

Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986

The medicine is dispensed with a physician's prescription only

Salbutec Respiratory Solution

Active substance: salbutamol (as sulfate) 5 mg/ml

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – 'Important information about some of the ingredients in the medicine' and section 6 – 'Additional information'.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Salbutec Respiratory Solution is used to treat severe attacks of asthma and other forms of bronchospasm.

Therapeutic group:

Fast-acting bronchodilators, short-acting selective agonist to beta-2 receptors.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to salbutamol sulfate or to any of the additional ingredients contained in this medicine (listed in section 6).
- non-I.V. formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion.

Special warnings regarding use of the medicine

Before the treatment with Salbutec Respiratory Solution, tell the physician if:

- you have active asthma (for example, you have frequent flare-ups or symptoms or limited physical ability). Your physician may prescribe for you a medicine for treatment of asthma or recommend to increase the dosage of the medicine you are using, such as an inhaled corticosteroid.
- you have high blood pressure.
- you are diabetic.
- you have an overactive thyroid gland.
- you have a history of heart problems such as an irregular or fast heartbeat or angina pectoris.
- you use another nebuliser solution, e.g., ipratropium bromide; make sure that the mist does not get into your eyes. This can be prevented by using a mouthpiece instead of a face mask or goggles.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.

- you are taking diuretics, sometimes used to treat high blood pressure or heart condition.
- you have taken other medicines used to relieve nasal congestion (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell the physician or pharmacist. Particularly if you are taking:

- medicines for an irregular or fast heartbeat (especially from the beta-blocker group, such as propranolol).
- other medicines for asthma.

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 physician or pharmacist for advice before using this medicine.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or use tools or machines.

Important information about some of the ingredients in the medicine Salbutec Respiratory Solution contains 0.1 mg benzalkonium chloride per ml.

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The medicine must only be used by inhalation from a nebuliser, and must not be injected or swallowed.

The nebuliser produces a fine mist, which you breathe in through a face mask or a mouthpiece.

Make sure that you know how to use it properly.

If you have problems, consult with your physician, nurse or pharmacist.

Do not let the medicine or the mist produced by the nebuliser get into your eyes.

Use your nebuliser in a well-ventilated room as some of the mist will be released into the air and may be breathed in by others.

Make sure you know how, when and how much solution you should use.

Your physician may have prescribed either intermittent or continuous treatment with Salbutec Respiratory Solution.

The dosage and treatment regimen will be determined by the physician only. The recommended dosage is usually:

Intermittent treatment – Can be given up to 4 times a day.

- **Adults and adolescents aged 12 years and over** – 0.5 ml to 1 ml of the medicine (2.5 to 5 mg salbutamol). Some patients may require up to 2 ml

(10 mg salbutamol).

- **Children aged 18 months to 12 years** – 0.5 ml to 1 ml of the medicine (2.5 to 5 mg salbutamol).

Your physician may have told you to dilute the medicine with a sterile saline solution before using it in the nebuliser. Remember to follow the instructions for dilution.

Continuous treatment

1 to 2 mg of salbutamol per hour. This dose can be obtained by diluting 1 or 2 ml of the medicine to 100 ml with sterile saline solution to produce a solution containing 50 or 100 micrograms/ml of salbutamol, and inhaling the mist from a suitable nebuliser.

Do not exceed the recommended dose.

How to use the medicine

1. Prepare the nebuliser for filling.
2. Measure out the right quantity of the medicine and put it in the nebuliser cup.
3. Add the right amount of sterile saline solution (make sure your physician has told you how much to use).
4. Put the top on the nebuliser cup and shake it gently to mix the contents.
5. Assemble the nebuliser and use it as directed.
6. After use, throw away any solution remaining in the nebuliser cup. Clean your nebuliser in the recommended way.

If you have accidentally taken a higher dosage

If you took a higher dosage than you should have, talk to your physician as soon as possible.

The following effects may happen:

- your heart beats faster than usual
- you feel shaky
- hyperactivity.

These effects usually wear off in a few hours.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take the medicine at the designated time, take it as soon as you remember. However, if it is time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

Even if your health condition improves, do not stop treatment with the medicine without consulting the physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your physician as soon as possible.

As with any medicine, use of Salbutec Respiratory Solution may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them. The following side effects may occur with this medicine:

Allergic reactions (may occur in up to 1 in 10,000 users)

If you have an allergic reaction, stop taking Salbutec Respiratory Solution and see a physician straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat that may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

Refer to your physician as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while.
- you may feel your heartbeat is uneven or it gives an extra beat.

These may occur in up to 1 in 10 users. If any of these appear, refer to your physician as soon as possible.

Do not stop using this medicine unless told to do so.

Additional side effects

Common side effects - These may affect up to 1 in 10 users:

- feeling shaky
- headaches.

Uncommon side effects - These may affect up to 1 in 100 users:

- mouth and throat irritation
- muscle cramps.

Rare side effects - These may affect up to 1 in 1,000 users:

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

Very rare side effects - These may affect up to 1 in 10,000 users:

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

Side effects of unknown frequency (The frequency of these effects has not been established yet):

- chest pain, due to heart problems such as angina pectoris. Tell your physician, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.
- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath, cold feet and hands, irregular heartbeat or thirst.

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, refer to your physician as soon as possible. Your breathing problem may be getting worse and you may need a different medicine. Do not take extra Salbutec Respiratory Solution unless your physician tells you to.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link 'Report Side Effects of Drug Treatment' found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Keep the bottle in the outer carton in order to protect from light.
- Do not leave solution in your nebuliser once you have finished a treatment.
- For use up to one month after first opening the bottle.
- Shelf life after dilution: 7 days
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
purified water, benzalkonium chloride 50%, sulfuric acid 10%.
- **What the medicine looks like and the contents of the package:**
An amber glass bottle with a drip nozzle containing 20 ml of colourless to light yellow solution.
Child resistant package.
- **Registration holder's and manufacturer's name and address:** Sam On Ltd.,
25 Ehad Cinnamon (Ha'avoda) St., Bat Yam
- Revised in July 2023 according to MoH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 172-07-36477-99