

AIROMIR® INHALER SALBUTAMOL

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

- 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. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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.

2. BEFORE YOU USE AIROMIR INHALER

DO NOT use Airomir Inhaler if you:

- are allergic (hypersensitive) to salbutamol or any of the other ingredients of this medicine.

Airomir Inhaler should NOT be used to treat premature labour or threatened miscarriage, as inhaled salbutamol products are not suitable for this purpose.

Take special care with Airomir Inhaler

Talk to your doctor before you start to take this medicine if you:

- have thyroid problems
- have severe asthma
- have hypoxia (a lack of oxygen in the body)
- have a history of heart disease or angina.

Taking other medicines

Talk to your doctor if you are taking any of the following:

- xanthines e.g. aminophylline or theophylline

- metronidazole
- disulfiram
- steroids
- water tablets (diuretics)
- long-term laxatives
- beta-blockers e.g. propranolol.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription.

Important information about some of the ingredients of Airomir Inhaler

- Airomir Inhaler contains a small amount of ethanol (alcohol)

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.

Driving and using machines

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

3. HOW TO USE AIROMIR INHALER

Always use Airomir Inhaler exactly as your doctor has told you. You should 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.

The usual 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.

Children

- **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.

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. An overdose is likely to cause agitation and fast heart beat.

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 may come 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, Airomir Inhaler 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).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

- feeling sick
- being sick
- a dry, sore mouth
- dizziness
- headache
- mild tremor (shaking) of the hands
- muscle cramps
- tachycardia (fast heart rate) or palpitations
- hyperactivity may occur rarely in children.

Using Airomir Inhaler may lead to 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.

If any of the side effects continue for more than a few days, get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE AIROMIR INHALER

Keep out of the reach and sight 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 sulphate 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.

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, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, United Kingdom.

The manufacturer is 3M Health Care Limited, Loughborough, Leicestershire, LE11 1EP, England.

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