Drug/ Drug Class:

Salbutamol
Azmasol HFA

Suspension Metered Dose Inhaler
Selective Beta-2-adrenoreceptor/Antagonist
For Oral Inhalation Only

Product Description

It is a homogenous suspension aerosol for inhalation, supplied in a pressurized container.

Formulation

Each actuation delivers:
Salbutamol sulfate BP
(Equivalent to Salbutamol) - 100 mcg

Availability

- Aluminum canister with plastic metering valve and polypropylene plastic actuator with dust cap x 200 actuations
- (Box of 1's).

Mechanism of Action

Salbutamol produces bronchodilation through stimulation of beta2-adrenergic receptors in bronchial smooth muscle, thereby causing relaxation of bronchial muscle fibers. This action is manifested by and improvement in pulmonary function as demonstrated by spirometry measurements. Although beta2-receptors are the predominant adrenergic receptors in bronchial smooth muscle and beta1-receptors are the predominant receptors in the heart, there are also beta2-receptors in the human heart comprising 10% to 50% of the total beta-adrenergic receptors. The precise function of these receptors has not been established, but they raise the possibility that even highly selective beta2-agonists may have cardiac effects. At therapeutic doses, salbutamol has little action on the beta1-adrenergic
receptors in cardiac muscle. A measurable decrease in airway resistance is typically observed within 5 to 15minutes after inhalation of salbutamol. The maximum improvement in pulmonary function usually occurs 60 to 90 minutes after salbutamol treatment, and significant bronchodilator activity has been observed to persist for 3 to 6 hours.

Indication

Adults and Children (4 years and older):
Salbutamol Sulphate inhalation aerosol is indicated for:
• the symptomatic relief and prevention of bronchospasm due to bronchial asthma, chronic bronchitis and other chronic bronchopulmonary disorders in which bronchospasm is a complicating factor.

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• the prevention of exercise-induced bronchospasm.
Pediatrics (<4 years of age):
The safety and efficacy in children below the age of 4 years has not been established.

Dosage & Administration

The dosage should be individualized, and the patient's response should be monitored by the prescribing physician on an ongoing basis.
Increasing demand for Salbutamol Sulphate (Azmasol HFA) in bronchial asthma is usually a sign of poorly controlled or worsening asthma and indicates that the patient should be re-evaluated, the treatment plan should be reviewed and the regular asthma controller treatment should be optimized. If inhaled salbutamol treatment alone is not adequate to control asthma, concomitant anti-inflammatory therapy should be part of the treatment regimen.
If a previously effective dose fails to provide the usual relief, or the effects of a dose last for less than three hours, patients should seek prompt medical advice since this is usually a sign of worsening asthma.
As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice. However, if a more severe attack has not been relieved by the usual dose, additional doses may be required. In these cases, patients should immediately consult their doctors or the nearest hospital.

	Relief of Acute Episodes of Bronchospasm	**Prevention of Bronchospasm**	**Prevention of Exercise-induced Bronchospasm**	**Maximum Daily Dose (Total daily dose should not exceed)**
Adults and Adolescent (≥ 12 years)	One to two puffs [100-200 mcg salbutamol]	One to two puffs [100 to 200 mcg salbutamol] every 4-6 hours to a maximum of 4 times/day.	Two puffs [200 mcg salbutamol] 15 minutes before exercise.	Eight puffs [800 mcg salbutamol].
Children (4to < 12)	One puff [100 mcg salbutamol] as needed. May be increased to two puffs (200 mcg salbutamol), if required.	One puff [100 mcg salbutamol] every 4-6 hours to a maximum of 4 times/day.	One puff [100 mcg salbutamol] 15 mins before exercise. May be increased to two puffs (200 mcg salbutamol), if required.	Four puffs [400 mcg salbutamol]

Missed Dose:
If a single dose is missed, instruct the patient to take the next dose when it is due or if they become wheezy.
Administration:
Salbutamol Sulphate (Azmasol HFA) is administered by the inhaled route only. To ensure administration of the proper dose of the drug, the patient should be instructed by the physician or other health professional in the proper use of the inhalation aerosol.
Inhaler actuation should be synchronized with inspiration to ensure optimum delivery of drug to the lungs. In patients who find coordination of a pressurized metered dose inhaler difficult, a spacer may be used with Salbutamol Sulphate (Azmasol HFA).
The use of open mouth technique to administer Salbutamol Sulphate (Azmasol HFA) has not been investigated in clinical trials.
Priming: It is recommended to test spray Salbutamol Sulphate (Azmasol HFA) into the air four times, away from the face, before using for the first time and in cases where the aerosol has not been used for more than 5 days.

Adverse Drug Reactions

As with other bronchodilator inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately and alternative therapy instituted.
Potentially serious hypokalemia may result from beta2-agonist therapy primarily from parenteral and nebulized routes of administration.
Peripheral vasodilation and a compensatory small increase in heart rate may occur in some patients.

Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia, extrasystoles) have been reported, usually in susceptible patients.
Other adverse reactions associated with salbutamol are nervousness and tremor. In some patients inhaled salbutamol may cause a fine tremor of skeletal muscle, particularly in the hands. This effect is common to all beta2-adrenergic agonists. Adaptation occurs during the first few days of dosing and the tremor usually disappears as treatment continues.
In addition, salbutamol, like other sympathomimetic agents, can cause adverse effects such as drowsiness, flushing, restlessness, irritability, chest discomfort, difficulty in micturition, hypertension, angina, vomiting, vertigo, central nervous system stimulation, hyperactivity in children, unusual taste and drying or irritation of the oropharynx, headache, palpitations, transient muscle cramps, insomnia, nausea, weakness and dizziness.
Immediate hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension, rash, oropharyngeal oedema, anaphylaxis and collapse have been reported very rarely. Rarely, in children, hyperactivity occurs and occasionally, sleep disturbances, hallucination or atypical psychosis have been reported.

Shelf life & Storage Condition

- 24 mos. (months)
- Store at temperatures not exceeding 30°C

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