

# BIOMOL<sup>®</sup> HFA METERED DOSE INHALER

Salbutamol sulphate 100mcg/actuation

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## What Biomol<sup>®</sup> HFA is used for

Biomol<sup>®</sup> HFA is indicated for:

- Treatment and prevention of bronchial asthma (narrowing of the airways going into the lungs)
- 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).

Biomol<sup>®</sup> HFA may be used to relieve attacks of acute dyspnea (sudden shortness of breath) and may also be taken preventively before action or to prevent exercise-induced-asthma.

## How Biomol<sup>®</sup> HFA works

Biomol<sup>®</sup> HFA contains a medicine called Salbutamol. This belongs to a group of medicines called 'bronchodilators'. It works by: (i) helping the airways in your lungs to stay open. This makes it easier for air to get in and out; (ii) helping to relieve chest tightness, wheezing and cough.

Biomol<sup>®</sup> 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.

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

## Before you use Biomol<sup>®</sup> HFA

### - When you must not use it

Do not take Biomol<sup>®</sup> HFA if you are allergic (hypersensitive) to Salbutamol sulphate or any of the other ingredients, including HFA 134a.

### *Pregnancy and lactation*

Do not take Biomol<sup>®</sup> HFA if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Biomol<sup>®</sup> HFA if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start to use it

Consult with your doctor or pharmacist before taking Biomol<sup>®</sup> HFA if you have:

- High blood pressure
- Overactive thyroid gland
- 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

Salbutamol and non-selective  $\beta$ -blocking drugs such as propranolol, should not usually be prescribed together.

## How to use Biomol<sup>®</sup> 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.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking Biomol<sup>®</sup> 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. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## While you are using Biomol<sup>®</sup> HFA

### - Things you must do

Take your medicine exactly as your doctor has told you.

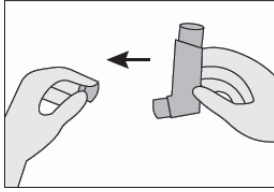
Tell all the doctors, dentists and pharmacists treating you that you are taking Biomol<sup>®</sup> HFA.

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

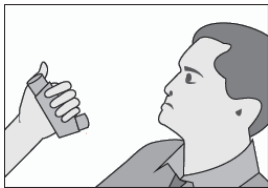
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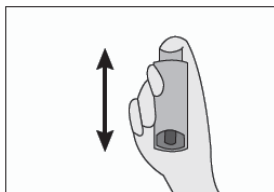
## Instruction for use:



If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of ten days, “test spray” the inhaler. Remove the cap from the mouthpiece;



The mouthpiece should be inspected for the presence of foreign objects before each use.



Spray the inhaler 2 times into the air after shaking the device prior to each actuation. Make sure the canister is fully and firmly inserted into the actuator.

Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister.

### *A handy tip for children*

Children and others who have weaker hands may have difficulty pressing down on the top of the can with just one hand. They can use both hands to make their inhaler work.

Breathe out fully through your mouth expelling as much air from your lungs as possible.



Thereafter, place the mouthpiece of the inhaler in your mouth between your teeth.

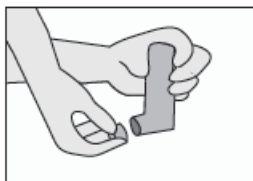


Close your lips around it (do not bite it) tilt your head slightly backwards. Start breathing in slowly through your mouth.



As you breathe in steadily and deeply, press down the canister to release one puff.

While holding your breath, you should take off the inhaler from your mouth and should continue holding your breath for 10 seconds or for as long as it is comfortable. Breathe out slowly.



After use, replace the mouthpiece cover.

## Cleaning:

Keeping the plastic actuator clean is very important to prevent medicine build up and blockage. The actuator should be washed, shaken to remove excess water and air-dried thoroughly at least once a week. The inhaler may stop spraying if not properly cleaned.

1. Gently pull the metal canister out of the plastic actuator of the

inhaler. Remove the mouthpiece cover.

2. Rinse the actuator (plastic body) and the mouthpiece cover in warm/running water.

3. Dry the actuator inside and outside thoroughly. Avoid excess heat.

4. Replace the canister and the mouthpiece cover correctly.

5. Do not put the metal canister in water.

### *- Things you must not do*

- Do not stop using Biomol<sup>®</sup> HFA unless advised by your doctor.

- Do not take any new medicines without consulting your doctor.

- Do not give Biomol<sup>®</sup> HFA to anyone else, even if they have the same symptoms or condition as you.

### *- Things to be careful of* *Driving and using machines*

This medicine may affect your ability to drive or use machines. If the medicine make you feel sick, dizzy or tired, or give you headache, do not drive or use machines and contact your doctor immediately.

## Side effects

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

- Immune system disorders: Hypersensitivity reactions (allergy) including angioedema (swelling under skin), urticarial (skin itch), bronchospasm (difficulty in breathing due to narrowed airways), hypotension (low blood pressure) and collapse.

- Metabolism and nutrition disorders: Hypokalemia (low blood potassium level). Potentially serious hypokalemia may result from  $\beta_2$ -agonist therapy.

- Nervous system disorders: Tremor, headache. Hyperactivity

- Cardiac disorder: Tachycardia (fast heart rate), palpitation (feeling of irregular heartbeats), cardiac arrhythmias (change from normal

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heartbeat).

- Vascular disorder: peripheral vasodilation (not central widening of blood vessel)
- Musculoskeletal and connective tissue disorders: Muscle cramps, feeling of muscle tension.
- Respiratory, thoracic and mediastinal disorders: Paradoxical bronchospasm

Biomol may cause a fine tremor of skeletal muscle usually the hands are obviously affected. This effect is common to all  $\beta$ -adrenergic stimulants. As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator. Biomol should be discontinued immediately, the patient assessed and if necessary alternative therapy instituted.

Mouth and throat irritation may occur with inhaled salbutamol.

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 visiting the website [npra.gov.my](http://npra.gov.my)

[Consumer  $\rightarrow$  Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of Biomol<sup>®</sup> HFA

### Storage

Keep medicine out of reach of children. Keep away from eyes. Store below 30°C. Protect from frost and direct sunlight. As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when canister is cold. The canister should not be broken, punctured or burnt, even when apparently empty. Handle

the inhaler with care when using with other device i.e spacer or nebulizer to avoid damage to the inhaler.

### 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

Biomol<sup>®</sup> HFA comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap. Each canister contains 200 puffs of 100 micrograms of salbutamol.

### -Ingredients

-Active ingredients

- Salbutamol sulphate BP

-Inactive ingredients

- Oleic acid

- Dehydrated alcohol

- Tetra-fluoro ethane (HFA 134a)

## MAL Number:

MAL16115014AZ

## Manufacturer

BioCare Manufacturing Sdn Bhd  
Lot 269, Taman Farmaseutikal,  
Bandar Baru Seri Iskandar, 32610  
Seri Iskandar, Perak.

## Product Registration Holder

BioCare Manufacturing Sdn Bhd  
No 67, Jalan Gasing,  
46000 Petaling Jaya, Selangor.

## Date of revision

05/08/2025

## Serial number

NPRA(R2/2)250819/1526

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