



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### SALRES 5 mg/2.5 ml Inhalation Solution for Nebulisation

Inhaled by mouth

Sterile

**Active substance:** Each single-dose 2.5 ml vial contains 6 mg Salbutamol sulfate equivalent to 5 mg Salbutamol

**Other ingredients:** Sodium chloride, sulfuric acid, water for injection.

**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 drug when you go to 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 use SALRES***
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### **1. WHAT SALRES IS AND WHAT IT IS USED FOR**

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

SALRES nebulisers are plastic ampoules containing salbutamol solution in normal saline. Each nebule contains 2.5 ml solution. SALRES is a liquid in the nebulisers, and is vaporized with the aid of a device called nebuliser. SALRES helps to open up the air passages in your lungs within a few minutes so that you can breathe more easily.

- It is used as to relieve the symptoms of asthma.
- It should not be used as a controller medicine.
- For reducing the symptoms in chronic obstructive pulmonary disease (COPD) and as immediate rescue. It is not preferred for regular treatment.

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

#### **DO NOT USE SALRES**

- If you have hypersensitivity to salbutamol or any other ingredients of SALRES.
- SALRES is not suitable for treatment of premature labor. SALRES preparations should not be used for threatened abortion.

#### **TAKE SPECIAL CARE with SALRES**

- If you have increased the use of short-acting medicines to open the airways (bronchodilator) in



order to relieve asthma symptoms, inform your doctor; this shows your asthma control is worsening.

- If you have an overactive thyroid gland, inform your doctor.
- SALRES should only be used by inhalation. It should only be inhaled through your mouth, not injected or swallowed.
- If you are receiving treatment at home with SALRES, consult your doctor if the benefit or duration of the effect of the medication decreases, do not increase your dose or dose frequency.
- As a result of SALRES use, the potassium levels in your blood may drop too low. Therefore, your doctor will regularly and closely monitor your blood potassium level.
- If you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma, inform your doctor.
- If you are sometimes taking water tablets (diuretics), used to treat high blood pressure or a heart condition, inform your doctor.
- SALRES use leads to metabolic changes such as increased blood sugar level. If you are a diabetic, inform your doctor.
- If you have severe heart disease and if you feel pain in your chest or irregularities in your heartbeat or if you feel that your heart disease is worsening after taking SALRES, consult your doctor.
- If your breathing or wheezing gets worse straight after taking this medicine, inform your doctor may need to change your treatment.
- If you are using nebulized anticholinergic drugs (such as ipratropium bromide) together with Salbutamol, be careful that the mist does not get in your eyes.
- If you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma, inform your doctor.

*If any of these warnings apply to you, please consult your doctor, even if they were applicable at any time in the past.*

### **Pregnancy**

*Ask your doctor or pharmacist for advice before taking this medicine.*

If you are pregnant, you should not use SALRES unless your doctor tells you to.

*If you become pregnant whilst taking this medicine you should tell your doctor or pharmacist as soon as possible.*

### **Breast-feeding**

*Ask your doctor or pharmacist for advice before taking this medicine.*

As SALRES is probably secreted in breast milk, you should not use SALRES unless your doctor tells you to.

### **Driving and using machines**

SALRES is not likely to have any effect your ability to drive or use any tools or machines. You should not use the nebulizer while driving or using machinery.

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

Unless you are hypersensitive to any of the ingredients of SALRES, no side effect associated with

these substances is expected.

It contains less than 1 mmol (23 mg) sodium in each dose; no sodium related side effect is expected at this dose.

### **Taking other medicines**

Do not take SALRES with other medicines without consulting your doctor.

If you are using medicine for irregular heartbeat or asthma, inform your doctor.

*If you are currently taking or have recently taken any drugs obtained with or without prescription, please inform your doctor or pharmacist about such drugs.*

## **3. HOW TO USE SALRES**

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

The starting dose is 2.5 mg via inhalation. The dose may be increased to 5 mg. The treatment may be repeated 4 times daily.

In adults, higher doses up to 40 mg daily may be given for the treatment of severe airway obstruction but only under the direction and supervision of a doctor in hospital.

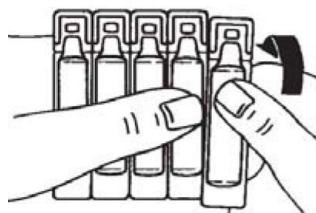
Salres can be used on an empty stomach or on a full stomach at any time of day.

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

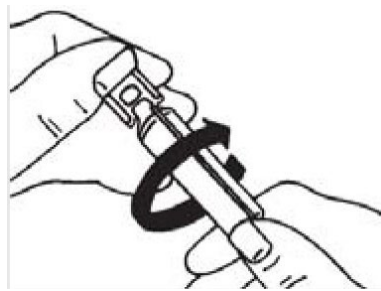
- **Do not inject or swallow the liquid.** SALRES nebule should only be inhaled using your nebuliser.
- **Do not let the liquid or the mist produced by the nebuliser get into your eyes.** You can wear glasses or goggles to protect them.
- Your doctor, nurse or pharmacist should show you how to use your medicine.
- Each small plastic container (nebule) contains some liquid.
- The liquid is put into a nebuliser. This makes a fine mist for you to breathe in through a face mask or mouthpiece.
- 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.

### **Using your nebules**

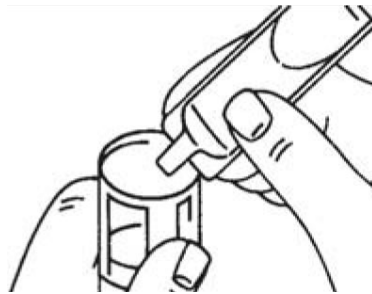
1. Your nebules are in a foil tray. Do not open the foil tray until you need to use them.
2. Hold the strip of nebules in one hand, with your other hand hold the last nebule in the row.
3. Twist the nebule downwards and away from you.



4. Return the remaining nebules to the foil tray and cover the tray with the lid foil.
5. Hold the top of the nebule you have just removed. Twist the body to open it.



6. Put the open end of the nebule into the nebuliser bowl and squeeze slowly. Make sure that all of the content is emptied into the nebulizer.



7. Assemble the nebulizer and use it as directed.

#### Diluting your Nebules

- **Do not dilute the contents of a nebule unless you are told to by your doctor.**
  - If your doctor has told you to dilute the solution, empty the content of the nebule into the nebuliser bowl.
  - Add the amount of sterile normal saline your doctor has told you to use.
  - Put the top on the nebuliser bowl and shake gently to mix the contents.
- If dilution is necessary then only sterile normal saline should be used.

#### After use

- Use a fresh nebule for each dose. Only open a new one when you are ready to use it. If there is any liquid left over, throw it away. Do not save it to use again.
- Throw away any solution remaining in the nebuliser bowl.
- Clean your nebuliser in the recommended way.

#### Different age groups

##### Use in children

Children aged 12 years and over: Use adult dosage.

Children aged 4 to 11 years: 2.5 mg to 5 mg up to 4 times a day.

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

Infants under 18 months: Clinical efficacy of nebulized salbutamol in infants under 18 months is uncertain. As transient hypoxia may occur, supplemental oxygen therapy should be considered.



### Use in elderly

There is no specific warning regarding the use in elderly.

### Special conditions

#### Kidney/liver failure

Not reported.

*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 take more SALRES than you should, talk to a doctor or pharmacist.*

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 forget to take SALRES

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

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

#### If you stop using SALRES

Do not stop using SALRES without talking to your doctor.

## 4. POSSIBLE SIDE EFFECTS

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible. If available, try a different fast-acting asthma medicine as soon as possible.

Like all medicines, side effects may occur in patients who are sensitive to the ingredients of SALRES.

**Stop taking SALRES, tell your doctor IMMEDIATELY or go to the nearest hospital emergency department if you experience any of the following side effects:**

#### Allergic Reactions

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

#### Lactic acidosis

An increase in the amount of lactic acid in the blood is a very rare side effect of SALRES. This most often affects people who have severe kidney disease. Symptoms of lactic acidosis include:

- Rapid breathing, shortness of breath (even if there is improvement in your wheezing)



- Feeling cold
- Stomach pain, nausea and vomiting.

These all are very serious side effects.

If you experience any of these, it means that you have a severe allergy to SALRES. You may need to urgent medical attention or hospitalization.

Side effects are listed as categorized below:

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

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

Uncommon : may affect less than 1 in 100 patients but more than 1 in 1.000 patients.

Rare : may affect less than 1 in 1.000 patients.

Very rare : may affect less than 1 in 10.000 patients.

Unknown : cannot be estimated from the available data.

### **Other side effects**

#### ***Common***

- Feeling shaky, headache
- Increased heart rate (Tachycardia)

#### ***Uncommon***

- Palpitation
- Mouth and throat irritation
- Muscle cramps

#### ***Rare***

- A low level of potassium in your blood (Hypokalemia)
- Increased blood flow to your extremities (Peripheral vasodilatation)

#### ***Very rare***

- Irregular heartbeat (Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles)
- Narrowing of bronchi due to reaction to the medicine (Paradoxical bronchospasm)
- Increased levels of lactic acid in the blood
- Hypersensitivity reactions observed with rash, hives (urticaria), pruritus and redness in the skin (erythema)
- Hyperactivity

#### ***Unknown***

- Lack of oxygen to some part of heart muscle (Myocardial ischemia)

*If you notice any side effects not listed in this package leaflet, please tell 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 to Turkey Pharmacovigilance Centre (TÜFAM) via clicking on the icon of 'Side Effect Reporting for Medicines' at [www.titck.gov.tr](http://www.titck.gov.tr) or calling +90 800 314 00 08 as the line of side effect reporting. 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 the reach and sight of children and in its original package.*

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

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

### **Use it 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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### ***Manufacturing site:***

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