

# Salbutamol Sandoz®

salbutamol sulphate inhalation ampoules

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Salbutamol Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may want to read it again.

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### What Salbutamol Sandoz is used for

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The name of your medicine is Salbutamol Sandoz. The medicine in your Salbutamol Sandoz is delivered through a device called a nebuliser. It contains the active ingredient salbutamol sulphate.

Salbutamol is inhaled into the lungs for the treatment of asthma. Asthma is a disease where the lining of the lungs become inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke, air-borne pollution and other irritants. Salbutamol opens up the air passages in people suffering from asthma, bronchitis and other breathing problems. It may also be used before exercise to keep your air passages open if you start to

wheeze or have difficulty breathing each time you exert yourself.

Salbutamol Sandoz belongs to a group of medicines called beta-2-agonists. These work rapidly to open up the air passages in your lungs.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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

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### Before you use Salbutamol Sandoz

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*When you must not use it*

**Do not use this medicine if you have an allergy to:**

- salbutamol, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other medicines used to treat breathing problems or any other beta-2-agonist medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start using this medicine, talk to your doctor.**

*Before you start to use it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- thyroid problems
- heart disease, irregular heart rhythm or angina
- high blood pressure
- diabetes
- glaucoma.

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell him/her before you start using Salbutamol Sandoz.**

*Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Salbutamol Sandoz may interfere with each other. These include:

- some medicines used to treat high blood pressure or heart conditions
- some hay fever, cough and cold preparations
- medicines used to treat depression or other mood disorders.

These medicines may be affected by Salbutamol Sandoz, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

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## How to use Salbutamol Sandoz

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

### *How much to use*

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly what dose and how often you should use this medicine. Your dose will depend on your condition, what it is being used for and other factors, such as your age, and whether or not you are taking other medicines at the same time.

**Follow the instructions they give you.**

If you use the wrong dose, Salbutamol Sandoz may not work as well and your problem may not improve.

The usual dose is 5mg for an adult and 2.5mg for a child over 4 years, given every four to six hours.

### *How to use it*

The content of Salbutamol Sandoz is inhaled through a nebuliser according to the manufacturer's instructions. The nebuliser changes the solution into a fine mist and delivers the medicine to your lungs when you inhale the mist through the mask.

**Step 1: Remove the strip of Salbutamol Sandoz from the carton and tear one ampoule from the strip. Open only one foil pack at a time, and use all 5 ampoules before opening the next foil pack.**

**Step 2: Never use an ampoule that has previously been opened. The ampoule may be opened by carefully holding it upright and twisting the top off.**

**Step 3: The content of the ampoule should be squeezed out into the nebuliser bowl.**

The nebuliser should be assembled and used as directed by your doctor. After using the nebuliser, discard any solution remaining in the nebuliser bowl. Follow the manufacturer's instructions on how to clean your nebuliser.

**Fresh solution must be used for each dose. After the full dose has been given, any solution remaining in the nebuliser must be thrown away. Nebulisers must be cleaned after use according to the manufacturer's instructions.**

### *If you miss a dose*

**Use your next dose at the normal time or earlier if you become wheezy or feel tight in your chest.**

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medication, ask your pharmacist for some hints.

### *If you use too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for**

**advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have used too much Salbutamol Sandoz. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you inhale too much salbutamol, you may experience some of the effects listed under Side effects below.

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## While you are using Salbutamol Sandoz

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### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Salbutamol Sandoz.**

**Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.**

**If you become pregnant while using this medicine, tell your doctor immediately.**

**Always follow your doctor's instructions carefully.**

**If you have an Asthma Action Plan that you have agreed on with your doctor, follow it closely at all times.**

If you find that the usual dose of Salbutamol Sandoz is not providing as much relief as before, or you need to use it more often, please contact your doctor so that your condition can be checked. This is important to ensure that your breathing problem is controlled properly.

**Continue using salbutamol for as long as your doctor tells you.**

**Visit your doctor regularly to check on your condition.**

### *Things you must not do*

**Do not use Salbutamol Sandoz to treat any other complaints unless your doctor tells you to.**

**Do not give this medication to anyone else, even if they have the same condition as you.**

**Do not stop using your medicine or lower the dose without checking with your doctor.**

**Do not take any other medicines for your breathing problems without checking with your doctor.**

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Salbutamol Sandoz.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- sore mouth, throat or tongue
- dry mouth
- coughing
- chest pain (due to heart problems such as angina)
- headache
- drowsiness
- feeling anxious, nervous, restless or upset
- difficulty sleeping
- dizziness
- sweating
- trembling or shaking
- aching or weak muscles
- cramps
- tingling or numbness in the hands or feet ('pins and needles')
- unpleasant taste in your mouth
- nausea or vomiting
- diarrhoea

- rash or itchy skin
- sore or puffy eyes.

These are the more common side effects of Salbutamol Sandoz. Mostly, these are mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- a feeling of warmth
- difficulty breathing or worsening of your breathing problems
- swelling or severe rash
- fast or irregular heart beat
- pounding heart beat.

The above list includes serious side effects that may require urgent medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After using Salbutamol Sandoz

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### Storage

Keep your medicine in the original container.

**Keep Salbutamol Sandoz ampoules in the foil pack until it is time to use them.**

If you take the ampoules out of the foil pack they may not keep well.

Once a foil pack has been opened, the ampoules must be used within 3 months.

**Discard any ampoules remaining after this time.**

Store below 25°C in a cool dry place, protected from light.

Do not store Salbutamol Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### What it looks like

Salbutamol Sandoz comes in 2 strengths:

- Salbutamol Sandoz 2.5mg/2.5mL
- Salbutamol Sandoz 5mg/2.5mL.

Each pack of Salbutamol Sandoz contains 30 (6x5) plastic ampoules.

Each ampoule contains 2.5mL of clear, colourless, preservative free solution.

**The ampoules are for inhalational use only.**

### Ingredients

Active ingredient:

- Salbutamol Sandoz 2.5mg/2.5mL - 2.5mg salbutamol in 2.5mL of solution.
- Salbutamol Sandoz 5mg/2.5mL - 5mg salbutamol in 2.5mL of solution.

Inactive ingredients:

- sodium chloride
- water.

The solution is sterile and preservative free.

*Supplier*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park NSW 2113  
Australia  
Tel: 1800 634 500

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**Australian Register Numbers**

Salbutamol Sandoz 2.5mg/2.5mL  
inhalation ampoules: AUST R  
140694

Salbutamol Sandoz 5mg/2.5mL  
inhalation ampoules: AUST R  
140695