

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

The dispensing of this medicine requires a doctor's prescription

Salbutrim CFC-free Inhaler

Each puff contains the active ingredient: salbutamol (as sulfate) 100mcg

Inactive ingredients: See section 6 “Additional Information”.
Read the entire leaflet carefully before using this medicine.
This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor 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 condition is similar to yours.

1. What is this medicine intended for?

Salbutrim contains a medicine called salbutamol. It belongs to a group of medicines called fast acting bronchodilators. Salbutrim Inhaler is used to relieve asthma symptoms and prevent them under conditions known to trigger asthma (such as exercise or exposure to an allergen).

Therapeutic group:

Beta-2 adrenoreceptor selective agonist.

Sabutrim Inhaler contains an ingredient called HFA 134a. This ingredient is less harmful to the environment than older inhalers. Older inhalers may taste different than Salbutrim Inhaler. This will make no difference to how your medicine works.

2. Before using this medicine

X Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).
- If you unexpectedly go into early labor (premature labor) or threatened abortion.

⚠ Special warnings about using this medicine

Talk to your doctor or pharmacist before taking Salbutrim Inhaler if:

- you have a history of heart problems such as an irregular or fast heartbeat or angina.
- you have an over active thyroid gland.
- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your doctor may start or increase a medicine to control your asthma such as an inhaled corticosteroid.

- you have high blood pressure.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

⚠ If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular tell the doctor or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat (especially beta blockers such as propranolol),
- other medicines for your asthma.
- medicines for depression (such as tricyclic anti-depressants, MAO blockers, and others).
- medicines that reduce potassium concentration in your blood (such as diuretics), which may cause hypokalemia.

⚠ Using the medicine and food

You can take Salbutrim Inhaler at any time of day, with or without food.

⚠ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

⚠ Driving and using machines

Salbutrim is not likely to affect your ability to drive or use any tools or machines.

3. How to use this medicine?

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure. Only your doctor will determine your dose and how you should take the medicine. The recommended dose is usually:

Adults and adolescents aged 12 years and over

To relieve asthma: One or two puffs.

To prevent asthma: Two puffs 10-15 minutes before exercise or exposure to an allergen.
For regular treatment: Two puffs up to 4 times a day.
The maximum dose is 8 puffs in a 24 hour period.

Children under 12 years of age

To relieve asthma: One puff. You may increase the dose up to 2 puffs if required.

To prevent asthma: One puff 10-15 minutes before exercise or exposure to an allergen. Two puffs, if required.
For regular treatment: Two puffs up to 4 times a day.
The maximum dose is 8 puffs in a 24 hour period.

- You may find an adaptor (spacer) device useful, with or without a face mask. If you have to give Salbutrim Inhaler to a baby or a child under 5 years old – speak to your doctor if you think you might need one of these.

Do not exceed the recommended dose.

Follow the **directions for use**, below.

If you have accidentally taken a higher dose consult your doctor as soon as possible. The following effects may happen:

- your heart beating faster than usual.
- tremor, you feel shaky.
- hyperactivity.

These effects usually wear off in a few hours.

If you forget to take the medicine

- 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.
- Persist with your treatment as recommended by the doctor.

If you stop taking this medicine

Do not stop taking Salbutrim Inhaler without talking to your doctor.

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

If you have any further questions about using this medicine, consult your doctor or the pharmacist.

4. 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.

Like all medicines, taking Salbutrim Inhaler may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

The following side effects may happen with this medicine:

Allergic Reactions (very rare, may affect up to 1 in 10,000 users). If you have an allergic reaction, stop taking Salbutrim Inhaler 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.

Consult your doctor immediately 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 your heart give an extra beat.
- these may happen in up to 1 in 10 people (common).

If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so.**

Additional side effects

Tell your doctor if you have any of the following side effects

which may also happen with this medicine:

Common side effects (may affect up to 1 in 10 users):

- feeling shaky.
- headache.

Uncommon side effects (may affect up to 1 in 100 users):

- mouth and throat irritation.
- muscle cramps.

Rare side effects (may affect up to 1 in 1,000 users):

- a low level of potassium in your blood.
- increased blood flow to your extremities.

Very rare side effects (may affect up to 1 in 10,000 users):

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

Side effects of unknown frequency:

- tremor, chest pain due to heart problems such as angina. Tell your doctor or pharmacist (do not stop using this medicine unless told to do so).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

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

If this medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your breathing problem may be getting worse and you may need a different medicine. Do not take extra doses of Salbutrim Inhaler unless your doctor tells you to.

Side effects and drug interactions in children and babies

Parents must inform their child's doctor about any side effect, as well as about any additional medicine given to the child!

You can report side effects to the Ministry of Health (MoH) by following the link “Reporting Side Effects of Medication” on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also follow this link: <https://sideeffects.health.gov.il>

You can also report side effects by email to: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/label. The expiry date refers to the last day of that month.
- Store in a cool place below 30°C. Do not freeze.
- Protect the inhaler from direct sunlight.
- After using the inhaler replace the cover by firmly pushing and clicking into position (do not use too much force).
- If the inhaler gets very cold, take the metal canister out

of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.

- Caution: The canister is pressurized. Do not puncture, break or burn it even when empty.

6. Additional information

- **In addition to the active ingredients this medicine also contains the following inactive ingredients:** 1,1,1,2-tetrafluoroethane (HFA 134a), absolute ethanol, oleic acid
- **What the medicine looks like and what are the contents of the package?**
This package contains a metal inhaler in plastic casing with a dust cap. Each inhaler contains 200 doses of medicine.

Registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Manufacturer: Laboratorio ALDO-UNIÃO, S.L., 08950 Esplugues de Llobregat, Barcelona, Spain.

Revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 149.19.33272.00

Directions for use

Inhale this medicine through your mouth into your lungs.

Do not take more than two puffs at once. When you need two puffs, wait about half a minute between puffs.

Testing your inhaler

Before using the inhaler for the first time, remove the mouthpiece cover by gently squeezing its sides (Figure 1), shake the inhaler well (Figure 2), and release one puff into the air to make sure that the inhaler works. If you have not used the inhaler for several days, shake it well and release one puff into the air to make sure that the inhaler works.

It is important to start to breathe as slowly as possible just before using your inhaler.

Using your inhaler

1. Remove the mouthpiece cover by gently pressing its sides (Figure 1).



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

4. Hold the inhaler upright (Figure 3) between your finger and thumb, with your thumb below the mouthpiece.

5. Breathe out as far as you can and then place the mouthpiece in your mouth between your teeth. Close your lips around it (Figure 3). Do not bite the inhaler.
6. Breathe in deeply and at the same time press down on the canister. This releases a measured dose of salbutamol (Figure 4).
7. Take the inhaler out of your mouth and hold your breath as long as is comfortable.
8. If you need to take more puffs, keep the inhaler upright and wait about half a minute before you take another puff. Repeat steps 3 to 7.
9. Replace the cover by firmly pushing and clicking into position. Rinse your mouth with water after each puff.

Do not rush Steps 5, 6, 7. It is important to breathe slowly before pressing down on the inhaler.

Practice in front of a mirror for the first few times. If you see a “mist” coming from the top of your inhaler or the sides of your mouth you should start again from Step 3.

If your doctor has given you different instructions for using the inhaler, follow those instructions carefully. Tell your doctor if you are having difficulties.

Young children may need their parents' help to operate the inhaler. 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 an adaptor (spacer) device useful, with or without a face mask. If you have to give Salbutrim Inhaler to a baby or a child under 5 years, 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. Your doctor or pharmacist will be able to advise you.

Cleaning your inhaler

Clean your inhaler at least once a week.

1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
2. Rinse the plastic casing thoroughly under warm running water.
3. Dry the plastic casing thoroughly inside and out.
4. Replace the metal canister in the plastic casing and put the mouthpiece cover back on.

Do not rinse the metal canister in water.

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