Aerotamol®

100 MCG

Each metered dose contains:
Salbutamol sulphate
equivalent to Salbutamol 100 mcg

Pressurized metered dose inhaler

AeroCare

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา

ใบอนุญาตโฆษณาเลขที่ ฆศ. 881/2558

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Each puff contains: - Salbutamol sulphate equivalent to Salbutamol 100 mcg

1. Pharmacodynamic properties:
Salbutamol is a selective beta2-adrenoceptor agonist. At therapeutic doses it acts on the beta2-adrenoceptors of bronchial muscle providing short acting (4-6 hour) bronchodilatation with a fast onset (within 5 minutes) in reversible airways obstruction.

2. Pharmacokinetic properties:
Salbutamol administered intravenously has a half life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulphate (phenolic sulphate) 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 metabolised 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 sulphate.
The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. 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%.

3. Mechanism of action:
Activation of beta2-adrenergic receptors on airway smooth muscle leads to the activation of adenylcyclase and to an increase in the intracellular concentration of cyclic-3',5'-adenosine monophosphate (cyclic AMP). This increase of cyclic AMP leads to the activation of protein kinase A, which inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in relaxation. Salbutamol relaxes the smooth muscles of all airways, from the trachea to the terminal bronchioles. Salbutamol acts as a functional antagonist to relax the airway irrespective of the spasmogen involved, thus protecting against all bronchoconstrictor challenges. Increased cyclic AMP concentrations are also associated with the inhibition of release of mediators from mast cells in the airway.

4. Indications:
For the relief and prevention of asthma symptoms in mild, moderate or severe asthma. 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). It provides short-acting (4 to 6 hour) bronchodilatation with fast onset (within 5 minutes) in reversible airways obstruction.

5. Posology and method of administration:
Aerotamol 100 mcg is for oral inhalation use only.
Adults (including the elderly): For the relief of acute asthma symptoms including bronchospasm, one inhalation (100 micrograms) may be administered as a single minimum starting dose. This may be increased to two inhalations if necessary. To prevent allergen- or exercise-induced symptoms, two inhalations should be taken 10-15 minutes before challenge. For chronic therapy, two inhalations up to four times a day.
Children: For the relief of acute asthma symptoms including bronchospasm, or before allergen exposure or exercise, one inhalation, or two if necessary. For chronic therapy, two inhalations up to four times a day.
On-demand use, it 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.

6. Contraindications:
- It is contraindicated in patients with a history of hypersensitivity to salbutamol, sympathomimetic amines, aerosol propellants or any other components. Rare cases of hypersensitivity reactions, including urticaria, angioedema, and rash have been reported after the use of salbutamol sulfate.
- Hyperthyroidism
- Tachyarrhythmia

7. Precautions:
- Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronized with inspiration of breath for optimum delivery of drug to the lungs.
- 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 beta2-agonists, to relieve symptoms, indicates deterioration of asthma control. The patient should be instructed to seek medical advice.
- 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.
- Salbutamol should be administered cautiously to patients with thyrotoxicosis.
- Potentially serious hypokalaemia may result from beta2-agonist therapy, mainly from parenteral and nebulised administration.

8. Warnings:
- *Paradoxical bronchospasm:* If paradoxical bronchospasm occurs, it should be discontinued immediately and alternative therapy instituted. It should be recognized that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister.
- *Deterioration of asthma:* Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses than usual, this may be a marker of destabilization of asthma and requires reevaluation of the patient and treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.
- *Use of anti-inflammatory agents:* The use of beta-adrenergic agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids, to the therapeutic regimen.
- *Cardiovascular effects:* Salbutamol, like all other beta2-adrenergic agonists, can produce clinically significant cardiovascular effects in some patients such as changes in pulse rate or blood pressure. If such effects occur, it may need to be discontinued.
- Do not exceed recommended dose
- *Immediate Hypersensitivity Reactions:* Immediate hypersensitivity reactions may occur after administration of salbutamol sulfate inhalation aerosol, as demonstrated by cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema. Discontinue if immediate hypersensitivity reactions occur.
- *Coexisting conditions:* Salbutamol, like other sympathomimetic amines, should be used with caution in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus and in patients who are unusually responsive to sympathomimetic amines.
- *Hypokalemia:* As with other beta-agonists, salbutamol may produce significant hypokalemia in some patients.

9. Drug interactions:
Beta-Blockers: Beta-adrenergic receptor blocking agents such as propranolol not only block the pulmonary effect of beta-agonists, such as salbutamol, but may produce severe bronchospasm in patients with asthma. Therefore, patients with asthma should not normally be treated with beta-blockers.
Other short-acting sympathomimetic aerosol bronchodilators should not be used concomitantly with salbutamol.
The effects of salbutamol may be enhanced by concomitant administration of aminophylline or other xanthines.
Diuretics: Caution is advised in the coadministration of beta-agonists with nonpotassium-sparing diuretics. Consider monitoring potassium levels.
Digoxin: Mean decreases of 16% to 22% in serum digoxin levels were demonstrated after single-dose intravenous and oral administration of salbutamol, respectively, to normal volunteers who had received digoxin for 10 days. The clinical relevance of these findings for patients with obstructive airway disease who are receiving inhaled salbutamol and digoxin on a chronic basis is unclear. Nevertheless, it would be prudent to carefully evaluate the serum digoxin levels in patients who are currently receiving digoxin and salbutamol.
Monoamine Oxidase Inhibitors or Tricyclic Antidepressants: Salbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants.

10. Pregnancy: Pregnancy category C
There are no adequate and well-controlled studies of salbutamol sulfate in pregnant women. During worldwide marketing experience, various congenital anomalies, including cleft palate and limb defects, have been reported in the offspring of patients being treated with salbutamol.

11. Lactation:
Plasma levels of sulbutamol sulfate and HFA-134a after inhaled therapeutic doses are very low in humans, but it is not known whether the components of formula are excreted in human milk.

12. Pediatric use:
The safety and effectiveness in children 4 years of age and older has been established based upon two 12-week clinical trials in patients 12 years of age and older with asthma and one 2-week clinical trial in patients 4 to 11 years of age with asthma.
Results from the 2-week pediatric clinical study in patients with asthma 4 to 11 years of age showed that this pediatric population had an adverse reaction profile similar to that of the adolescent and adult populations.

13. Geriatric use:
Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

14. Effects on ability to drive and use machines:
None reported

15. Undesirable effects: -
Immune system disorders: Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.
Metabolism and nutrition disorders: Rare: Hypokalaemia. Potentially serious hypokalaemia may result from beta2 agonist therapy.
Nervous system disorders: Common:-Tremor, headache. Very rare: Hyperactivity.

16. Overdose:
Symptom: 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.
Treatment: Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy such as cardio-selective beta-blocking agents in patients presenting with cardiac symptoms (e.g. tachycardia, palpitations).

HOW SUPPLIED/STORAGE AND HANDLING
Available pack: Aerotamol 100 mcg is supplied in the following packs as a pressurized aluminum canister sealed with a metering valve, actuator and dust cap. Each 13.34 g canister contains 200 metered actuations providing 100 micrograms of salbutamol (as Salbutamol Sulphate BP).
Storage: Keep in tight containers, protected from light. Store below 30°C

Handling precaution:
Keep out of reach of children. Avoid spraying in eyes.
Contents under pressure: Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 50°C may cause bursting. Never throw container into fire or incinerator.
Store the inhaler with the mouthpiece down. For best results, the inhaler should be at room temperature before use. SHAKE WELL BEFORE EACH SPRAY.
It does not contain chlorofluorocarbons (CFCs) as the propellant.

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