

Salbutamol Sandoz 100 microgram/dosis CFK-vrij, aërosol, suspensie salbutamol (als salbutamol sulfaat)

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT SALBUTAMOL IS AND WHAT IT IS USED FOR

This inhaler contains salbutamol which belongs to a group of medicines known as broncholidators. These medicines help the airways in your lungs to stay open, which makes it easier for air to get in and out. They also help to relieve chest tightness, wheezing and cough.

Your inhaler is used in adults, adolescents and children aged 4 to 11 years:

- to **treat breathing problems** in people with asthma and similar conditions (e.g. chronic bronchitis and emphysema).
- to prevent asthma following exercise or other “triggers” (common triggers include house dust, pollen, cats, dogs and cigarette smoke).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SALBUTAMOL

Do not use Salbutamol:

- 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 this medicine if you:

- have a history of **heart disease**, such as irregular or fast heart rhythm, myocardial infarction or angina (chest pain)
- have severe and untreated **high blood pressure**
- have an **overactive thyroid** gland
- have **low potassium** levels in your blood
- have an **enlarged artery** (aneurysm)
- have **diabetes** (extra checks of blood glucose levels are recommended when beginning treatment with this medicine)

- have a **tumour** of the adrenal medulla (pheochromocytoma). The adrenal medulla are two glands situated above the kidneys
- have had to stop using this or another medicine for the treatment of this disease due to **allergies** or some other problem
- are taking **diuretics**, sometimes used to treat high blood pressure or heart problems.

Reports of dental caries have been reported with the use of salbutamol. It is recommended with especially in children, pay attention to good oral hygiene and regular dental check-ups.

Other medicines and Salbutamol

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, especially the following:

- beta-blockers such as **propranolol**
- certain **medicines to treat depression e.g.** monoamine oxidase inhibitors (e.g. moclobemide), tricyclic antidepressants (e.g. amitriptyline)
- **anaesthetics** (e.g. halothane)
- **medicines to treat irregular heartbeat** (e.g. digoxin)
- **xanthines** (used to help breathing), such as theophylline
- **steroids** (e.g. cortisone)
- **diuretics** (water tablets), such as furosemide

Pregnancy and breast-feeding

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

This medicine can be used during pregnancy when considered necessary by your doctor. Do not change the dose yourself, always follow your doctor's instructions.

Information on whether this medicine passes into breast milk is not sufficient to assess the risk to the child. Therefore, only use this medicine if your doctor has recommended to.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

3. HOW TO USE SALBUTAMOL

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

The recommended dose is:

Adults and adolescents aged 12 years and over

Relief of asthma attacks:

1-2 inhalations (100 – 200 micrograms) as required.

Prevent asthma symptoms caused by exercise or triggers:

2 inhalations (200 micrograms) before exercise, taken 10-15 minutes before challenge.

The maximum dose is 8 inhalations (800 micrograms) per day.

Children (4 - 11 years)

Relief of asthma attacks:

1 inhalation (100 micrograms). The dose may be increased to two inhalations if required.

Prevent asthma symptoms caused by exercise or triggers:

1 or 2 inhalations (100 – 200 micrograms) before exercise.

To prevent allergen- or exercise-induced symptoms, one inhalation, or two if necessary, should be taken 10-15 minutes before challenge.

The recommended dosage for long term use is:

Adults, children aged 12 years and over: Up to two inhalations (200 micrograms) four times a day.

Generally, the maximum dose to be taken in 24 hours is 8 inhalations (800 micrograms).

Children <4 years can benefit from the use of this medicinal product by using an inhalation chamber for paediatric patients fitted with a mask (such as Babyhaler). Please consult your doctor.

Contact your doctor if the treatment is not effective enough or if you need more doses per day than usual.

Salbutamol 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 Salbutamol 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.

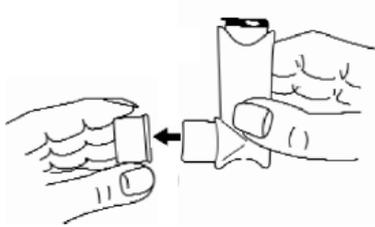
Inhaler check:

Before using the inhaler for the first time, remove the mouthpiece protector, shake the inhaler thoroughly and release two sprays into the air to ensure proper function of the inhaler. If the inhaler has not been used for 5 or more days, shake it thoroughly and release two sprays into the air to make sure it works.

Instructions for use:

The inhalation should be performed sitting or standing, wherever possible.

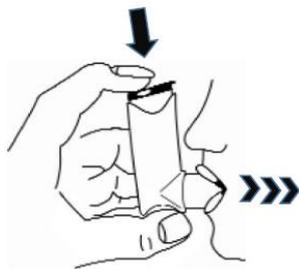
1. Remove the protective cap.
2. Check for foreign particles inside and outside the inhaler to make sure that the mouthpiece is clean.



3. Shake the inhaler well for a couple of seconds before use to make sure that the contents of the inhaler are mixed properly.

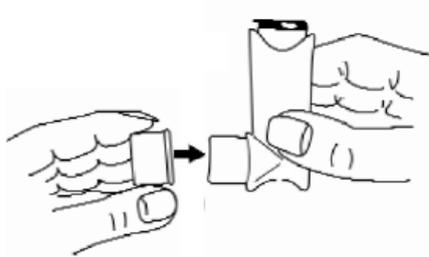


4. Hold the inhaler upright with the bottom of the container upwards, put your thumb on the base, below the mouthpiece. Breathe out as much air as reasonably possible, but do not breathe into the mouthpiece.
5. Place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.
6. 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.



7. Hold your breath, take the inhaler out of your mouth and remove your finger from the top of the inhaler. Continue to hold your breath as much as reasonably possible.
8. If you need another puff, hold the inhaler upright and wait about half a minute before repeating steps 3 to 7.

9. After use always replace the mouthpiece cover to keep dust and foreign particles out of the mouthpiece. Replace mouthpiece cover firmly and snap into position.



Patients who find it difficult to coordinate the handling of the inhaler with inhalation can use a *Volumatic* type inhalation chamber (adults and children over 5 years) or *Babyhaler* (children 1 to 5 years).

Young children may need help with an adult handling the inhaler for them. Encourage the child to breathe out and actuate the inhaler just after the child begins to breathe in. Practice the technique together.

Cleaning the inhaler

To prevent the inhaler blocking up or if it does block up, clean it at least once a week, as follows:

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.

Inhaler content:

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

Cold temperature use:

If the inhaler has been stored below 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 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
- chest pain
- psychotic reactions

If you forget to use Salbutamol

- if you forget a dose, take the next dose as planned or if your breathing or wheezing gets worse.
- do not take a double dose to make up for a forgotten dose.

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 everyone gets them.

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

- **allergic reaction**, with symptoms such as swelling of the face, tongue or throat, difficulties in swallowing, skin rash or hives (nettle rash), breathing difficulties
- **breathing immediately becomes worse** after taking this medicine. 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).

Do not stop using this medicine unless told to do so. It is not known how often this happens.

Other side effects:

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 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, pharmacist or nurse. 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

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

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

This medicinal product does not require any special storage conditions.

Immediately after use, place the cap back on the mouthpiece and press firmly into position. Do not force the cap.

Store the inhaler 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 medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Salbutamol contains:

The active substance is 100 micrograms of salbutamol (as salbutamol sulfate) per metered dose (ex-valve).

Target delivered dose is 80 micrograms of salbutamol (as salbutamol sulfate).

The other ingredients are propellant gas: norflurane (tetrafluoroethane or HFC 134a).

This medicine contains fluorinated greenhouse gases.

Each inhaler contains 17.54 g of norflurane (HFC-134a) corresponding to 0.025 tonnes CO₂ equivalent (global warming potential GWP = 1430).

What Salbutamol looks like and contents of the pack

This medicine is a white to off white pressurised inhalation suspension in aluminium canister with metering valve and fitted in white colour polypropylene homopolymer actuator with blue colour dust cap.

Pack size(s):

- 1 canister x 200 metered actuations
- 2 canisters x 200 metered actuations
- 3 canisters x 200 metered actuations

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:

Sandoz B.V.
Hospitaaldreef 29
1315 RC Almere
Nederland

Fabrikant:

Glenmark Pharmaceuticals s.r.o.
Fibichova 143, 566 17
Vysoké Mýto
Tsjechië

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland:	SalbuHEXAL Dosieraerosol
Nederland:	Salbutamol Sandoz 100 microgram/dosis CFK-vrij, aërosol, suspensie

Deze bijsluiter is voor het laatst goedgekeurd in november 2025.