

AZMASOL 100MCG/DOSE HFA METERED DOSE INHALER

Salbutamol sulphate 100 mcg

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What Azmasol HFA is used for

Azmasol HFA is indicated for:

- Treatment and prevention of bronchial asthma
- Treatment of reversible airways obstruction associated with bronchitis (inflammation in the main passages of the lungs that carry air to the lungs) and emphysema (chronic disease of the lungs causing difficulty in breathing).

Azmasol HFA may be used to relieve attacks of acute dyspnea (sudden shortness of breath) and may also be taken preventively before exertion or to prevent exercise-induced-asthma. It is suitable for treating bronchospasm in patients with coexisting heart disease or hypertension (high blood pressure), including those taking beta blockers, because of its selective action on the bronchial receptors and lack of effects on the cardiovascular system (heart and blood vessels).

How Azmasol HFA works

Azmasol HFA contains a medicine called Salbutamol. This belongs to a group of medicines called 'bronchodilators'. It works by:

- Helping the airways in your lungs to stay open. This makes it easier for air to get in and out
- Helping to relieve chest tightness, wheezing and cough.

Azmasol HFA is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by exercise or other "triggers". These are things, which bring on asthma symptoms in some people. Common triggers include house dust, pollen, cats, dogs and cigarette smoke.

Azmasol HFA contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Azmasol HFA inhaler. This will make no difference to how your medicine works.

Before you use Azmasol HFA

- When you must not use it

Do not take Azmasol HFA if you:

Are allergic (hypersensitive) to Salbutamol Sulphate or any of the other ingredients, including HFA 134a.

Pregnancy and lactation

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. As salbutamol is probably secreted in breast milk its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk.

- Before you start to use it

Consult your doctor or pharmacist before taking Azmasol HFA if you:

- Have an overactive thyroid gland
- Have a history of heart problems such as an irregular or fast heartbeat or angina

In the event of a previously effective dose of inhaled salbutamol failing to give relief for at least three hours, you are advised to seek medical advice in order

that any necessary additional steps may be taken.

- Taking other medicines

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

In particular tell your doctor or pharmacist if you are taking any of the following:

- Medicines for an irregular or fast heartbeat
- Other medicines for your asthma.
- Medicines used to treat depression e.g. Monoamine Oxidase inhibitors (MAOIs).
- Steroids
- Diuretics

How to use Azmasol HFA

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults (including elderly)

To relieve asthma: 1-2 puffs.

To prevent allergen or exercise induced symptoms: 2 puffs, 10-15 min before challenge.

For chronic therapy: 2 puffs up to 4 times a day.

Children

To relieve asthma or before allergen exposure: 1-2 puffs

For chronic therapy: 2 puffs up to 4 times a day.

Should not exceed 8 inhalations in any 24 hours. Reliance on such frequent supplementary use, or a sudden increase in dose, indicates poorly controlled or deteriorating asthma.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Azmasol HFA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. The following effects may happen:

- Your heart may beat faster than usual
 - You may feel shaky.
- Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

When using your new inhaler for the first time or if it has not been used for 14 days or more, you should prime your inhaler before use. To prime, simply shake the inhaler well and then spray 4 times into the air away from your face, shaking well before each spray.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Azmasol HFA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop using the Azmasol HFA unless advised by your doctor.

Do not use any new medicines without consulting your doctor.

Do not give Azmasol HFA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This inhaler is a pressurised canister, do not puncture, break or incinerate even when apparently empty.

Driving and using machines

Azmasol® HFA is not likely to affect you being able to drive or use any tools or machines.

Side effects

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

Common

- feeling shaky
 - headache
- Uncommon
- palpitations (awareness of heartbeats)
 - mouth and throat irritation
 - muscle cramps

The following side effects can also happen but the frequency of these are not known:

- chest pain, due to heart problems such as myocardial ischaemia (reduced blood flow to the heart cause by blockage).

Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Azmasol HFA

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- Disposal

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.

Product Description

- What it looks like

Azmasol HFA comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap.

- Ingredients

- Active ingredient
Salbutamol Sulphate BP
- Inactive ingredients
 - Oleic Acid
 - Dehydrated Alcohol
 - Tetra-fluoro ethane (HFA 134a)

- MAL number:

MAL 09082796A

Manufacturer

Beximco Pharmaceuticals Ltd
126, Kathaldia, Auchpara,
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Product Registration Holder

Vitamode Sdn.bhd
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28/1/2015

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