BIOMOL™ 100mcg/dose HFA METERED DOSE INHALER

Salbutamol sulfate 120 mcg equivalent to Salbutamol 100mcg/actuation

Description: Biomol™ 100mcg/dose HFA Metered Dose Inhaler 200 doses pressurized inhaler is a homogenous suspension aerosol for inhalation supplied in a pressurised container. On visual examination, there is no sign of physical damage or leakage.

Pharmacodynamics: Salbutamol is a selective β2- adrenoceptor agonist. At therapeutic doses, it acts on the β2- adrenoceptors of bronchial muscle, with little or no action on the β1- adrenoceptors of cardiac muscle. It is suitable for the management and prevention of attack in asthma.

Pharmacokinetics: Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renal and partly by metabolism to the inactive 4'-O-sulfate (phenolic sulfate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. After administration by the inhaled route between 10 and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation, but is not metabolized by the lung. On reaching the systemic circulation it becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged drug and as the phenolic sulfate. The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. Both unchanged drug and conjugate are excreted primarily in the urine. Most of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

Indication: Biomol™ 100mcg/dose HFA Metered Dose Inhaler provides short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airway obstruction. It is particularly suitable for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). Biomol™ 100mcg/dose HFA Metered Dose Inhaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

Recommended Dose: Biomol™ 100mcg/dose HFA Metered Dose Inhaler has a duration of action of four to six hours in most patients. Increasing use of beta-2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered. As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice. Biomol™ 100mcg/dose HFA Metered Dose Inhaler is administered by the oral inhaled route only.

RELIEF OF ACUTE BRONCHOSPASM- Adults: 100 or 200 micrograms. Children: 100 micrograms. The dose may be increased to 200 micrograms if required.

PREVENTION OF ALLERGEN or EXERCISE-INDUCED BRONCHOSPASM- Adults: 200 micrograms should be taken 10-15 minutes before challenge or exertion. Children: 100 micrograms before challenge or exertion. This dose may be increased to 200 micrograms if required.

CHRONIC THERAPY- Adults: Up to 200 micrograms four times daily. Children: Up to 200 micrograms four times daily. On demand use of Biomol 100mcg/dose HFA Metered Dose Inhaler should not exceed 8 inhalations in any 24 hours. Reliance on such supplementary use or a sudden increase in dose indicates deteriorating asthma.

Route of administration: Respiratory Inhalation

Contraindication: Although intravenous Salbutamol, and occasionally Salbutamol tablets, are used in the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy. Salbutamol inhaler preparations are not appropriate for managing premature labour. Salbutamol preparation should not be used for threatened abortion during the first or second trimesters of pregnancy. Salbutamol inhaler in contraindicated in patients with a history of hypersensitivity to any of its components.

Warnings: Patient's inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of drug to the lungs. Patients should be warned that they may experience a different taste upon inhalation compared to their previous inhaler. Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma.

Severe asthma requires regular medical assessment, including lung-function testing, as patients are at risk of severe attacks and even death. Physicians should consider using the maximum recommended dose of inhaled corticosteroid and/or oral corticosteroid therapy in these patients. The dosage or frequency of administration should only be increased on medical advice. If a previously effective dose of inhaled salbutamol fails to give relief lasting at least three hours, the patient should be advised to seek medical advice. Increasing use of bronchodilators, in particular short-acting inhaled β2-agonists, to relieve symptoms, indicates deterioration of asthma control. The patients should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required. In this situation the patient should be assessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid). Severe exacerbations of asthma must be treated in the normal way.

Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving salbutamol should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin. Salbutamol should be administered cautiously to patients with thyrotoxicosis. Potentially serious hypokalaemia may result from β2-agonist therapy, mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics. Serum potassium levels should be monitored in such situations. 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. Inhaler should be discontinued immediately, the patient assessed, and if necessary, a different fast-acting bronchodilator instituted for on-going use. Keep out of reach of children. Jauhi dari kanak-kanak.

Interactions with other medicaments: Salbutamol and non-selective β-blocking drugs such as propranolol, should not usually be prescribed together.

Pregnancy and lactation: Fertility: There is no information on the effects of Salbutamol on human fertility. Pregnancy: Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. Lactation: As Salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether Salbutamol in breast milk has a harmful effect on the neonate.

Side effects: Immune System Disorders: Hypersensitivity reactions including angioedema, urticarial, bronchospasm, hypotension and collapse. Metabolism and Nutrition Disorders: Hypokalemia. Potentially serious hypokalaemia may result from β2-agonist therapy. Nervous System Disorders: Tremor, headache, hyperactivity. Cardiac disorder: Tachycardia, palpitation, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles. Vascular disorder: peripheral vasodilation. 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 β-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.

Symptoms and Treatment of Overdose: The most common signs and symptoms of overdose with Salbutamol are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity and metabolic effects including hypokalaemia. Hypokalaemia may occur following overdose with Salbutamol. Serum potassium levels should be monitored. Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

Storage Condition: 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 the canister is cold. The canister should not be broken, punctured or burnt, even when apparently empty.

Shelf-life : 3 years

Dosage form: Preparation for Inhalation in form of Pressurised Metered-Dose Inhaler

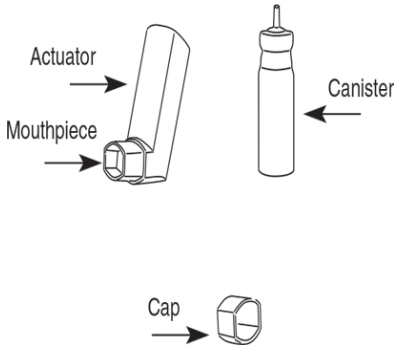
Packaging available: Each canister contains 200 metered doses, each containing 120mcg of Salbutamol sulfate BP. equivalent to 100mcg of salbutamol. It does not contain CFC as propellant.

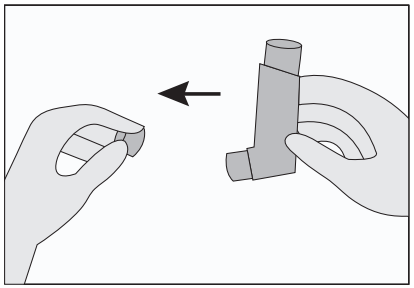
Distributed by:
BioCare Pharmaceutical (M) Sdn. Bhd.
(652530-K)
BioCare™

Manufactured by:
Biocare Manufacturing Sdn Bhd
Lot 269, Taman Farmaseutikal,
Bandar Baru Seri Iskandar,
32610 Seri Iskandar, Perak.
E-mail :productinfo@bcpharm.net

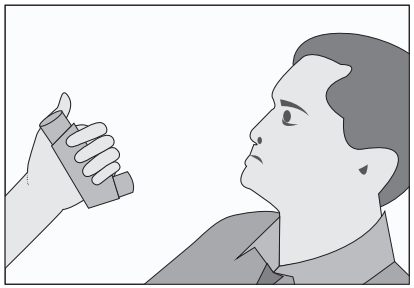
PLEA01-04
Date of revision: 06/08/25

HOW TO USE YOUR INHALER CORRECTLY

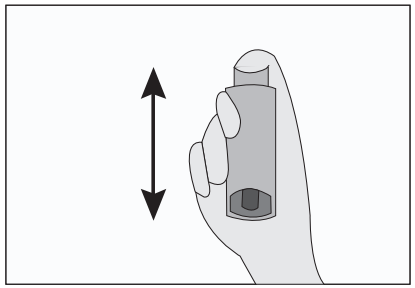




1. If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of ten days, "test spray" the inhaler. Remove the cap from the mouthpiece; the mouthpiece should be inspected for the presence of foreign objects before each use.



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



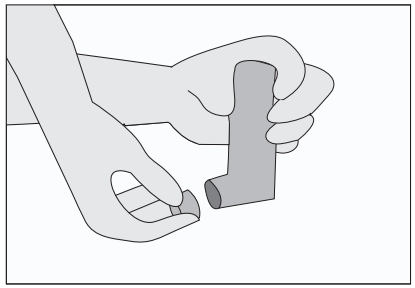
3. Spray the inhaler 2 times into the air after shaking the device prior to each actuation. Make sure the canister is fully and firmly inserted into the actuator. Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister. Breathe out fully through your mouth expelling as much air from your lungs as possible.

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

5. 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.

6. 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.

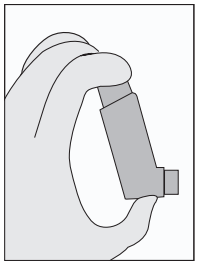


7. Replace the mouthpiece cap after each use.

In case of emergency situation when you feel you are not relieved despite using your inhaler, you can use inhaler along with spacer (a device that your doctor advise to use with your inhaler). This may save your life on the way to hospital. For more information, consult with your doctor.

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.



Cleaning your Inhaler

Keeping the plastic actuator clean is very important to prevent medicine buildup 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.

Shake well the inhaler before each use

How to clean your Inhaler?

1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly with warm water /running water.
3. Dry the actuator thoroughly inside and outside.
4. Replace the metal canister and the mouthpiece cover.
5. Do not put the metal canister in water.

Your Inhaler should be cleaned at least once a week

Precaution

1. Pressurised canister, do not puncture, break or incinerate even when apparently empty.
2. Avoid storage in direct sunlight or heat.
3. Store below 30° C
4. Keep away from eyes
5. Keep away from children
6. Handle the inhaler with care when using with other device i.e spacer or nebulizer to avoid damaged to the inhaler.