

Applicant: Unimed Healthcare (Pty) Ltd
Product name: Azmaler
Dosage form and strength: Metered Dose Inhaler. 100 µg Salbutamol Sulphate

PATIENT INFORMATION LEAFLET AZMALER

SCHEDULING STATUS

S2

AZMALER

Salbutamol Sulphate

-Read all of this leaflet carefully because it contains important information for you.

AZMALER is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use AZMALER carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share AZMALER with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

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1. What AZMALER is and what it is used for:

Each metered dose contains salbutamol sulphate equivalent to 100 µg salbutamol, which is one of a group of medicines called fast acting bronchodilators.

Salbutamol relaxes the muscles in the walls of the air passages in the lungs. This helps to open up the airways and helps to relieve chest tightness, wheezing and cough, so you can breathe more easily.

AZMALER is used for the relief of bronchospasm in all types of bronchial asthma, chronic bronchitis and emphysema. It helps the airways in your lungs to stay open, making it easier for air to get in and out.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AZMALER

Do not use AZMALER:

- If you are hypersensitive (allergic) to salbutamol or any of the other ingredients of AZMALER (see section 6).
- In the treatment of premature labour (you unexpectedly go into early labour) or threatened abortion.
- If you are taking propranolol, sotalol, timolol or other beta-blockers for heart disorders, high blood pressure or glaucoma, as these medicines counteract the effects of AZMALER and should not be taken concurrently (see '**Other medicines and AZMALER**').
- If you are taking mono-amine oxidase inhibitors, including selegiline for Parkinson's disease or moclobemide for depression, or within 14 days after stopping such medicines. Please ask your doctor or pharmacist for advice (see '**Other medicines and AZMALER**').
- If you are pregnant or breastfeeding your baby, as safety has not been established (see '**Pregnancy, breastfeeding and fertility**').

Warnings and precautions:

Special care should be taken with AZMALER:

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- If you have an overactive thyroid gland
- If you have a history of heart problems, such as coronary artery disease, an irregular or fast heartbeat or angina (chest pain)
- If you have high blood pressure
- If you are using any medicines that mimics the sympathetic nervous system
- If you are taking beta blocking medicines, such as propranolol
- Paradoxical bronchospasm (constriction of the airways after using a bronchodilator), with an immediate increase in wheezing, after using AZMALER (see **POSSIBLE SIDE EFFECTS**), please seek medical attention. The use of AZMALER should be discontinued immediately.
- Acute severe asthma and you are using xanthine derivatives (e.g. theophylline), corticosteroids (e.g. prednisone) and water tablets (diuretics, (e.g. furosemide, hydrochlorothiazide), because there is a risk of serious hypokalaemia (a condition of low potassium levels in the blood) when AZMALER is used in combination with these medicines. Your doctor may regularly monitor your blood potassium levels.
- Unstable or severe asthma, AZMALER should not be your main or only treatment. Consult your doctor for routine medical assessments to ensure adequate control. When using corticosteroid therapy in the prevention of asthma attacks, AZMALER is used as rescue medicine to treat acute asthma attacks. Seek urgent medical attention if AZMALER fails to provide relief.
- Hypoxia (a condition where there are insufficient levels of oxygen in your blood and body tissues). Do not exceed the maximum dose.
- If you have diabetes, your blood sugar levels should be monitored regularly.
- If you have to increase the use, or experience a decrease in duration of relief of AZMALER, because this may indicate worsening of asthma. Consult your doctor for routine medical assessments to ensure adequate control. Seek medical attention if a previous effective dose of AZMALER fails to relieve bronchospasm for a duration of at least three hours.
- If you take part in competitive sport activities. The use of salbutamol as contained in AZMALER may lead to a positive test for prohibited substance.

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- AZMALER may cause a fine tremor of your hands or other muscles (see '**Possible Side Effects**'). If this side effect should continue or become bothersome, please discuss the continued use of AZMALER with your doctor.
- Older people maybe more sensitive to the side effects of AZMALER.

Other medicines and AZMALER

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.) Please discuss the use of the following medicines in combination with AZMALER with your doctor or pharmacist:

- Halogenated anaesthetics, such as cyclopropane, halothane or other halogenated anaesthetics (used in surgery)
- Cardiac glycosides, e.g. digoxin (used to treat heart failure)
- Quinidine (used to treat heart rhythm disorders)
- Tricyclic antidepressants or monoamine oxidase inhibitors (such as phenelzine or selegiline (used to treat depression)
- Beta-blocking medicines, e.g. propranolol (used to treat tremors, angina (chest pain), hypertension (high blood pressure), heart rhythm disorders, or other heart or circulatory conditions)
- Corticosteroids, e.g. prednisone (used to treat allergic disorders, skin conditions, ulcerative colitis, arthritis, lupus, psoriasis or breathing disorders)
- Diuretics, also called "water pills" (use to treat high blood pressure)
- Xanthine derivatives, e.g. theophylline (also used to treat asthma)

If you are also using other inhalation medicines for the treatment of asthma or tightness of the chest (e.g. steroid or ipratropium inhalations), use ASTHAVENT ECOHALER 5 minutes before your other medicine(s), unless otherwise directed by your doctor.

Pregnancy and breastfeeding

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If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your healthcare provider for advice before using AZMALER. Safety during pregnancy and breastfeeding has not been established.

Driving and using machinery

AZMALER is not likely to affect your ability to drive a vehicle or use any tools or machines. However, take special care when performing tasks that require your attention, until you know how you will react to AZMALER.

AZMALER contains a small amount of alcohol (ethanol). This medicine contains 4,329 mg of alcohol (ethanol) in each puff of this inhaler. The amount in each puff of this medicine is equivalent to less than 0,108 ml of beer or 0,433 ml wine.

Using AZMALER with food and drink:

You can use AZMALER at any time of the day, with or without food.

3. HOW TO USE AZMALER

Always use AZMALER exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure (see instructions below).

AZMALER is used by the inhaled route only (breathed in through the mouth). Confirm with your doctor that you use the correct inhaler technique. Make sure that the aerosol actuation is at the same time as the inspiration of breath, for optimum delivery of AZMALER to your lungs. You may experience a different taste when using AZMALER, if you have previously used another inhaler.

Shake well before use.

One (1) or two (2) inhalations (puffs), repeated every 4 hours if required. The bronchodilator effect of each administration of AZMALER lasts for at least 4 hours and more frequent use of AZMALER should

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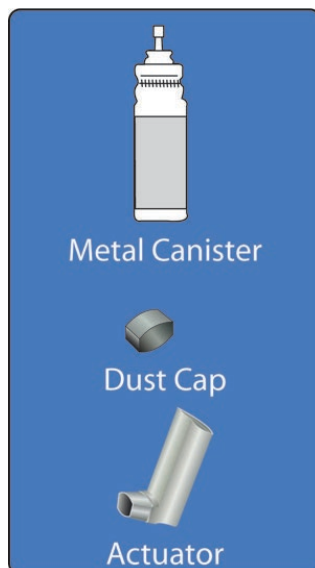
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be unnecessary. Consult your doctor if the effect of a previously adequate dose lasts for less than 3 hours.

AZMALER acts rapidly and may be used when necessary to relieve attacks of sudden shortness of breath (acute dyspnoea). AZMALER may be used, before exercise or exposure to a “trigger” to prevent asthma.

If you have severe or unstable asthma, you may also use other asthma medicine and have regular medical check-ups, as the condition is potentially life-threatening.

Parts of the inhaler:



Testing your inhaler:

Before using your inhaler for the first time, remove the dust cap and shake the inhaler well. To test whether the inhaler is in working order, release 2 (two) puffs into the air. If you did not use your inhaler for a few days, test the inhaler by shaking it well and releasing 1 (one) puff into the air before using.

Directions for use:

Study the directions for use carefully before using your inhaler.

1. Shake well:

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Remove the dust cap and ensure that the mouthpiece is clean on the inside and outside. Shake the inhaler before each use.

2. Exhale gently:



Holding the inhaler away from the mouth, breathe out gently (but not fully).

3. Press:



Hold the inhaler between the finger(s) and thumb, place the thumb under the mouthpiece, to support the base. Place the mouthpiece in the mouth, between your teeth, and close the lips around it (make sure not to bite the mouthpiece). After starting to breathe in slowly and deeply through your mouth, press the metal canister down firmly to release the suspension, and continue to breathe in.

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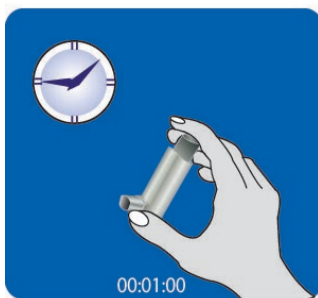
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4. Hold breath for 10 seconds:



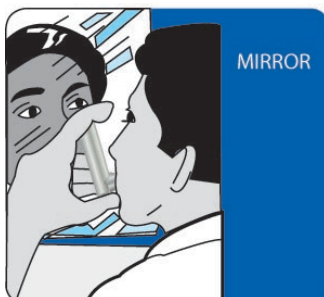
Remove the inhaler from your mouth and continue to hold your breath for 10 seconds, or as long as it is comfortable, then breathe out slowly.

5. Second inhalation (if required) – Wait 1 minute:



If you are to take a second inhalation, you should wait for at least one minute before repeating steps 2, 3 and 4. Replace the dust cap on the mouthpiece after use.

NOTE:



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Do not rush steps 3 and 4. It is essential that you breathe in as slowly as possible when using your inhaler. Check your technique in front of a mirror from time to time. If you see a white mist during the inhalation, you may not have closed your lips properly around the mouthpiece, or you may not be breathing in as you press the canister. This indicates failure of technique. If this happens, repeat the procedure from step 2 carefully. Consult your healthcare provider if you are having any difficulties with the technique.

Directions for cleaning:



It is very important that the actuator (plastic casing) and mouthpiece are cleaned regularly to prevent the build-up of spare suspension. Remove the metal canister and wash the plastic mouthpiece in warm water at least twice a week. Wipe the plastic casing and mouthpiece with a damp cloth. Leave the plastic casing to dry in a warm place overnight. Avoid excessive heat. Replace the metal canister and dust cap. No harm will come from washing the mouthpiece every day. For further assistance or information, please consult your healthcare provider.

If you use more AZMALER than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdosage may include tachycardia (fast irregular heartbeat), tremor (shaking), hyperactivity, metabolic effects (including low levels of potassium, elevated serum lactate and metabolic acidosis), feeling agitated or irritated and hallucinations (seeing or hearing things that do not exist). Discontinue the use of AZMALER in the case of overdosage.

If you forget to take AZMALER

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If you forget to inhale a dose, inhale the next dose when it is due, or if you become wheezy.

Do not use a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

AZMALER can have side effects.

Not all side effects reported for AZMALER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using AZMALER, please consult your healthcare provider for advice.

If any of the following happens, stop using AZMALER and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AZMALER. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

Frequent side effects

- Fast, strong, irregular heartbeat.
- 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.
- Chest pains due to heart problems.

These are all a serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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Frequent side effects

- Shaking or trembling of the hands
- Headache.

Less frequent side effects:

- Mouth and throat irritation (this may be prevented by rinsing the mouth after using the inhaler)
- Muscle cramps
- Low levels of potassium in your blood (you may feel weak or experience muscle cramps and spasms)
- Increased blood flow to your extremities (peripheral dilatation)
- Changes in sleep patterns and changes in behaviour, such as restlessness and excitability
- Stomach pain, rapid breathing or shortness of breath, cold feet and hands, irregular heartbeat, thirst or nervousness (a condition called lactic acidosis)
- Shortness of breath, difficulty breathing and wheezing

Side effects of unknown frequency:

- Difficulty in urinating and completely emptying your bladder
- Changes in metabolism (you may experience mood changes, extreme tiredness and generally feel unwell)
- Sweating, increased amount of saliva in the mouth
- Hyperactivity, agitation, nervousness, fatigue, fear, restlessness, dizziness, confusion, inability to sleep (insomnia)
- Flushing of the skin
- Loss of appetite, nausea (feeling sick), vomiting (being sick).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AZMALER.

5. HOW TO STORE AZMALER

Replace the mouthpiece cover firmly and snap it into position.

Store at or below 30 °C.

Protect from frost and direct sunlight.

The canister should not be damaged, punctured or burnt, even when apparently empty.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. CONTENT OF THE PACK AND OTHER INFORMATION:

What AZMALER contains:

The active ingredient is salbutamol sulphate.

Other inactive ingredients include ethanol (7,5 % *m/v*), HFA-134a propellant gas and oleic acid.

What AZMALER looks like and contents of the pack:

An aluminium canister containing a milky white coloured suspension of salbutamol sulphate with a propellant. AZMALER is a metered dose inhaler comprising of an aluminium canister with a metered valve contained within an actuator. The actuator has a blue body and a light blue cap with "SQUARE" logo embossed on the cap. Each canister provides 200 inhalations.

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Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Corner Birch Road & Bluegum Avenue,

Anchorville,

Lenasia, 1827

South Africa

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