

**PART III: CONSUMER INFORMATION**

**PrSandoz Salbutamol (5 mg/mL)**  
Salbutamol sulphate inhalation solution

**This leaflet is part III of a three-part "Product Monograph" for Sandoz Salbutamol and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Sandoz Salbutamol. Please read this insert carefully before you start your medicine.**

**Contact your doctor or pharmacist if you have any questions about the drug. This medicine is for you only. Only your doctor can prescribe it for you. Never give it to someone else. It may harm them even if his/her symptoms are the same as yours.**

**ABOUT THIS MEDICATION****What the medication is used for:**

Sandoz Salbutamol is used in Adults and Children 5 years or older. It treats severe, worsening breathing problems (bronchospasm) associated with:

- Chronic bronchitis
- Bronchial Asthma

Bronchospasm is a sudden worsening of shortness of breath and wheezing.

The safety and effectiveness of salbutamol in children below the age of 5 years are not known.

**What it does:**

Salbutamol is one of a group of medicines called bronchodilators. Salbutamol relaxes the muscles in the walls of the small air passages in the lungs. This helps to open up the airways and so helps to relieve chest tightness, wheezing and cough so that you can breathe more easily.

**When it should not be used:**

Do not use Sandoz Salbutamol if:

- if you are allergic to it or any of the components of its formulation
- if your heart beats faster than normal
- for the treatment of preterm labour or miscarriage

**What the medicinal ingredient is:**

Salbutamol Sulphate

**What the nonmedicinal ingredients are:**

Benzalkonium Chloride (as a preservative), Sulphuric acid (to adjust pH) and Water for Injection

**What dosage forms it comes in:**

Respirator Solution contains salbutamol 5 mg per mL.

**WARNINGS AND PRECAUTIONS**

BEFORE you use Sandoz Salbutamol talk to your doctor or pharmacist if:

- You have ever had to stop taking another medicine for this illness because you were allergic to it or because it caused problems.
- You are having treatment for a thyroid condition.
- You are having treatment for high blood pressure or a heart problem.
- You have diabetes.
- You have a past history of seizures.
- You have low levels of potassium in your blood (hypokalemia), especially if you are taking:
  - Drugs known as xanthine derivatives (such as theophylline)
  - Steroids to treat asthma
  - Water pills (diuretics)
- You are pregnant or intend to become pregnant. Taking Sandoz Salbutamol during pregnancy may cause harm to your baby. Your doctor will consider the benefit to you and the risk to your baby of taking Sandoz Salbutamol while you're pregnant.
- You are breastfeeding. It is not known if Sandoz Salbutamol passes into breast milk.

Rare cases of lactic acidosis (too much lactic acid in the blood) have been reported in patients receiving high doses of salbutamol sulphate. If you suffer symptoms (see Serious Side Effects Table), contact your doctor immediately.

If the relief of wheezing or chest tightness is not as good as usual, or the effect lasts for less than three hours, tell your doctor as soon as possible. If you notice a sudden worsening of your shortness of breath and wheeze shortly after taking your medicine, tell your doctor as soon as possible. It may be that your chest condition is worsening and you may need to add another type of medicine to your treatment.

You should always carry other asthma medication with you to use immediately in case you experience an asthma attack.

**Effects on Children**

Children may experience:

- Changes in sleep patterns
- Changes in behaviour such as restlessness, excitability (hyperactivity)
- Seeing or hearing things that are not there

**INTERACTIONS WITH THIS MEDICATION**

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Sandoz Salbutamol:

- Anti-depressants
- Allergy medication
- Blood pressure-lowering drugs, including propranolol
- Diuretics ("water pills")
- Bronchodilators used to open the airway (such as other asthma medication)

- Epinephrine
- Digoxin, a heart medication

### PROPER USE OF THIS MEDICATION

Sandoz Salbutamol **should only be inhaled** from a nebulizer. It must not be injected or swallowed.

Do not let the Sandoz Salbutamol or the mist produced by the nebulizer, get in your eyes.

At home, Sandoz Salbutamol should be diluted immediately before use.

Use your nebulizer in a well ventilated room. Some of the mist will be released into the air and may be breathed in by others.

Use Sandoz Salbutamol only as directed by your doctor. During administration your doctor may want to monitor your blood.

The action of Sandoz Salbutamol may last for up to 6 hours and should last at least 4 hours. **Call your doctor immediately if the effect lasts for less than 3 hours or if you suddenly get worse shortness of breath and you wheeze after using your Sandoz Salbutamol.** Do not increase the dose or how often you take your medicine without informing your doctor, **as this may make you feel worse.** If symptoms get worse, tell your doctor as soon as possible.

When using Sandoz Salbutamol, other medicines (including asthma medicines) should only be used when prescribed by your doctor.

Please follow these instructions carefully. It is important that you use your Sandoz Salbutamol properly to ensure that you receive the maximum benefit from your medicine.

Sandoz Salbutamol contains salbutamol 5 mg per mL. For proper administration, 1 mL of the solution is usually diluted with 2 mL to 5 mL of sterile normal saline.

**If you regularly use Sandoz Salbutamol two or more times a day, and take no other asthma medication, you should talk to your doctor who may want to reassess your treatment plan.**

In the home, Sandoz Salbutamol may be diluted immediately before use. Pre-diluted solutions of Sandoz Salbutamol should not be stored.

#### Usual dose:

**Adults and Adolescents 13 years and older:** 0.5 mL to 1.0 mL (2.5 mg to 5 mg of salbutamol). Dilute in 2 mL to 5 mL or more of sterile normal saline. Treatment may be repeated 4 times a day if necessary.

**Children (5-12 years):** 0.25 mL to 0.5 mL (1.25 mg to 2.5 mg of salbutamol). Dilute in 2 mL to 5 mL or more of sterile normal saline. Patients who have not improved on this dose may need 1 mL (5 mg salbutamol). Treatment may be repeated four times a day if necessary.

#### How to use Sandoz Salbutamol:

It is important that you use Sandoz Salbutamol properly. This will ensure that you receive the maximum benefit from your medicine. Make sure you know how, when and how much solution you should use. Follow your doctor's instructions carefully. If you are not sure, ask your doctor.

1. When preparing the solution for inhalation, use a graduated syringe to draw up Sandoz Salbutamol from the bottle at the dose directed by your physician. **Note:** close the Sandoz Salbutamol bottle as soon as the solution is drawn into the syringe. Keep the bottle closed at all times and do not open it unnecessarily. Discard unused, diluted Sandoz Salbutamol after each use.
2. Inject the solution into the nebulizer through the appropriate opening.
3. Draw into the syringe the amount of diluting fluid (sterile normal saline) directed by your physician and add it to the nebulizer.  
1 mL of Sandoz Salbutamol is usually diluted with 2 mL to 5 mL of sterile normal saline.
4. Gently shake the nebulizer and connect it with the mouthpiece or face mask.
5. Connect the apparatus to the air pump or oxygen and start the treatment.
6. Breathe calmly and evenly as much as possible until no more mist is formed in the nebulizing chamber. At this point, treatment is finished.
7. Any unused solution in the nebulizer should be discarded.

**Children** – Sandoz Salbutamol should be used under the supervision of an adult who understands the proper use of the nebulizer or respirator, and only as prescribed by the doctor.

#### Care of the Sandoz Salbutamol and Nebulizer

**Cleaning:** after each use, clean the syringe and nebulizer as instructed in the nebulizer manual or as follows:

#### **To clean the nebulizer:**

1. Disassemble the supply tube and the nebulizer.
2. Wash in warm detergent solution. Rinse the tube with water.
3. To wash the suction tubes:
  - a. Place 3 mL of detergent solution in the vial, assemble the unit and operate for 2 minutes.
  - b. Disassemble and rinse the vial with warm water, place 3 mL of warm water in the vial, assemble the unit and operate for 2 minutes.
  - c. Disassemble and rinse with warm water.
4. To dry the external passage:
  - a. Connect the nebulizer tube to the pump with the supply tube.
  - b. Turn the pump and blow air through for 1 minute.
5. If there is evidence of clogging, clean the openings and tube connectors with the detergent, then rinse with water.
6. Reassemble.

**To clean the syringe:**

1. Clean the syringe and needle several times in detergent solution by alternatively drawing up and expelling the detergent solution.
2. Repeat using a rinse of warm water.
3. Dry the needle by drawing air into the syringe several times, by moving the plunger back and forth in the barrel of the syringe. Remove the needle.
4. Remove the plunger from the syringe, allow to air dry.
5. Keep unassembled needle, plunger and barrel of syringe wrapped in clean tissue, stored in a refrigerator along with the Sandoz Salbutamol bottle.

Follow all the instructions of the nebulizer and air pump manufacturers for the proper care and maintenance of the apparatus.

**Overdose:**

If you accidentally take a **larger dose than prescribed**, you are more likely to get side effects like a faster heartbeat, headaches and feeling shaky or restless. These effects usually wear off within a few hours, but you should tell your doctor as soon as possible.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Take this leaflet or your medication with you so that the hospital or poison control centre will know what you have taken.

**Missed Dose:**

If you forget to inhale a dose do not worry: inhale the next dose at the time you would normally take it or inhale a dose sooner than when it is due if you become wheezy.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include:

Effects on heart

- Faster heart beat than usual
- Palpitations
- Hypertension

Effects on nervous system

- Headache
- Feeling a little shaky
- Feeling anxious or irritable
- Feeling tired or weak
- Trouble sleeping (insomnia)
- Hyperactivity in children
- Dizziness, vertigo
- Drowsiness

Effects on muscles and joints

- Muscle cramps

Other Effects

- Nausea and vomiting
- Chest pain or discomfort
- Flushing
- Difficulty urinating
- Unusual taste in your mouth
- Dry or irritated throat

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Rare	<b>Bronchospasm:</b> Increased wheezing or tightness in the chest or difficulty in breathing.			✓
	<b>Allergic reactions: (Hypersensitivity)</b> Swelling of the eyelids, face, lips, tongue or throat, accompanied by difficulty in breathing, speaking or swallowing (signs of angioedema). Skin rash, skin eruption or other effect on the skin or eyes, itching or fever. Fainting when the blood pressure is too low (sign of hypotension).			✓
	Deep and rapid breathing, vomiting, abdominal pain, weight loss, fatigue, malaise (sign of lactic acidosis- too much lactic acid in the blood)			✓
Rare	Low level of potassium in your blood (hypokalemia)	✓		
	<b>Hallucinations in Children:</b> see or hear things that are not there		✓	

*This is not a complete list of side effects. If you have any unexpected effects after receiving Sandoz Salbutamol, contact your doctor or pharmacist.*

**HOW TO STORE IT**

**Keep your Sandoz Salbutamol in a safe place where children cannot reach them. Your medicines may harm children.**

Store between 15°C and 25°C. Protect from light.

One month after opening the bottle, throw away any solution which is left over.

**REPORTING SUSPECTED SIDE EFFECTS**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at MedEffect™  
([www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect));
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect™  
([www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)).

***NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.***

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Sandoz Canada Inc. at 1-800-361-3062.

or by written request at:  
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Or by e-mail at :  
[medinfo@sandoz.com](mailto:medinfo@sandoz.com)

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