

LEAFLET: INFORMATION FOR THE USER

Airomir Inhaler, aerosol, 100 microgram/dose
salbutamol hemisulfate

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. WHAT IS AIROMIR INHALER AND WHAT IS IT USED FOR?

Airomir Inhaler belongs to a group of medicines called short-acting bronchodilators (effect lasts about 4-6 hours). Bronchodilators relax the muscles in the walls of the small air passages in the lungs. Airomir Inhaler:

- helps keep the airways in the lungs open, making it easier to breathe in and out
- helps relieve shortness of breath, wheezing, and gasping breathing

Airomir Inhaler is used for the treatment of shortness of breath attacks in chronic lung diseases (asthma, chronic bronchitis, emphysema).

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR SHOULD YOU BE EXTRA CAREFUL?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

When should you be extra careful with this medicine?

Increasing use of short-acting bronchodilators indicates worsening of the disease. If this is the case, your treatment should be adjusted by your doctor. You should be aware that a sudden or severe worsening of your asthma can lead to a life-threatening situation. In that case, contact your doctor as soon as possible.

Before you start using the Airomir Inhaler, you should inform your doctor if you:

- have or have ever had a heart condition, an irregular heartbeat, or a feeling of tightness in the chest

- have an overactive thyroid or weakness of the heart muscle
- are using the medicine digoxin (a medicine used for heart rhythm disorders)

Reports of tooth decay (caries) have been reported with the use of salbutamol. It is recommended to pay particular attention to good oral hygiene and regular dental check-ups, especially in children.

Contact your doctor or pharmacist before using this medicine.

Are you using any other medicines?

Are you using any other medicines besides the Airomir inhaler, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist.

The risk of low potassium levels in the blood (hypokalemia) can particularly occur with nebulization and parenteral (intravenous) administration of Airomir Inhaler. The risk of hypokalemia is increased with simultaneous use of theophylline (a medicine for asthma), corticosteroids (anti-inflammatories), diuretics (water pills), or due to low oxygen levels in your body (hypoxia).

Simultaneous use of salbutamol and non-selective beta-blockers such as propranolol (a medicine used to treat, among other things, high blood pressure) should be avoided unless there are compelling reasons to use them.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Your doctor will determine if you can use Airomir Inhaler during pregnancy and breastfeeding.

Driving and using machines

It is unlikely that Airomir Inhaler affects the ability to drive and use machines.

Airomir Inhaler contains ethanol

This medicine contains 5.5 mg of alcohol (ethanol) per dose. The amount per dose in this medicine is equivalent to less than 1 ml of beer or 1 ml of wine.

There is a small amount of alcohol in this medicine. This is so little that you will not notice it.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Airomir Inhaler is intended for inhalation use only, by breathing in through the mouth.

The usual dosage is:

Adults and adolescents (12 years and older):

- For the treatment of acute asthma attacks: the usual starting dose is 1-2 inhalations (100-200 micrograms once a day). Maximum 8 inhalations (800 micrograms) per day.

- To prevent exercise-induced asthma: 2 inhalations (200 micrograms) 10 to 15 minutes before exercise.
- As maintenance treatment according to your doctor's instructions, up to 8 inhalations per day.

Children (6 to 12 years):

- For the treatment of acute asthma attacks: the usual starting dose is 1 inhalation (100 micrograms) once a day. The dose can be increased to 2 inhalations (200 micrograms) if necessary. The maximum daily dose of 400 micrograms should not be exceeded.
- To prevent exercise-induced asthma: 1 inhalation (100 micrograms) up to 15 minutes before exercise.
- If necessary: the usual starting dose is 2 inhalations (200 micrograms) up to four times a day.

For children under 6 years, other formulations with corresponding spacer are available.

Airomir Inhaler should be used as needed rather than regularly.

If your asthma is active (you often have symptoms or flare-ups, such as shortness of breath that makes talking, eating, or sleeping difficult, coughing, wheezing, a feeling of tightness in the chest, or your physical ability is limited), tell your doctor immediately. Your doctor may advise you to start or increase the use of an asthma control medication, such as an inhaled corticosteroid.

Tell your doctor as soon as possible if your medication no longer seems to work as well as usual

(for example, if you need more inhalations to relieve your breathing problems or if using your inhaler provides relief for less than 3 hours), as this may indicate that your respiratory symptoms are worsening and you may need another medication.

If you use this medication more than twice a week to treat your asthma symptoms, not counting use to prevent exercise-induced asthma, it is a sign that your asthma is not well controlled. This can increase the risk of severe asthma attacks (worsening of asthma), which can have serious consequences and be life-threatening or even fatal. Contact your doctor as soon as possible to reassess your asthma treatment.

Do you use a daily medication for inflammation of your lungs, such as an 'inhaled corticosteroid'? Then it is important that you continue to use that medication regularly, even if you feel better.

Method of administration

Instructions for correct use

Your doctor, nurse, or pharmacist should give you instructions on the correct use of your inhaler. They should regularly check how you use the inhaler. If you do not use your Airomir inhaler as prescribed, it may mean that it does not help or is insufficient for the condition for which Airomir is prescribed.

The medication is in a metal canister under pressure. This canister is in a plastic holder with a mouthpiece (together with the inhaler). The inhaler produces a fine mist that must be inhaled into your lungs.

Testing your inhaler

1. If you are using the inhaler for the first time, test if it works properly. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pulling off the cover.
2. To ensure it works properly, shake the inhaler well. Point the mouthpiece away from you and press the canister, releasing two puffs into the air. If you have not used your inhaler for 5 days or more, you should release two puffs of medication into the air before use.

Using your inhaler

Before using your inhaler, it is important to start by inhaling as slowly as possible.

1. Stand or sit up straight when using your inhaler.
2. Remove the mouthpiece cover. Check the inside and outside of the mouthpiece to ensure it is clean and free of dust or dirt.
3. Hold the inhaler upright, with your thumb on the bottom and your forefinger on top of the canister. Shake the inhaler vigorously up and down.

Shake the inhaler well to ensure that loose objects (such as coins, pieces of plastic, or dust that may be present in your bag or clothing) are removed and that the contents are evenly mixed.

4. Breathe out gently as far as you can, but without forcing.
5. Place the mouthpiece in your mouth, between your teeth. Close your lips around it. Do not bite it.
6. Inhale through your mouth. Immediately after you start inhaling, press firmly with your index finger on the top of the canister to spray a puff of medicine into your mouth while continuing to inhale evenly and deeply.
7. Remove the inhaler from your mouth and hold your breath for 10 seconds, or as long as you can without much effort.
8. If you need more than one inhalation, wait about half a minute and then repeat steps 3 to 7.
9. Always replace the protective cap over the mouthpiece immediately after use to keep it dust-free.
10. Practice the first few times in front of a mirror. If you see 'mist' at the top of your inhaler or at the corners of your mouth, you need to start over.

Do not perform steps 4 to 7 too quickly. It is important that you start inhaling slowly before using the aerosol.

The care of your inhaler

Clean your inhaler every week. This is important because sometimes the small hole where the medicine comes out can become blocked. The inhaler will then not work properly.

You should clean your inhaler as follows:

- Remove the metal canister from the plastic holder. This canister should not be immersed in water.
- Remove the protective cap from the mouthpiece.
- Wash the plastic holder and the protective cap with warm running water for at least 30 seconds and let the water flow through the plastic holder as shown in figure A.
- Turn the plastic holder upside down and let the water flow through it again for at least 30 seconds as shown in figure B. This is important because sometimes the small hole where the medicine comes out becomes blocked.
- Shake the water off the holder and let the holder dry (preferably overnight) as shown in figure C.
- Replace the metal canister as shown in figure E.
- Replace the protective cap on the mouthpiece.

If you want to use your inhaler before it is dry, shake the water off the plastic holder and place the metal canister back as shown in figure E. Spray the first two puffs into the air before inhaling a dose yourself. Then wash the mouthpiece again and dry it as indicated in figures A, B, and C.

What to do if your inhaler is not working properly?

If your inhaler is blocked or if too little medication comes out when you press the inhaler (see figure D), you should consider the following:

The mouthpiece is dirty or clogged. Maintain your inhaler as indicated in figures A, B, and C.

Your inhaler is empty (see: How to determine if your inhaler is empty?).

The metal canister is incorrectly placed in the plastic holder. See figures E and F for this.

Figure E shows a cross-section of your inhaler with the canister in the correct position. Ensure that the valve stem is correctly placed in the plastic holder.

Figure F shows a cross-section of your inhaler with the canister incorrectly placed. The inhaler will not work properly in this case. You will notice this because no puff comes out when you press the inhaler.

Each inhaler is delivered complete. When it is empty, you can dispose of both the metal canister and the plastic holder.

How to determine if your inhaler is empty?

Remove the metal canister from the plastic holder and shake it. You will hear or feel the liquid in the canister; if not, it is empty. You should replace the canister as indicated in figure E.

You can also use the CountAir dose counter. Preference is given to an inhalation device with a dose counter or indicator to prevent using an empty inhaler.

Attention

The metal canister is under pressure. Do not pierce or throw it into the fire, even when it is empty.

Have you used too much of this medication?

It is important that you use Airomir Inhaler according to your doctor's instructions. If you have taken more inhalations of Airomir Inhaler than prescribed by your doctor, the following symptoms may occur: accelerated heartbeat (tachycardia), palpitations, irregular heart rhythm (arrhythmia), chest pain, and strong tremor, particularly of the hands but also of the whole body. Nausea, dizziness, increased systolic blood pressure, and decreased diastolic blood pressure. Occasionally, psychological reactions where the individual has lost contact with reality (psychotic reactions) have been observed after excessive dosing of salbutamol. If these symptoms occur, you should contact your doctor.

Have you forgotten to use this medication?

If you have forgotten to inhale your medication, you should take the next dose at the prescribed time. Do not take a double dose to make up for a forgotten dose.

If you stop using this medication

You may only discontinue the use of the Airomir Inhaler on your doctor's prescription.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can cause side effects. Not everyone will experience them.

The frequencies of the side effects mentioned below are classified as follows:

Very common: in more than 1 in 10 patients

Common: in 1 to 10 in 100 patients

Uncommon: in 1 to 10 in 1,000 patients

Rare: in 1 to 10 in 10,000 patients

Very rare: in less than 1 in 10,000 patients

Not known: cannot be determined from the available data

The following side effects have been reported with the use of Airomir Inhaler.

Common:

- tremor
- headache
- increased heart rate (tachycardia)

Uncommon:

- feeling shaky and a fast or irregular heartbeat (palpitations)
- muscle cramps
- irritation of the mouth and throat

Rare:

- low potassium levels in the blood (hypokalemia)
- vasodilation (peripheral vasodilation)

Very rare:

- hypersensitivity reactions, including itchy swellings caused by (allergic) hypersensitivity reactions (angioedema), hives (urticaria), muscle cramps around the windpipe (bronchospasms), low blood pressure (hypotension), and fainting (collapse)
- hyperactivity
- arrhythmias

Although it is not exactly known how often it occurs, some people may occasionally feel chest pain. This pain may be caused by heart problems. Inform your doctor (or if you are pregnant, your midwife) if you experience such symptoms while using salbutamol. Do not stop using salbutamol on your own, only do so if advised by your doctor.

Unknown (spontaneously reported):

- oxygen deficiency of the heart muscle (myocardial ischemia)
- tooth decay (caries)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store below 30°C. Do not store in the refrigerator or freezer.

Avoid exposure to direct sunlight. The container is under pressure. Do not pierce or burn.

When you use your inhaler for the first time or if you have not used it for 5 days or longer, you should first shake the inhaler and then spray the first two puffs into the air instead of inhaling them.

Do not use this medicine after the expiry date. You can find it on the packaging after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is salbutamol hemisulfate. Each dose contains an amount of salbutamol hemisulfate equivalent to 100 µg salbutamol.
- The other substances (excipients) in this medicine are ethanol, propellant tetrafluoroethane HFA-134a, and oleic acid.

This medicine contains fluorinated greenhouse gases.
Each inhaler contains 7.24 grams of tetrafluoroethane. This is equivalent to 0.01035 tons CO₂ (global warming potential GWP = 1430).

What does the Airomir Inhaler look like and what is in a package?

Airomir inhaler is an aerosol containing 200 metered doses of salbutamol hemisulfate, equivalent to 100 µg salbutamol per dose.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Teva Nederland B.V.

Swensweg 5

2031 GA Haarlem

Netherlands

Manufacturer:

Norton (Waterford) Limited T/A Teva Pharmaceuticals Ireland

Unit 27/35, IDA Industrial Park, Cork Road, Waterford

Ireland

Registered under

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