



PACKAGE LEAFLET

SALRES 2.5 mg / 2.5 ml Inhalation Solution for Nebulization

For inhalation by mouth.

Sterile

Active ingredients: Each single dose 2.5 ml vial contains 3 mg salbutamol sulfate equivalent to 2.5 mg salbutamol.

Excipients: Sodium chloride, sulfuric acid, water for injection.

Read all of this LEAFLET carefully before you start using this medicine. It contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you visit a doctor or hospital while using this medicine, tell them that you are using this medicine.*
- *Please follow the instructions in this leaflet. Do not use any **higher** or **lower** doses than the recommended dose of this medicine.*

The main topics of this leaflet are:

- 1. WHAT SALRES IS AND WHAT IT IS USED FOR**
- 2. WHAT YOU NEED TO KNOW BEFORE YOU USE SALRES**
- 3. HOW TO USE SALRES**
- 4. POSSIBLE SIDE EFFECTS**
- 5. HOW TO STORE SALRES**

1. WHAT SALRES IS AND WHAT IT IS USED FOR

SALRES contains salbutamol as the active substance. It belongs to a group of medicines called fast-acting bronchodilators.

SALRES nebulizers are presented as plastic vials containing salbutamol solution in normal physiological saline. Each nebulizer contains 2.5 ml of solution. The liquid SALRES in the nebulizer is transformed into vapor using a device called nebulizer. SALRES, which is inhaled through the mouth and absorbed by the lungs, helps to open up the air passages within a few minutes so that you can breathe more easily.

- It is a reliever medication to reduce the symptoms in asthma by reducing bronchoconstriction (narrowing of the bronchi).
- It should not be used as a controller medication.
- It is used to reduce the symptoms and as a rescue medication in chronic obstructive pulmonary disease (COPD). It is not preferred in regular treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SALRES

DO NOT USE SALRES in the following conditions:

If you are allergic (hypersensitive) to salbutamol or any of the other ingredients of SALRES (excipients are listed at the beginning of this leaflet),

- SALRES is not suitable for premature labor. SALRES should not be used to manage the threatened miscarriage.

If you think any of these apply to you, **do not use SALRES** until you talk to your doctor.

USE SALRES CAREFULLY in following conditions:

Consult your doctor, pharmacist or nurse before using SALRES in the following conditions:



- If your asthma is active (for example, if you have frequent symptoms or exacerbations or limited physical activity). Your doctor may start or increase a medication such as an inhaled corticosteroid to control your asthma.
 - If you have high blood pressure,
 - If you are diabetic,
 - If your thyroid gland is overactive,
 - If you have a history of heart problems e.g. irregular or fast heartbeat or chest pain (angina),
 - If you use another nebulizer solution (for example, ipratropium bromide), be careful not to get the vapor into your eyes. This can be prevented by using a mouthpiece instead of using a mask or goggles.
 - If you use xanthine derivatives (such as theophylline) or steroids to treat your asthma,
 - If you are taking diuretics (water pills), which are sometimes used to treat high blood pressure or heart disease,
 - If you are using other medicines (such as ephedrine or pseudoephedrine) to relieve nasal congestion or to treat your asthma,
 - If you have low potassium levels in your blood.
- Your doctor will monitor your potassium levels if you are using any of the medications listed here. If you think any of these may apply to you, **consult your doctor**.

Conditions you need to look out for:

High doses of SALRES may rarely cause a condition called "lactic acidosis". To reduce the risk of any problems while using SALRES you need to pay attention to certain symptoms. See "Conditions you need to look out for" in section 4 of this leaflet.

If any of these warnings apply to you, even if in the past, please consult your doctor.

Taking SALRES with food and drink

SALRES may be used on an empty or full stomach at any time of the day.

Pregnancy

Ask your doctor or pharmacist before you start to use this medicine.

The use of SALRES during pregnancy is generally not recommended. **If you are pregnant, think you may be pregnant or are planning to become pregnant, do not use SALRES** before talking to your doctor. Your doctor will evaluate the benefit to you and the risk to the baby of using SALRES during pregnancy.

Talk to your doctor or pharmacist immediately if you find out that you are pregnant during treatment.

Breastfeeding

Ask your doctor or pharmacist before you start to use this medicine.

Since salbutamol probably passes into breast milk, SALRES is not recommended during breastfeeding. Ask your doctor before using SALRES.

Driving and using machines

SALRES is not expected to have any effect on your ability to drive or use machines. A nebulizer should not be used while driving or using machines as it will create a vapor for you to inhale.



Important information about some of the excipients of SALRES

Undesirable effects are not expected unless you are allergic to the excipients of SALRES.

Using with other medicines

Inform your doctor or pharmacist if you are using, have recently used or may use any other medication, including medicines and herbal preparations you obtain without a prescription. If you go to the hospital, do not forget to take this medicine with you.

Some medicines can affect how SALRES works or cause you to experience more side effects. These include:

- Medicines used to treat heart disease or high blood pressure (such as metoprolol or propranolol)
- Other medicines used to treat asthma

SALRES can be used together with a group of medicines known as monoamine oxidase inhibitors (MAOIs).

Your doctor or pharmacist will decide whether you can use SALRES with these medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO USE SALRES

Instructions for appropriate use and dose/frequency of administration

Always take this medicine exactly as your doctor has told you. If you are not sure, talk to your doctor or nurse.

The starting dose is 2.5 mg by moist inhalation. This dose may be increased up to 5 mg.

The treatment may be repeated 4 times a day.

Adults with very severe airway obstruction may be administered high doses up to 40 mg per day under strict medical supervision in the hospital.

SALRES can be used on an empty or full stomach at any time of the day.

Route and method of administration

- **Do not inject or drink the liquid.** SALRES nebule should only be inhaled using a nebulizer.

- **Do not let the solution or the mist produced by the nebulizer get into your eyes.** You may wear glasses to protect your eyes.

- Your doctor, nurse, or pharmacist should show you how to use your medicine.

- Each small plastic container (nebule) contains some liquid.

- The liquid is placed into a nebulizer. The mist is then produced which you can inhale through a face mask or mouthpiece.

- Use your nebulizer in a well-ventilated room because some of the mist may disperse into the air and be inhaled by other people.

Use only the nebulizer advised by the doctor and supervise your child while using the nebulizer. Even if there is a short-term improvement following the use of the prescribed nebulized medication, if the nebulized medication does not work, seek medical help immediately.

Instructions for the use of nebules

1. Nebules are available in a foil package. Do not open the foil package until you start using it.
2. Hold the last nebule with one hand while holding the nebule card with the other hand.
3. Separate the nebule you hold from other nebules by turning it forward.



4. Place the remaining nebules into the foil package. Put the foil package back into the box.
5. Hold the top of the nebule that you have separated from the nebule card. Open the nebule by twisting it off.



6. Point the open mouth of the nebule into the container of the nebulizer and squeeze the nebule slowly. Make sure that all the liquid in the nebule is transferred to the nebulizer container.



7. Operate the nebulizer and use it properly.

Dilution of nebules

- **Do not dilute the solution in the nebule unless your doctor has told you.**
- If your doctor has told you to dilute the solution, pour the liquid in the nebule into the nebulizer container.
- Add the normal sterile saline in the amount that your doctor has told you.
- Close the lid of the nebulizer container and shake it to ensure that the contents are thoroughly mixed.

Only normal sterile saline should be used when dilution is required.

After administration

- Use a newly opened nebule for each dose. Open the nebule only when you are ready to use your medicine. If there is any remaining unused liquid, discard it. Do not store it for reuse.
- Discard any solution that may be left in the nebulizer container.



- Clean your nebulizer properly.

Special age groups

Use in children

Children aged 12 years and older: According to adult dose.

Children aged 4-11 years: 2.5 mg to 5 mg (up to 4 times a day)

Other pharmaceutical forms may be more appropriate for children under 4 years of age.

It should not be used in babies younger than 18 months.

Use in the elderly

There is no special warning regarding its use in elderly patients.

Special conditions for use

Kidney/Liver failure

There is no data.

If you think the effect of SALRES is too strong or too weak, talk to your doctor or pharmacist.

If you take more SALRES than you should

Talk to a doctor or pharmacist if you have used more SALRES than you should.

If you use more SALRES than you should, consult a doctor as soon as possible. The following effects may occur:

- Faster heart rate than usual
- Feeling unwell
- Hyperactivity

These effects usually disappear within a couple of hours.

If you forget to use SALRES

If you forget a dose, take it as soon as you remember, however if it is almost time for your next dose, skip the missed dose.

Take your next dose at the usual time. If you develop wheezing or other symptoms of an asthma attack, you can take your next dose sooner.

Do not take a double dose to make up for a missed dose.

Possible effects if you stop using SALRES

Continue using SALRES for the period recommended by your doctor. Do not stop using SALRES without consulting your doctor.

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

4. POSSIBLE SIDE EFFECTS

If your breathing or wheezing get worse immediately after taking this medicine, stop using it immediately and tell your doctor as soon as possible. If available, use another fast-acting asthma medication as soon as possible.

Like all other medicines, SALRES may cause side effects in people with hypersensitivity to its ingredients.



Conditions you need to look out for:

If any of the following occur, stop using SALRES and IMMEDIATELY inform your doctor or refer to the emergency department of the nearest hospital:

Allergic reactions:

If you experience an allergic reaction, stop using SALRES and immediately seek advice from a doctor. These reactions occur very rarely. Signs of an allergic reaction include:

- Hives (urticaria) or redness
- Swelling of the face, lips, mouth, throat or tongue (angioedema), which may cause difficulty in swallowing or breathing
- Difficulty breathing or coughing, wheezing
- Feeling suddenly weak or dizzy (may cause collapse (sudden circulatory failure) or loss of consciousness.)

These are all very serious side effects.

If you have one of them, you are severely allergic to SALRES.

You may need immediate medical intervention or hospitalization.

Lactic acidosis:

Increased lactic acid level in the blood (lactic acidosis) is a very rare side effect of SALRES. This affects people with severe kidney disease more often. Symptoms of lactic acidosis include:

- Rapid breathing, shortness of breath (even if your wheezing has improved)
- Chills
- Abdominal pain, nausea and vomiting.

If you experience any of these symptoms, **inform your doctor immediately. Stop using SALRES.**

If any of the following occur, talk to your doctor as soon as possible:

- If you feel your heart beating faster or stronger than normal (palpitations). This is usually harmless and goes away after using your medicine for a while.
- If you feel that your heartbeat is irregular or that your heart is beating faster.

These may occur at most one in 10 patients. If you experience any of these, see your doctor as soon as possible. **Do not stop using your medicine unless your doctor tells you to.**

Side effects are classified according to the categories below:

Very common : May occur at least one in 10 patients.

Common : May occur less than one in 10 but more than one in 100 patients.

Uncommon : May occur less than one in 100 but more than one in 1,000 patients.

Rare : May occur less than one in 1,000 but more than one in 10,000 patients.

Very rare : May occur less than one in 10,000 patients.

Unknown : Cannot be estimated from the available data.

Inform your doctor if you have any of the following side effects that may occur when using this medicine:

Common

- Shaking
- Headache
- Increased heart rate (tachycardia)



Uncommon

- Irregular heartbeat (palpitations)
- Mouth and throat irritation
- Muscle cramps

Rare

- Falling of blood potassium levels below normal (hypokalemia)
- Increased blood flow to the arms and legs (dilation of blood vessels) (peripheral vasodilation)

Very rare

- Heart rhythm disorders (cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia, and extrasystoles)
- Narrowing of bronchi due to the medication (paradoxical bronchospasm)
- Hyperactivity
- Hypersensitivity reactions, including swelling of the face, lips, mouth, throat or tongue (angioedema), hives (urticaria) or redness, narrowing of the bronchi (bronchospasm), low blood pressure (hypotension) and sudden circulatory failure (collapse)
- Changes in sleep patterns and behavior, such as restlessness and excitability
- Lactic acidosis (increased level of lactic acid in the blood). This condition may cause abdominal pain, breathing faster and deeper than normal (hyperventilation), shortness of breath even if wheezing improves, cold hands and feet, irregular heartbeat, and thirst.

Unknown

- Oxygen deprivation of a part of the heart muscle (myocardial ischemia)
- Chest pain due to heart problems such as angina. If this occurs, inform your doctor, nurse or pharmacist. Do not stop using your medicine unless you are told to do so.

If any of the side effects listed here **become severe or worse**, or if you experience any side effects not listed here, **contact your doctor or pharmacist**.

If you think this medicine is not effective enough for you:

If you think that this medicine is not working as well as usual, see your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medication. Do not use more SALRES unless your doctor tells you to.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SALRES

Keep SALRES in its package and out of the reach and sight of children.

Store SALRES at room temperature below 25°C away from light.

Once the sachets are opened, the vials should be protected from light and used within 3 months.

Use it in accordance with the expiry date.

Do not use SALRES after the expiry date stated on the package.



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 protect the environment.

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