

Airomir® Inhaler

Salbutamol



Package leaflet: Information for the user

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Airomir Inhaler is and what it is used for
2. What you need to know before you use Airomir Inhaler
3. How to use Airomir Inhaler
4. Possible side effects
5. How to store Airomir Inhaler
6. Contents of the pack and other information

1. What Airomir Inhaler is and what it is used for

Airomir Inhaler contains salbutamol, which is a bronchodilator. It opens up the breathing tubes of the lungs and makes breathing easier. Salbutamol can help you feel less tight chested and less breathless or less wheezy.

Airomir Inhaler is used:

- to treat asthma
- to prevent asthma following exercise
- for the relief of wheezing and shortness of breath caused by certain other chest diseases.

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2. What you need to know before you use Airomir Inhaler

Do not use Airomir Inhaler:

- if you are allergic to salbutamol or any of the other ingredients of this medicine (listed in section 6).
- unexpectedly go into early labour (premature labour) or threatened abortion.

Airomir Inhaler should be used as required rather than regularly.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Airomir Inhaler if :

- your asthma is active (for example you have frequent symptoms or flare ups, such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability), you should tell your doctor right away who may start or increase a medicine to control your asthma such as an inhaled corticosteroid
- you have high blood pressure
- you have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina
- 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.

Tell your doctor as soon as possible if your medicine does not seem to be working as well as usual (for example you need higher doses to relieve your breathing problems or your inhaler fails to give relief for at least 3 hours) as your asthma may be getting worse and you may need a different medicine.

If you use Airomir Inhaler more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

Children and adolescents

Consult a doctor immediately if your usual treatment is not working or if you need more than 8 puffs per day (adult) or 4 puffs per day (children) or in case of worsening asthma symptoms. Your dose or frequency should only be increased on medical advice.

Other medicines and Airomir Inhaler

Tell your doctor or pharmacist if you are taking any other medicines:

- | | |
|--|--|
| • xanthines e.g. aminophylline or theophylline | • metronidazole |
| • disulfiram | • steroids |
| • water tablets (diuretics) | • long-term laxatives |
| • beta-blockers e.g. propranolol | • medicines used to treat heart disease e.g. digoxin |
| • monoamine oxidase-inhibitors | • tricyclic antidepressants e.g. amitriptyline or |
| (anti-depressants) e.g. phenelzine | trazodone. |

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.

If you are having treatment that requires a general anaesthetic, please tell your anaesthetist that you are taking Airomir Inhaler. Do not use this medicine for at least six hours before the intended anaesthetic.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking this medicine. Airomir Inhaler should only be used if recommended by a doctor.

Driving and using machines

Airomir Inhaler may cause dizziness. If you are affected, DO NOT drive or operate machinery.

Airomir Inhaler contains ethanol

This medicine contains 4 mg of alcohol (ethanol) in each puff (metered dose). The amount in each puff (metered dose) of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Airomir Inhaler

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you see any other doctor or dentist, please tell them that you are using Airomir Inhaler.

Use in children and adolescents

The recommended dose is:

Adults (including the elderly)

- **For the relief of symptoms such as wheezing and shortness of breath**
Either one or two puffs as needed.
- **For asthma due to exercise**
Two puffs before exercising.

Do not take more than eight puffs in 24 hours.

Children (aged 4 to 11 years)

- **For the relief of symptoms such as wheezing and shortness of breath**
Usually one puff. This may be increased to two puffs if necessary.
- **For asthma due to exercise**
Usually one puff before exercising. This may be increased to two puffs if necessary.
- **For chronic therapy**
Usually up to two puffs four times daily.

Children (aged 12 years and over)

Dose as per adult population.

Children using this inhaler should be supervised by an adult and should use this inhaler only as advised by the doctor.

All patients

- **If you have taken a dose of two puffs, then you should wait four hours before taking another dose. You should not take more than eight puffs in 24 hours.**
- **You should check with your doctor or pharmacist about when to use your inhaler and how many puffs you must use each day if you are not sure.**
- **If your usual treatment is not working or you need more than eight puffs per day, please tell your doctor. You should not increase your dose without consulting your doctor.**

If you use more Airomir Inhaler than you should

If you accidentally take more puffs than your doctor told you to, please contact your nearest hospital casualty department or tell your doctor immediately. You may notice that your heart is beating faster than usual, that you feel shaky or tense, you may have a headache or your skin may look flushed and feel hot. These effects normally wear off in a few hours. Your doctor may want to check your blood potassium levels.

If you stop using Airomir Inhaler

DO NOT stop taking your medicine without talking to your doctor first even if you feel better.

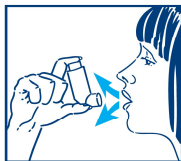
How to use the Airomir Inhaler device

- This inhaler has a different feel and taste to CFC inhalers you may have used before.
- **If this is a new inhaler or you have not used the inhaler for two weeks or more, it must be tested before use by shaking the unit and then releasing four puffs into the air.**

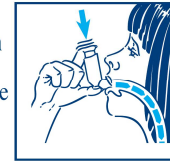
1. Remove the cover from the mouthpiece and shake the inhaler vigorously.



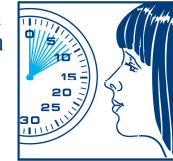
2. Holding the inhaler as shown, breathe out gently (but not fully) and then immediately place the mouthpiece in your mouth and close your lips around it.



3. Start to breathe in slowly and deeply through your mouth, and press down on the canister inside the inhaler as shown. This releases one puff of medication. It is important that you continue to breathe in after releasing the puff.



4. Hold your breath for 10 seconds, then breathe out slowly. After use, replace the cover on the mouthpiece



Some people find it difficult to press their inhaler and breathe in at the same time.

A spacer device helps to overcome this problem. The spacer that fits **Airomir Inhaler** is called the AeroChamber Plus[®] spacer device. If you use the AeroChamber Plus[®] spacer device please follow the instructions provided with it. Your doctor, nurse or pharmacist will be able to advise you about the AeroChamber Plus[®] device.

Airomir Inhaler is also still suitable for use with the original AeroChamber[®] device.

How to tell when your Airomir Inhaler is empty

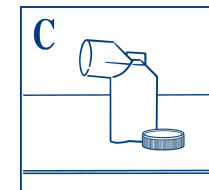
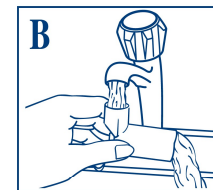
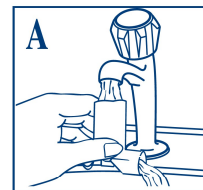
Remove the metal canister from the plastic inhaler unit and shake it. You should be able to hear or feel the sensation of liquid inside the canister. Replace the canister as shown in picture E.

How to clean and care for your Airomir Inhaler

- **Clean your inhaler every week.** This is very important because sometimes the small hole where the medicine comes out can become blocked and therefore the inhaler is unable to work properly.

To clean your inhaler

- Take the metal canister out of the plastic inhaler unit. The canister should not be put in water.
- Remove the plastic mouthpiece cover.
- Rinse both the plastic parts in **warm**, running water for at least 30 seconds.
- Let the water run through the mouthpiece as shown in picture A.
- Turn the plastic inhaler unit around and let the water run through the unit as shown in picture B for another 30 seconds. This is very important as sometimes the small hole where the medicine comes out can become blocked.
- Shake off the excess water and leave the plastic parts to dry completely (overnight if possible) as shown in picture C.
- When the mouthpiece is dry replace the canister and the mouthpiece cover.

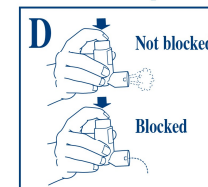


If you need to use your inhaler before it is dry, shake off any excess water from the plastic mouthpiece and insert the metal canister. Spray two puffs into the air before taking your usual dose. Then wash the mouthpiece again and dry completely as shown in pictures A, B and C. **NOTE:** Blockage from medication build-up is more likely to occur if the mouthpiece is not allowed to dry thoroughly.

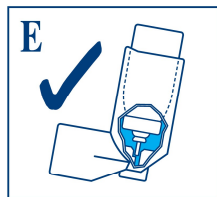
If your inhaler does not work properly

If your inhaler is blocked, or little or no medicine comes out when you press down the metal canister (see picture D), this may be for the following reasons:

- A dirty or clogged mouthpiece. Wash and dry the mouthpiece as described in pictures A, B and C.
- Your inhaler may be empty. Check by shaking the canister.



- Your inhaler may be incorrectly put together. See pictures E and F.



Picture E shows the inside of your inhaler with the canister in the correct position. Note that the narrow stem of the metal canister should be fitted into the small socket.

Picture F shows the inside of your inhaler with the canister in the wrong position. When this happens, your inhaler will not release a puff of medication when you press down on the canister. This is because the metal nozzle (stem) is not in the small socket.

Further questions

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If, immediately after inhaling a puff, your asthma worsens, do not take any more puffs and contact your doctor straight away.

Stop using the Airomir Inhaler and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives, and a fall in blood pressure. You might collapse in very rare circumstances). This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

Common: may affect up to 1 in 10 people

- feeling tense
- headache
- dizziness
- mild tremor (shaking), especially of the hands.

Uncommon: may affect up to 1 in 100 people

- mouth and throat irritation
- Muscle pain, muscle cramps.

Rare: may affect up to 1 in 1,000 people

- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- sleep disturbances and sensing things that are not real have been reported especially in children
- faster heart beat
- abnormal heart beat
- widening of blood vessels
- feeling sick
- vomiting

Very rare: may affect up to 1 in 10,000 people

- Difficulty in sleeping
- Difficulty in breathing or wheezing
- Irregular heart beat, especially when used with beta-blockers
- Chest pain

- Itching skin.

Not known: frequency cannot be estimated from the available data.

- Restriction of blood supply to the heart.

Using Airomir Inhaler may rarely lead to a build up of lactic acid or low potassium levels in your blood. Your doctor may wish you to have regular blood tests to check your blood potassium levels.

Although it is not known exactly how often this happens, some people may experience chest pain (due to heart problems such as angina). Tell your doctor as soon as possible if you develop these symptoms whilst receiving treatment with Airomir, but do not stop taking this medicine unless told to do so.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Airomir Inhaler

Keep this medicine out of the sight and reach of children.

Store this inhaler below 30°C. Avoid storage in direct sunlight or heat. Protect from frost.

The metal canister is pressurised. Do not attempt to puncture it or burn it, even when empty.

Do not use Airomir Inhaler after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

Chlorofluorocarbons (CFCs) have been shown to damage the ozone layer in the atmosphere. Your Airomir Inhaler does not contain CFCs, instead the inhaler contains a hydrofluoroalkane (HFA-134a) as an inactive ingredient. HFAs have been developed as a replacement for CFCs because they do not damage the ozone layer.

What Airomir Inhaler contains:

- The active ingredient is salbutamol.
Each puff contains salbutamol sulfate equivalent to salbutamol 100 micrograms.
- The other ingredients are oleic acid, ethanol, propellant HFA-134a. Propellant HFA-134a is a new propellant which has been developed to replace chlorofluorocarbons (CFCs). This inhaler does not contain CFC propellants.
- This medicine contains fluorinated greenhouse gases.
- Each inhaler contains 7.24 g of norflurane (HFA-134a) corresponding to 0.01035 tonne CO₂ equivalent (global warming potential GWP = 1430).

What Airomir Inhaler looks like and contents of the pack:

- The Airomir Inhaler is a pressurised inhalation suspension.
- This inhaler contains 200 puffs.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

The manufacturer is Kindeva Drug Delivery Limited, Derby Road, Loughborough, LE11 5SF, UK.

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