



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### SALRES 2 mg/5 ml Syrup

Taken by mouth.

**Active substance:** Each 5 ml syrup (1 spoonful) contains 2.4 mg salbutamol sulfate equivalent to 2 mg salbutamol.

**Excipients:** Trisodium citrate dihydrate, anhydrous citric acid, hydroxypropyl methyl cellulose 4000 SR, sodium benzoate, sodium saccharine, sodium chloride, orange flavor 506304 CE, deionized water.

**Read all of this PACKAGE 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 or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you.*

#### **In this leaflet:**

- 1. What SALRES is and what it is used for***
- 2. What you need to know before you take SALRES***
- 3. How to take SALRES***
- 4. Possible side effects***
- 5. How to store SALRES***

### **1. WHAT SALRES IS AND WHAT IT IS USED FOR**

SALRES is a member of a group of medicines called selective beta<sub>2</sub> adrenergic receptor agonists. It contains salbutamol as an active ingredient and widens the airways in the lungs, allowing you to breathe more easily.

SALRES is available as a homogeneous, colorless, orange-scented solution in a 150 mL bottle.

- They are reliever medications used as symptom relievers in asthma.
- They should not be used as a controller medicine.
- They are used in chronic obstructive pulmonary disease (COPD) to reduce symptoms and as rescue medicines. They are not preferred in regular treatment.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SALRES**

#### **Do not take SALRES**

- Do not use SALRES if you are allergic to salbutamol or any of the other components of the medicine listed at the beginning of this leaflet.
- SALRES should not be used for premature labor or threatened miscarriage.

#### **Take special care with SALRES**

- Inform your doctor if you have increased the use of short-acting bronchodilators to relieve asthma



symptoms, this indicates worsening of your asthma control.

- Tell your doctor if your medicine does not relax you as much as before or if the usual duration of action has been shortened.
- Consult your doctor about the use of short-acting inhaled bronchodilators to relieve symptoms.
- Oral short-acting beta<sub>2</sub> agonists have been associated with fatal cardiovascular events such as heart attack in the mother, accumulation of water in the lungs and heart enlargement in the baby during the period of use, although they do not provide the continuation of lasting efficacy in stopping preterm labor and relaxation of the uterine muscles. Oral short-acting beta<sub>2</sub>-agonist medicines should not be used under any circumstances related to childbirth, as the benefits of oral formulations in these situations do not outweigh the potential risks.
- Inform your doctor if your thyroid gland is overactive.
- Inform your doctor if you have high blood pressure.
- Tell your doctor if you have severe heart disease and if, after taking SALRES, you experience chest pain, irregular heartbeat, or signs of worsening heart disease.
- Inform your doctor if you are using xanthine derivatives such as theophylline, or corticosteroids for the treatment of asthma.
- Inform your doctor if you are using diuretic medication for the treatment of high blood pressure.
- As a result of using SALRES, the level of potassium in your blood may be excessively decreased. For this reason, your doctor may closely monitor the level of potassium in your blood on a regular basis.
- The use of SALRES can cause metabolic changes such as increased blood sugar levels. Inform your doctor if you have diabetes.
- Sudden and progressive worsening of asthma control is potentially life threatening. If you experience such a situation, inform your doctor.

SALRES is suitable for the treatment of children and adults who prefer liquid medicines.

*Please consult your doctor even if these warnings were applicable to you at any time in the past.*

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

If you are pregnant, use SALRES only if your doctor has decided that you should.

*If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.*

### **Breast-feeding**

*Consult your doctor or pharmacist before taking this medicine.*

Since SALRES probably passes into breast milk, use it only if your doctor has decided that you should if you are breastfeeding.

### **Driving and using machines**

SALRES is not expected to have an adverse effect on the ability to drive and use machines.

### **Important information about some of the ingredients of SALRES**

Each 5 ml of SALRES contains 5.59 mg sodium. This should be taken into account for patients on a controlled sodium diet.



### **Taking other medicines**

Do not use SALRES with other medicines without consulting your doctor.  
SALRES and non-selective beta-blockers such as propranolol should generally not be used together.  
Inform your doctor if you are taking any other medicine for heart rhythm disorder or asthma.  
SALRES can be used with a medicine group called monoamine oxidase inhibitors (MAOIs).

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

## **3. HOW TO TAKE SALRES**

### **Instructions for proper use and dose/administration frequency**

The general effective dose is 4 mg (10 ml) taken 3 or 4 times a day.  
Your doctor may increase or decrease the dose of your medicine depending on the severity of your condition. Each single dose may be increased up to 8 mg (20 ml).

### **Route and method of administration**

SALRES is taken by mouth.

Take your medicine as recommended by your doctor. Do not increase the frequency of taking your medicine without the advice of your doctor. Do not exceed the dose prescribed for you. If you think that your medicine is not working properly, consult your doctor.

### Dilution

SALRES can be diluted with purified water. The mixture should be protected from light and used within 28 days.

To avoid microbial contamination, the purified water should be freshly prepared during dilution or alternatively it should be boiled and then cooled just before use.

It is not recommended to mix SALRES with other liquid medicines.

### **Different age groups**

#### Use in children

*Use in children aged 2 to 6 years: 1 to 2 mg (2.5 to 5 ml) 3 or 4 times a day.*

*Use in children aged 6 to 12 years: 2 mg (5 ml) 3 or 4 times a day.*

*Use in children over 12 years: 2 to 4 mg (5 to 10 ml) 3 or 4 times a day.*

#### Use in the elderly (over 65 years)

2 mg (5 ml) 3 or 4 times a day.

### **Special conditions**

#### Kidney/Liver failure

Not reported.

#### Use in people sensitive to beta-adrenergic stimulant drugs

2 mg (5 ml) 3 or 4 times a day.

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



**If you take more SALRES than you should**

If you (or someone else) have used more SALRES than needed, or if you think a child has used it, immediately go to the nearest hospital emergency department or call your doctor.

Symptoms of overdose include: decreased potassium in the blood which can lead to involuntary muscle contractions or weakness, and irregular heartbeat.

*If you take more SALRES than you were told to, contact your doctor or pharmacist.*

**If you forget to take SALRES**

*Do not take a double dose to make up for a forgotten dose.*

**If you stop taking SALRES**

Do not stop using SALRES without speaking with your doctor.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, side effects may occur in people with sensitivity to ingredients of SALRES.

**If you experience any of the following, stop using SALRES and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:**

**Allergic reactions**

If you experience an allergic reaction, stop taking SALRES and consult a doctor immediately. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

These are all very serious side effects.

If you have any of these, it means you have a serious allergy to SALRES. You may need emergency medical attention or hospitalization.

Side effects are classified in the following frequencies:

Very common : may occur in at least 1 in 10 patients.

Common : may occur in less than 1 in 10 but more than 1 in 100 patients.

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

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

Very rare : may occur in less than 1 in 10,000 patients.

Not known : cannot be estimated from the available data.

**Very common**

- Feeling shaky

**Common**

- Headache
- Acceleration of heartbeat (tachycardia)
- Heart palpitations
- Muscle cramps



**Rare**

- Lower level of potassium in the blood (hypokalemia)
- Heart rhythm disorders (cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles)
- Enlargement of arm and leg veins (peripheral vasodilation)

**Very rare**

- Hypersensitivity reactions including swelling of the face, lips, throat and/or tongue (angioedema), hives (urticaria), narrowing of the bronchi (bronchospasm), low blood pressure (hypotension) and sudden circulatory failure (collapse)
- Hyperactivity
- Muscle tension

**Not known**

- Lack of oxygen in a part of the heart (myocardial ischemia)

*If you experience any side effects not listed in this leaflet, 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 out of reach and sight of children and in its original package.*

Store at room temperature below 25°C protected from light.

If SALRES is diluted, it must be protected from light and used within 28 days.

**Use this medicine in accordance with the expiry date.**

*Do not use SALRES after the expiry date, which is 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.

***Marketing Authorization Holder:***

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