



PACKAGE LEAFLET: INFORMATION FOR THE USER

SALRES 100 mcg Aerosol Inhaler Inhaled by mouth

Active substance: Each puff contains 120.50 mcg Salbutamol sulfate equivalent to 100 mcg Salbutamol.

Excipients: HFA 134a Pharma Grade

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. Before you use SALRES***
- 3. How to use SALRES***
- 4. Possible side effects***
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1. WHAT SALRES IS AND WHAT IT IS USED FOR

SALRES contains salbutamol as active substance. It is the member of a group of medicines called short-acting bronchodilators which helps to open up the air passages in your lungs within a few minutes so that you can breathe more easily.

SALRES inhaler is a specially designed metered dose device with an actuator. Inhaler contains 200 puffs and 100 microgram of salbutamol is released with each puff.

- It is a relief medication used for the relive of symptoms in asthma.
- It should not be used to manage the disease. Regular use of SALRES is not recommended for asthma.

SALRES is used:

- For providing short-term (4 hours) widening of bronchia with its fast onset in reversible airways obstruction due to asthma, advanced permanent damages of airways in the lungs (emphysema) and in long-term inflammations of airways (chronic bronchitis),
- For preventing the symptoms in those circumstances known to precipitate an asthma attack such as exercise, allergen exposure,
- For reducing the symptoms in chronic obstructive pulmonary disease (COPD) and as rescue medicine.

It is not preferred for regular treatment.



If your asthma is active (for example you have frequent symptoms or exacerbations or limited physical ability). Your doctor may start a medicine to control your asthma such as an inhaled corticosteroid

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SALRES

DO NOT USE SALRES

- If you have hypersensitivity to salbutamol or any of the excipients (HFA 134a) of SALRES.

SALRES inhaler 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 which open the airways (bronchodilator) in order to relieve asthma symptoms, inform your doctor, this shows your asthma control is worsening.
- You have an overactive thyroid gland.
- You have high blood pressure.
- A previously effective dose of your medicine fails to give relief for at least 3 hours, consult your doctor.
- You have severe heart disease and if you feel pain in your chest and irregularity in your heartbeat or if you notice symptoms of worsening of your heart disease, consult your doctor.
- As a result of use of SALRES, the level of potassium in your blood may drop too low. Therefore, your doctor will closely monitor your blood potassium level regularly.
- You are taking xanthine derivatives (such as theophylline) or steroids to treat asthma, inform your doctor.
- You are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition, inform your doctor.
- You develop an immediate increase in wheezing after taking your medicine; inform your doctor immediately, your doctor may need to change your treatment.

As a result of use of SALRES, the level of potassium in your blood may drop too low. Therefore, your doctor will closely monitor your blood potassium level regularly.

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

Pregnancy

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

If you are pregnant, use SALRES only if your doctor decides that you need to use it.

If you realize that you are pregnant during the treatment consult your doctor or pharmacist immediately.

Breast-feeding

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

As SALRES is probably secreted in breast milk, use SALRES only if your doctor decides that you need to use it.

Driving and using machines

SALRES is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of SALRES

Unless you are hypersensitive to any of the other ingredients of SALRES, no side effect associated with these substances is expected.

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.

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take other medicines, including medicines obtained without a prescription. This includes herbal medicines.

3. HOW TO USE SALRES

Instructions for proper use and dose/administration frequency:

Adults and Adolescents (children 12 years and over):

- To relieve asthma – 1 or 2 puffs.
- To prevent asthma – 2 puffs 10-15 minutes before exercise or exposure to allergen.
- The maximum dose is 8 puffs in a 24 hour period.

Constant need for “using as necessary” or sudden increases in dose indicate that your asthma is getting worse.

As overdose will cause occurrence of undesirable effects, increase the dose of your medicine and the frequency of administration only by your doctor’s advice.

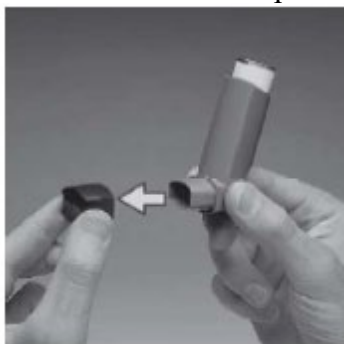
Route and method of administration

Testing the inhaler:

- When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides of cover. To make sure that it works, shake it well, release one puff into the air.
- If you have not used the inhaler for 5 days or more shake it well and release 1-2 puffs into the air to make sure that it works.

Using the inhaler:

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.



2. Check inside and outside of the inhaler including the mouthpiece to make sure that the mouthpiece is clean and free of objects.
3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.



5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.



6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.



7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.



8. If your doctor has told you to take 2 doses, keep the inhaler upright and wait about half a minute before you take another puff by repeating steps 3 to 7.

9. After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

IMPORTANT:

Do not rush Stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your inhaler.

Practice in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or the sides of your mouth you should start again from stage 2.

Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practice the technique together. You may find the face mask of spacer device useful if you have to give SALRES to a baby or a child under 5 – speak to your doctor if you think you might need one of these.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.



Cleaning your inhaler:

To stop your inhaler blocking, it is important to clean it at least once a week.



To clean your inhaler:

- Remove the metal aerosol tube from the plastic casing.
- Remove the mouthpiece cover.
- Rinse the plastic casing under warm running water.
- Dry the plastic casing thoroughly inside and out (e.g. in the night).
- Replace the metal aerosol tube and the mouthpiece cover.

Do not put the metal aerosol tube in water.

Different age groups

Use in children

For children between the ages of 2-12 years:

- To relieve asthma – 1 puff. 2 puffs if required
- To prevent asthma – 2 puffs 10-15 minutes before exposure to allergen or exercise
- The maximum dose is 8 puffs in a 24 hour period.

Use in elderly

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

Use in special conditions

Kidney/Liver failure

Not reported.

Please talk your doctor or pharmacist if you think that effect of SALRES is too strong or weak.

If you take more SALRES than you should:

If you take more SALRES than you should, talk your doctor or pharmacist.

The following effects may happen:

- your heart beating 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 taking 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 immediately. If available, try a different fast-acting asthma



medicine as soon as possible.

Like all medicines, SALRES can cause side effects in patients with hypersensitivity to its ingredients.

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 or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

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 in this package leaflet are defined as given in the following categories:

Common	: affects 1 to 10 patients in 100
Uncommon	: affects 1 to 10 patients in 1000
Rare	: affects 1 to 10 patients in 10.000
Very rare	: affects less than 1 patient in 10,000
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

- Narrowing of bronchi due to reaction to the medicine (Paradoxical bronchospasm)
- Irregular heartbeat (cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles)
- Hyperactivity

Unknown

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

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 Center (TÜFAM) via clicking on the icon of 'Side Effect Reporting for Medicines' at 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.

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

5. HOW TO STORE SALRES

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

Keep at room temperature below 30°C.

Protect from direct sunlight and frost. Aerosol tube should not be broken, punctured or burnt even when empty.

Replace the mouthpiece cover firmly when not in use.

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

DEVA Holding A.Ş.

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Çerkezköy Organize Sanayi Bölgesi

Karaağaç Mah. Atatürk Cad., No: 32

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