

Package leaflet: Information for the patient

Salbutamol Sandoz 100 micrograms/dose pressurised inhalation, suspension

salbutamol (as sulphate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Salbutamol Sandoz is and what it is used for
2. What you need to know before you use Salbutamol Sandoz
3. How to use Salbutamol Sandoz
4. Possible side effects
5. How to store Salbutamol Sandoz
6. Contents of the pack and other information

1. What Salbutamol Sandoz is and what it is used for

Salbutamol Sandoz is used to **treat** breathing difficulties caused by the following diseases:

- **asthma**
- **chronic obstructive pulmonary disease (COPD)** including
 - chronic bronchitis
 - emphysema

Salbutamol Sandoz is additionally used to **prevent asthma symptoms** caused by:

- exercise or
- triggers, such as house dust, pollen, cats, dogs and cigarette smoke

Salbutamol Sandoz expands the airways, allowing the air to flow more freely. Salbutamol Sandoz should primarily be used to relieve symptoms rather than as a regular treatment.

Salbutamol Sandoz is indicated for adults, adolescent and children from 4 to 11 years.

2. What you need to know before you use Salbutamol Sandoz

Do not use Salbutamol Sandoz

- if you are **allergic to salbutamol** or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Salbutamol Sandoz if any of the following conditions apply to you:

- a history of heart disease, such as irregular or fast heart rhythm or angina

- severe and untreated high blood pressure
- an overactive thyroid gland
- too little potassium in the blood
- enlarged artery (aneurysm)
- diabetes (extra checks of blood glucose levels are recommended when beginning treatment with Salbutamol Sandoz)
- tumour of the adrenal medulla (pheochromocytoma). The adrenal medulla are two glands situated above the kidneys.

Other medicines and Salbutamol Sandoz

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

The following medicines can influence or be influenced by Salbutamol Sandoz:

- **heart and vascular medicines** which can narrow the airways and containing active substances ending in “-ol” such as propranolol (betablockers)
This may cause spasms in the lung airways.
- certain **medicines to treat depression:**
 - monoamine oxidase inhibitors (e.g. moclobemide)
 - tricyclic antidepressants, such as amitriptyline
- **anaesthetics** (agent that induces partial or total loss of sensation), such as halothane
- **medicines against irregular heartbeat**, such as Digoxin
- **xanthin derivatives** (used to help breathing), such as theophylline
- **steroids** (group of hormones), such as cortisone
- **diuretics** (water tablets), such as furosemide

Pregnancy and breast-feeding

Limited knowledge exists regarding use during pregnancy, but there is also a risk for the unborn child, if your asthma is untreated during pregnancy. Therefore, you should use Salbutamol Sandoz only if your doctor indicates it is clearly necessary. Do not change the dose by yourself, but always use it according to your doctor's recommendation.

It is unknown, whether salbutamol passes into the mother's milk. Therefore, only use Salbutamol Sandoz if your doctor indicates it is clearly necessary.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Therefore, do not drive or operate machines until you know how the medicine is affecting you.

Salbutamol Sandoz contains ethanol

This medicine contains 0.72 mg of alcohol (ethanol) in each metered dose which is equivalent to 2.1% w/w. The amount in metered dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Salbutamol Sandoz

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

[Nationally completed name] should be used as required rather than regularly.

If your asthma is active (for example you have frequent symptoms or flare ups, such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability), you should tell your doctor right away who may start or increase a medicine to control your asthma such as an inhaled corticosteroid.

Tell your doctor as soon as possible if your medicine does not seem to be working as well as usual (for example you need higher doses to relieve your breathing problems or your inhaler fails to give relief for at least 3 hours) as your asthma may be getting worse and you may need a different medicine.

If you use [Nationally completed name] more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

The recommended dose is:

Adults and adolescents aged 12 years and over

- Relief of attacks:
1-2 inhalations as required.
- Prevent symptoms caused by exercise or triggers:
2 inhalations 10-15 minutes beforehand
- Maximum dose: 8 inhalations per day.

Children (4-11 years)

- Relief of attacks:
1 inhalation as required. The dose may be increased to two inhalations if required.
- Prevent symptoms caused by exercise or triggers:
1 inhalation, or 2 if necessary 10-15 minutes beforehand
- Maximum dose: 8 inhalations per day.

Children below 4 years of age

No recommendations can be made for dose since the effect has not yet been determined.

Contact your doctor if the treatment is not effective enough or if you need more doses per day than usual. Never increase your dose or change the duration of use without your doctor's approval.

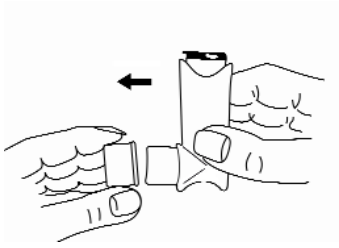
Inhaler test before use:

Check that the inhaler is functioning, if you use a new inhaler or if it has not been used for 7 days or more. Remove the protective cap, shake the inhaler and spray twice into the air.

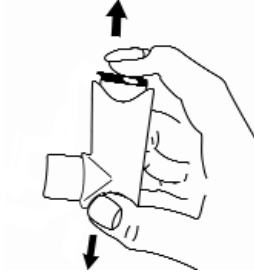
Instructions for use:

Inhale sitting or standing, wherever possible.

- 1 Remove the protective cap. Check inside and outside to make sure that the mouthpiece is clean.



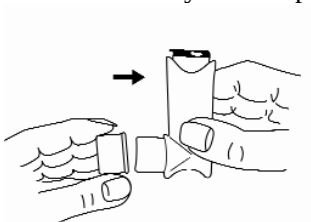
- 2 Shake the inhaler thoroughly for a couple of seconds before use.



- 3 Hold the inhaler upright with the bottom of the container upwards, put your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable, but do not breathe into the mouthpiece.
- 4 Place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.
- 5 Just after starting to breathe in through your mouth press down on the top of the inhaler to release a puff while still breathing in steadily and deeply.



- 6 Hold your breath for 5-10 seconds. Take the inhaler from your mouth and your finger from the top of the inhaler.
- 7 If you need another puff keep the inhaler upright and wait about half a minute before repeating steps 2 to 6.
- 8 After use always replace the mouthpiece cover to keep out dust and fluff. Replace mouthpiece cover firmly and snap into position.



Some people find it difficult to release a puff of medicine just after they start to breathe in. In this case, as well as for children, the Vortex® or AeroChamber® Plus spacer device can be used. Please refer to the product information of the spacer device for its correct handling.

Cleaning

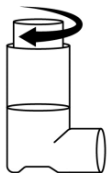
If the inhaler does block up, clean it as follows; to prevent the inhaler blocking up, this step **must** be performed at least **once a week**.

Preferably, this cleaning step should be performed when you retire to bed.

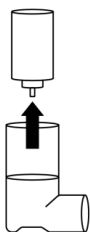
- 1 Pull the metal canister out of the plastic case of the inhaler and remove the mouthpiece cover.
- 2 Rinse the plastic case and the mouthpiece cover in lukewarm water. Do not attempt to remove any build up of medicine around the mouthpiece with a sharp object, such as a pin. A mild detergent may be added to the water, then rinse thoroughly with clean water before drying. Do not put the metal canister into water.
- 3 Leave the plastic case and the mouthpiece cover to dry in a warm place. Avoid excessive heat.
- 4 Replace the canister and mouthpiece cover.

If the inhaler needs to be used immediately, following steps can be conducted:

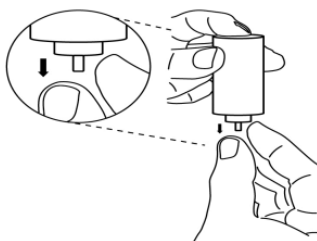
1. Hold the inhaler upright with the bottom of the canister upwards. Turn the metal canister inside the plastic case clockwise by one full turn.



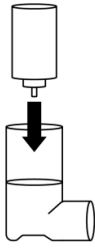
2. Pull the metal canister out of the plastic case of the inhaler.



- 3 Hold the bottom of the canister upwards. With two fingers of the other hand gently move the small white plastic stem by pulling it down carefully. Do not use any tools like e. g. tongs.



4. Replace the canister into the plastic case.

**Inhaler content:**

Shake the spray to check the remaining amount of medicine in your inhaler. Do not use Salbutamol Sandoz if you do not detect any liquid in the inhaler while shaking.

Cold temperature use:

If the inhaler has been stored beneath 0 °C, warm it in your hands for 2 minutes, shake it and spray into the air twice before use.

If you use more Salbutamol Sandoz than you should

In this case always contact your doctor or hospital.

Typical symptoms of overdose are:

- trembling
- headache
- rapid heart beat
- nausea or vomiting
- inability to keep still
- irritability, excitation
- seizures
- sleepiness

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Salbutamol Sandoz and contact your doctor immediately if you develop any of the following very rare side effects:

- allergic reaction symptoms such as
 - swelling of the face, tongue or throat
 - difficulties in swallowing
 - signs which resemble nettle sting
 - breathing difficulties
-
- breathing immediately becomes worse after taking Salbutamol Sandoz, although Salbutamol Sandoz reduces symptoms. This may mean your disease is worsening and other treatment is urgently needed.

Contact your doctor as soon as possible if you:

- experience chest pain (symptom of angina) whilst receiving treatment with Salbutamol Sandoz. Do not stop using this medicine unless told to do so. It is not known how often this happens.

Side effects can occur with the following frequencies:

Common, may affect up to 1 in 10 people:

- trembling

- increased heart rate
- headache
- muscle cramps

Uncommon, may affect up to 1 in 100 people:

- rapid heartbeat
- irritation in mouth and throat

Rare, may affect up to 1 in 1,000 people:

- reduced potassium level in the blood
- flushing

Very rare, may affect up to 1 in 10,000 people:

- allergic reactions, See “Stop using Salbutamol Sandoz and contact your doctor”
- collapse
- itchy rash
- decreased blood pressure
- increased activity
- sleep disturbances
- irregular heart rhythm
- worsening of breathing immediately after taking your inhaler

Frequency not known (the frequency cannot be estimated from the available data):

- lactic acidosis (a condition with increased lactic acid production in the body)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salbutamol Sandoz

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store the inhaler lying flat or in an inverted position, with the mouthpiece pointing downward.

The canister contains a pressurized liquid. Do not expose to temperatures higher than 50° C, even for a short period of time. Protect from heat, direct sunlight and frost! Do not pierce or burn the canister, even when empty.

Do not throw away any medicines via wastewater [or household waste](#). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What SalbutamolSandoz contains

- The active substance is salbutamol.
Each metered dose contains 100 micrograms salbutamol (as sulphate).
Each delivered dose through the mouthpiece is 90 micrograms of salbutamol (as sulphate).
- The other ingredients are norflurane (HFA 134a), anhydrous ethanol, oleic acid
- This medicine contains fluorinated greenhouse gases.
- Each inhaler contains 8.50 g of HFA-134a corresponding to 0.0122 tonne CO₂ equivalent (global warming potential GWP = 1430).

What Salbutamol Sandoz looks like and contents of the pack

This medicine is a white pressurised inhalation suspension in aluminium containers with metering valve and plastic applicator.

Packs containing

200 metered actuations (equivalent to 8.5 g pressurised inhalation, suspension)

2 x 200 metered actuations (equivalent to 2 x 8.5 g pressurised inhalation, suspension)

3 x 200 metered actuations (equivalent to 3 x 8.5 g pressurised inhalation, suspension)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last revised in 2025-01-24.

[To be completed nationally]