**Salbutamol Aerosol 100 micrograms/dose, aerosol, suspension**

Salbutamol (as sulfate)

**what is salbutamol and what is it used for?**

Salbutamol is used for the treatment of respiratory problems resulting from the following diseases:

* Asthma
* Chronic obstructive pulmonary disease (COPD), including
* Chronic bronchitis
* Emphysema
* Salbutamol is also used to prevent asthma symptoms caused by:
* Physical activity or
* Triggering factors such as house dust, pollen, cats, dogs, and cigarette smoke

This medicine widens the airways, making it easier for air to flow through. It should primarily be used to relieve symptoms and not as the main treatment.

Salbutamol is intended for use in adults, adolescents, and children aged 4 to 11 years.

**When should you not use this medicine or use it with extra caution?**

**When should you not use this medicine?**

* You are allergic to any of the substances in this medicine.
* When should you use this medicine with extra caution? (Follow the instructions of your doctor or pharmacist).
* Contact your doctor or pharmacist before using this medicine if you have any of the following conditions:
* You have had heart problems in the past, such as an irregular heartbeat, rapid heartbeat, or chest pain (angina).
* Severe, untreated high blood pressure.
* An overactive thyroid gland.
* Low potassium levels in the blood.
* A dilated artery (aneurysm).
* Diabetes (it is recommended to monitor blood sugar levels carefully when starting treatment with Salbutamol).
* Tumor of the adrenal medulla (pheochromocytoma). The adrenal glands are two glands located above the kidneys.

**Are you using any other medications?**If you are using other medications alongside Salbutamol, have used them recently, or plan to use other medications in the near future, inform your doctor or pharmacist.

**The following medications can affect Salbutamol or be affected by it:**Medications for heart and blood vessels that can narrow the airways and contain active ingredients ending in '-ol,' such as propranolol (beta-blockers). These can cause constriction of the airways.

* Certain medications for the treatment of depression:
* Monoamine oxidase inhibitors (e.g., moclobemide).
* Tricyclic antidepressants, such as amitriptyline.
* Anesthetics (agents that cause partial or complete loss of consciousness), such as halothane.
* Medications for irregular heartbeat, such as digoxine.
* Xanthine derivatives (used to assist with breathing), such as theophylline.
* Steroids (a group of hormones), such as cortisone.
* Diuretics (water pills), such as furosemide.

**Pregnancy and breastfeeding:**There is limited knowledge about the use of Salbutamol during pregnancy, but there is also a risk to the unborn child if asthma is not treated during pregnancy. Therefore, you should only use this medicine if your doctor indicates that it is strictly necessary. Do not change the dosage on your own, but always take the medicine as prescribed by your doctor.

It is not known whether salbutamol passes into breast milk. Therefore, you should only use this medicine if your doctor indicates that it is strictly necessary.

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Contact your doctor or pharmacist before using this medication.

**Driving and using machinery:** No research has been conducted on the effects on driving ability and the ability to operate machinery. Therefore, you should not drive or operate machinery until you know how you react to this medicine.

**How to use this medicine?**Always use this medicine exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct use, contact your doctor or pharmacist. The usual dosage is as follows:

**Adults and adolescents aged 12 years and older:** Relief of attacks: 1-2 inhalations as needed.
Prevention of symptoms triggered by physical activity or other factors: 2 inhalations 10-15 minutes before exercise or exposure to triggers.

**Maximum dosage: 8 inhalations per day.**

**Children (aged 4 - 11 years):** Relief of attacks: 1 inhalation as needed. The dose may be increased to 2 inhalations if necessary.

Prevention of symptoms triggered by physical activity or other factors: 1 inhalation, or 2 if needed, 10-15 minutes before exercise or exposure to triggers.

Maximum dosage: 8 inhalations per day.

**Children younger than 4 years:** No dosing recommendations can be given as the effectiveness has not been established. Consult your doctor if the treatment is not effective enough or if you need more doses per day than usual. You should never increase the dose or change the duration of use without approval from your doctor.

**Test the inhaler before use:** If you are using a new inhaler or if it has not been used for 7 days or longer, check if it works properly. Remove the protective cap, shake the inhaler, and release two puffs into the air.

**Instructions for use:**

1. Inhale while in a sitting or standing position, if possible.
2. Remove the protective cap. Check both the inside and outside to ensure the mouthpiece is clean.
3. Shake the inhaler vigorously for a few seconds before use.
4. Hold the inhaler upright with the bottom of the container pointing upwards, place your thumb on the bottom under the mouthpiece. Exhale as deeply as possible, but not 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. Press down on the canister immediately after starting to inhale through the mouth to release a puff while continuing to breathe in deeply and calmly.
7. Hold your breath for 5-10 seconds. Remove the inhaler from your mouth and take your finger off the top of the inhaler.
8. If you need another puff, keep the inhaler upright, wait about half a minute, and then repeat steps 2 to 6.
9. After use, replace the protective cap on the mouthpiece to protect it from dust and dirt. The cap must be firmly placed on the mouthpiece, and you should hear a click indicating that it is properly secured.

Some people find it difficult to release a puff immediately after starting to inhale. In such cases, and also with children, the Vortex® or AeroChamber® Plus spacer device can be used. Refer to the product information of the spacer device for its use.

**Cleaning:**To prevent the inhaler from becoming blocked, it is essential to clean it at least once a week following the instructions below.

1. Remove the metal canister from the plastic holder of the inhaler and remove the protective cap from the mouthpiece.
2. Rinse the plastic holder and the mouthpiece in lukewarm water. If there is medication around the mouthpiece, do not attempt to remove it with a sharp object such as a pin. You can add a mild detergent to the water. Rinse the mouthpiece thoroughly with clean water before drying it. Do not immerse the metal canister in water.
3. Let the plastic holder and the cap of the mouthpiece dry in a warm place. Avoid excessive heat.
4. Place the canister back into the inhaler and reattach the protective cap to the mouthpiece.
5. Shake the inhaler to check how much medication it contains. Do not use this medicine if you do not hear any liquid when shaking the inhaler.

**Use at low temperature:** If the inhaler has been stored at a temperature below 0°C, hold it in your hands for 2 minutes to warm it up. Then shake it and release two puffs into the air before using it.

**Have you used too much of this medicine?**In this case, always contact your doctor or go to the hospital.

**Typical symptoms of an overdose are:**

* Tremors
* Headache
* Rapid heartbeat
* Nausea or vomiting
* Restlessness
* Irritability, excitement
* Seizures
* Drowsiness
* If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

**Possible side effects**Like all medicines, this medicine can have side effects, although not everybody gets them. Stop using this medicine and immediately contact a doctor if you experience any of the following very rare side effects:

* Symptoms of an allergic reaction, such as:
* Swelling of the face, tongue, or throat
* Difficulty swallowing
* Hives-like symptoms
* Breathing difficulties
* Breathing becomes immediately more difficult after using this medicine, even though it is supposed to relieve symptoms. This means your condition is worsening, and you urgently need alternative treatment.

**Inform your doctor immediately if you experience:** Chest pain (angina) during your treatment with this medicine. Do not stop using this medicine unless your doctor tells you to. The frequency of this occurrence is unknown.

**Side effects can occur with the following frequencies:**

**Common (affects less than 1 in 10 users):**

* Tremors
* Increased heart rate
* Headache
* Muscle cramps

**Uncommon (affects less than 1 in 100 users):**

* Rapid heartbeat
* Irritation of the mouth and throat

**Rare (affects less than 1 in 1000 users):**

* Decreased potassium levels in the blood
* Facial redness

**Very rare (affects less than 1 in 10,000 users):**

* Decreased blood pressure
* Fainting
* Increased activity
* Sleep disorders
* Irregular heartbeat
* Itchy skin rash

**How to store this medicine?**

* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date stated on the label and the box after "EXP". The expiry date refers to the last day of that month.
* Store below 30°C.
* Store the inhaler flat or upside down with the mouthpiece facing downward.
* The canister contains a liquid under pressure. Do not expose it to temperatures above 50°C, even for a short time. Protect it from heat, direct sunlight, and frost. Do not puncture or burn the canister, even if it is empty.
* Do not flush medicines down the sink or toilet or throw them into the trash. Ask your pharmacist how to dispose of medicines no longer needed. These measures will help protect the environment.