

Airomir® Autohaler®

(airo-meer auto-hailer)

Active ingredient: *Salbutamol sulfate (sal-bute-a-mol sull-fate)*

Consumer Medicine Information (CMI)

This leaflet provides important information when using AIROMIR Autohaler. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions when using AIROMIR Autohaler.**

Where to find information in this leaflet:

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1. Why am I using AIROMIR?

AIROMIR contains the active ingredient salbutamol sulfate.

Salbutamol sulfate is a direct acting sympathomimetic agent belonging to the beta-agonist family of medicines. It opens up the airways to your lungs, thereby relieving wheezing and the feeling of tightness in your chest, helping you to breathe more easily.

Asthma causes the lining of your lungs to become inflamed (red and swollen), making breathing difficult. AIROMIR is designed to enable the medicine to be inhaled into the lungs to treat asthma and other conditions where breathing is difficult.

AIROMIR is known as a RELIEVER medicine.

AIROMIR may also help prevent wheezing and chest tightness when you exercise. That's why your doctor or pharmacist may advise you take one or two puffs before exercise.

AIROMIR is designed to be part of a general plan to help you manage your asthma. Every asthma patient is different. Ask your doctor or pharmacist for an ASTHMA MANAGEMENT PLAN that suits you and visit them regularly to check whether your plan needs to be changed.

2. What should I know before using AIROMIR?

Warnings

Do not use AIROMIR:

- If you are allergic to salbutamol sulfate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue, or other parts of the body

- rash, itching or hives on the skin.

- After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you:

- Have allergies to any other medicines, foods, preservatives or dyes.
- Have or have previously suffered from the following:
 - Heart, liver or kidney problems
 - Diabetes (high blood sugar)
 - High blood pressure
 - Problems with your thyroid gland
 - Hypoxia (reduced oxygen in the tissues).
- Have any other medical conditions or take any medicines for any other condition.
- Are unsure whether you should start using AIROMIR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use AIROMIR if you are pregnant or intend to become pregnant. AIROMIR should be avoided as it is probable that the active ingredient, salbutamol sulfate, can pass through the placenta, and may affect your developing baby if used during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with AIROMIR and affect how it works.

These include:

Any medications for high blood pressure or angina

Theophylline or any steroids

Fluid tablets (diuretics).

These medicines may be affected by AIROMIR or may affect how well they work. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AIROMIR.

4. How do I use AIROMIR?

How much to take:

Adults & Children

- The usual dose is one or two puffs to relieve wheezing or before exercise.
- Do not use more than 16 puffs per day unless your doctor or pharmacist has prescribed a specific dose for you.
- Children should be supervised by a responsible adult when using AIROMIR.

Elderly

- Follow the instructions as prescribed by your doctor.

When to use AIROMIR:

Carefully follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

How to use AIROMIR:

Even if you have been using another type of Autohaler read the instructions in this leaflet before you start. If you do not understand the instructions, ask your doctor or pharmacist for help.

Airomir Autohaler Instructions for Use:

If your AIROMIR Autohaler is new or you have not used it for two weeks, you must test fire it by releasing two puffs into the air away from your face.

STEP 1: Remove the Mouthpiece Cover and Shake:

Remove the mouthpiece cover by unclipping it from the back.

Check that the mouthpiece is clean before use.

Hold the autohaler unit upright between your thumb and index finger and shake well.

STEP 2: Hold Upright and Push Lever Up:

Push the lever up so that it stays up.

Keep holding the autohaler unit upright making sure your hand is not blocking the air vent at the bottom.

STEP 3: Breathe Out and Position Mouthpiece:

Breathe out as far as you comfortably can and immediately close your lips around the mouthpiece.

STEP 4: Breathe In:

Breathe in slowly and deeply through the mouthpiece.

Do not stop breathing when you hear the 'click and whoosh' and feel the puff in your mouth. It is important to keep breathing in after the puff is released.

STEP 5: Hold Your Breath:

Hold your breath for 10 seconds and then breathe out slowly.

STEP 6: Push Lever Down:

After each puff return the lever to the down position whilst holding the autohaler unit upright.

If your doctor has prescribed more than one puff repeat steps 2 to 6.

Replace the mouthpiece cover after use.

Remember to push the lever up before each puff and gently back down afterwards, always holding the autohaler upright. This prepares the autohaler for your next dose. The lever

should be left down between treatments and the mouthpiece replaced to keep your Autohaler clean.

How to Test Fire or Tell if Your Airomir Autohaler is Empty:

STEP 1: Remove the Mouthpiece Cover:

By unclipping it from the back and shake the Autohaler.

STEP 2: Hold the Autohaler Upright:

Point the mouthpiece away from you so that the puffs of medicine will go into the air.

STEP 3: Push the Lever Up:

So that it stays up.

STEP 4: Release a Puff:

By pushing the dose release slide (on the bottom of the autohaler unit) in the direction of the arrow.

STEP 5: To Release a Second Puff:

First return the lever to its down position, then repeat steps 2 and 3. Repeat until you have released four puffs altogether.

STEP 6: Always Push the Lever Back Down after Test Firing:

This prepares the AIROMIR Autohaler for your next dose.

If your AIROMIR Autohaler is empty you will not feel or hear a puff being discharged when you test fire.

Do not use the dose release slide to take your medicine.

Your AIROMIR Autohaler will automatically release a dose when you begin to breathe in from the mouthpiece.

AIROMIR Autohaler is designed for ease of use. To make it work you just breathe in through the mouthpiece. **There is no need to press and breathe in at the same time.**

A click and whoosh sound tells you that the Autohaler has automatically released the correct dose of medicine.

If Your Airomir Autohaler Doesn't Work Properly:

When your Autohaler is blocked, little or no medicine comes out when you press down on the metal canister. This may be due to one of the following reasons:

- A dirty or clogged mouthpiece: Wash the mouthpiece as described in Step 1 and air dry thoroughly as described in Step 2 (for instructions see "Looking after your medicine" of this leaflet).
- It may be empty. Check by shaking.
- It may be put together incorrectly.

It is important that the canister is in the correct position in your Autohaler. The narrow stem of the metal canister should be fitted into the small socket.

If the stem of the metal canister is not in the small socket, your autohaler will not work.

Do not take your Autohaler apart. Do not drop or hit your Autohaler because this may damage it.

If you take too much AIROMIR:

Taking too much of any asthma medication may be harmful. Potential unwanted side effects may include feeling tense and shaky and experiencing an increase heart rate.

If you think that you have taken too much AIROMIR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using AIROMIR?

Things you should do:

- If you are about to start on any new medicines, remind any doctor, dentist or pharmacist you visit that you are using AIROMIR.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using AIROMIR. It may affect other medicines used during surgery.
- If you have an Asthma Management Plan, always follow it closely.
- Continue using AIROMIR for as long as your doctor or pharmacist tells you. Visit your doctor regularly to check on your asthma condition.

Call your doctor straight away if you:

- Become pregnant while using AIROMIR
- Do not feel well while you are using AIROMIR
- Feel that your usual dose of AIROMIR does not seem to be working or it is not lasting as long as before
- Think your asthma is getting worse (ie: you suffer more frequent asthma attacks).

Things you should not do:

- Do not use AIROMIR to treat any other conditions unless your doctor or pharmacist tells you to do so.
- Do not give your medicine to anyone else to use, even if they have the same condition as you.
- Do not use more puffs than the recommended dose unless your doctor or pharmacist tells you to.

Driving or using machines:

Be careful before you drive or use any machines or tools until you know how AIROMIR affects you.

Drinking alcohol:

Tell your doctor if you drink alcohol.

Looking after your medicine:

Follow the instructions in this leaflet on how to properly take care of your medicine.

Care and Cleaning:

Keeping the plastic mouthpiece clean is very important to prevent the Autohaler from becoming dirty and clogged.

Your Autohaler should be cleaned at least once a week as follows:

STEP 1: Wash mouthpiece under warm running water

Remove the canister and put aside in a safe place. Never immerse the canister in water.

Wash the mouthpiece through the top and bottom with warm running water for 30 seconds.

Wash the mouthpiece cover as well.

STEP 2: Shake off excess water and air dry

To dry, shake off excess water and leave the mouthpiece and cover in a safe place to air dry thoroughly, such as overnight.

When the mouthpiece is dry, replace the canister and the mouthpiece cover.

If you need to use your Autohaler before it is completely dry, shake off excess water, replace the canister and remove most of the water remaining in the mouthpiece by test spraying twice into the air away from your face. Then take your dose as prescribed. After use, wash the Autohaler again and air dry thoroughly as recommended above.

NOTE: a blockage from a build-up of medication is more likely to occur if the mouthpiece is not allowed to air-dry thoroughly.

Storage:

Store below 30°C and protect from heat.

Store the AIROMIR Autohaler with the mouthpiece cover attached to protect your medicine.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine:

Do not puncture the container or throw it into the fire even when it is empty as the canister may explode.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious common side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Headache• Minor irritation to your mouth and throat• Fine shaking in the hands• Dizziness• Light headedness• Feeling tense• Nausea• Leg cramps• Itching and irritation.	Speak to your doctor or pharmacists if you have any of these less serious common side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Chest pain• Heart palpitations (when your heart beats faster and harder than normal)	Call your doctor or pharmacist straight away, or go straight to the Emergency Department at your

Serious side effects	What to do
<ul style="list-style-type: none"> Lowering of the potassium level in your blood. 	nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects:

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What AIROMIR contains:

Active ingredient (main ingredient)	Salbutamol sulfate
Other ingredients (inactive ingredients)	Ethanol Oleic acid Norflurane
Potential allergens	Ethanol

Do not take this medicine if you are allergic to any of these ingredients.

What AIROMIR looks like:

AIROMIR AUTOHALER is homogenous creamy-white to greyish-white coloured suspension supplied in a metal canister sealed inside a plastic autohaler unit. At the bottom of the autohaler unit is a mouthpiece with a plastic cover. At the top of the autohaler unit is a lever. Available in pack sizes of 200 doses.

Australian registration number: AUST R 67257

Who distributes AIROMIR:

Australia

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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