanta to give your baby, based on your baby's weight.

#### **When to give Survanta**

- The doctor will determine when your baby should be given Survanta. This could be as early as within 15 minutes of birth and up to 48 hours after birth.
- Your baby's doctor will determine how frequently your baby receives Survanta.

#### **How to give Survanta**

- Survanta is given by highly specialised doctors and medical teams in hospitals with the facilities to care for premature babies.
- The doctor will give Survanta directly into the windpipe.

- Your baby may be moved into different positions while the medicine is given to help the liquid spread through the lungs.
- Your baby will continue to be monitored by the doctor and/or nurse to ensure your baby is given the correct amount of oxygen.

Please look for the QR code on the medicine pack. Scan this code for more information on Survanta.

## **5. What should I know about using Survanta?**

### **Things you should do**

Make sure you understand the risks and benefits of your baby receiving Survanta.

### **Things you should not do**

Survanta is given by specialised doctors: therefore, there are no particular directions for you or your baby during treatment.

### **Driving or using machines**

Survanta is for premature babies; therefore, there is no available information regarding its use and driving or operating machinery.

## **Drinking alcohol**

Survanta is used for premature babies; therefore, there is no available information regarding use with alcohol.

## **Looking after your medicine**

- The hospital will store Survanta in a refrigerator (at 2°C to 8°C).
- You may see the medicine sitting out of the refrigerator before it is used. This allows it to warm slightly before use and is usual.

## **Getting rid of any unwanted medicine**

Any unused medicine left in a vial will be thrown away by your baby's doctor or nurse.

## **6. Are there any side effects?**

All medicines can have side effects. If your baby experiences any side effects, the doctor and medical team may have to use medical equipment to treat him/her.

Premature babies are at risk of complications. Survanta is only used to treat breathing problems. It will have no effect on any other potential problems that may occur in a premature baby.

See the information below and, if you need to, ask your baby's doctor, nurse or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Breathing-related effects:</b></p> <ul style="list-style-type: none"> <li>• bubbling or rattling sounds in the lungs</li> <li>• moist breath sounds.</li> </ul>	<p><b>Your doctor and medical team will monitor for all side effects</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Heart-related effects:</b></p> <ul style="list-style-type: none"> <li>• slowing of the heart rate</li> </ul> <p><b>Breathing-related effects:</b></p> <ul style="list-style-type: none"> <li>• brief episodes of failing to breathe</li> <li>• reduced oxygen levels in the blood</li> <li>• blockage of the breathing tube</li> <li>• bleeding in the lungs</li> </ul>	<p><b>Your doctor and medical team will monitor for all side effects. Some may require their urgent attention.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Brain:</b></p> <ul style="list-style-type: none"> <li>• bleeding in the brain</li> </ul> <p><b>Body as a whole:</b></p> <ul style="list-style-type: none"> <li>• Infections, sometimes serious.</li> </ul>	

Other side effects not listed here may occur in some babies.

## Reporting side effects

After your baby has received medical attention for any side effects experienced, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only available with a doctor's prescription.

This medicine is only available in hospitals with the facilities to care for premature babies.

Survanta is a mixture of natural extracts from young cow's lungs, balanced with other surfactants.

## What Survanta contains

<b>Active ingredient (main ingredient)</b>	Beractant
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• colfosceril palmitate</li><li>• palmitic acid</li><li>• phosphatidyl choline</li><li>• sodium chloride</li><li>• tripalmitin</li><li>• water for injections.</li></ul>

## What Survanta looks like

Survanta is an off-white to light-brown liquid. It is supplied in glass vials for single use. (Aust R 48406).

## Who distributes Survanta?

AbbVie Pty Ltd

ABN 48156 384 262

241 O'Riordan Street

MASCOT NSW 2020

This leaflet was prepared in 29 October 2020.