



# Albuterol Sulfate Inhalation Aerosol 90 mcg per actuation

PRODUCT	DELIVERY SYSTEM	UNIT SIZE	UNITS / BOX	NDC#
Albuterol Sulfate Inhalation Aerosol 90 mcg per actuation	Inhalation	8.5 g	1	17270-0740-0

WHOLESALE ITEM NUMBERS			
NDC#	CENCORA	CARDINAL	MCKESSON
17270-0740-0	10291509	5938477	2977684

**TO PLACE AN ORDER, PLEASE CALL 1-800-423-4136**

**ARMSTRONG PHARMACEUTICALS INC.**

25 John Road, Canton, MA 02021

[www.amphastar.com](http://www.amphastar.com)

Please see reverse for important safety information, including Warnings and Precautions and Indications and Usage, for Albuterol Sulfate Inhalation Aerosol.



Rx Only  
09-24  
01-026-01

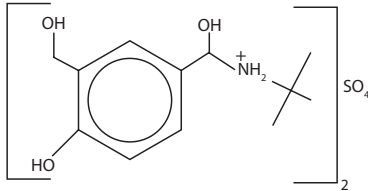
# Albuterol Sulfate

## Inhalation Aerosol

### 90 mcg per actuation

#### DESCRIPTION

The active ingredient of Albuterol Sulfate Inhalation Aerosol is albuterol sulfate, a racemic salt, of albuterol. Albuterol sulfate has the chemical name  $\alpha^1$ -[(*tert*-butylamino) methyl]-4-hydroxy-*m*-xylene- $\alpha,\alpha'$ -diol sulfate (2:1) (salt), and has the following chemical structure:



The molecular weight of albuterol sulfate is 576.7, and the empirical formula is  $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$ . Albuterol sulfate is a white to off-white crystalline powder. It is soluble in water and slightly soluble in ethanol. Albuterol sulfate is the official generic name in the United States, and salbutamol sulfate is the World Health Organization recommended generic name. Albuterol Sulfate Inhalation Aerosol is a pressurized metered-dose aerosol unit with a dose counter. Albuterol Sulfate is for oral inhalation only. It contains a microcrystalline suspension of albuterol sulfate in propellant HFA-134a (1, 1, 1, 2-tetrafluoroethane) and ethanol.

Prime the inhaler before using for the first time and in cases where the inhaler has not been used for more than 2 weeks by releasing three sprays into the air, away from the face. After priming, each actuation delivers 108 mcg albuterol sulfate, from the actuator mouthpiece (equivalent to 90 mcg of albuterol base). Each canister provides 200 actuations (inhalations). This product does not contain chlorofluorocarbons (CFCs) as the propellant.

#### INDICATIONS AND USAGE

Albuterol Sulfate Inhalation Aerosol is a beta2-adrenergic agonist indicated for:

- Treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.
- Prevention of exercise-induced bronchospasm in patients 4 years of age and older.

#### DOSAGE AND ADMINISTRATION

For oral inhalation only

- Treatment or prevention of bronchospasm in adults and children 4 years of age and older: 2 inhalations every 4 to 6 hours. In some patients, one inhalation every 4 hours may be sufficient.
- Prevention of exercise-induced bronchospasm in adults and children 4 years of age and older: 2 inhalations 15 to 30 minutes before exercise.
- Priming information: Prime Albuterol Sulfate Inhalation Aerosol before using for the first time, or when the inhaler has not been used for more than 2 weeks. To prime Albuterol Sulfate Inhalation Aerosol, release 3 sprays into the air away from the face. Shake well before each spray.
- Cleaning information: At least once a week, wash the actuator with warm water, shake off excess, and air dry thoroughly.
- Albuterol Sulfate Inhalation Aerosol inhaler should be discarded when the dose counter displays 0 or after the expiration date on the product, whichever comes first.

#### CONTRAINDICATIONS

Hypersensitivity to albuterol and any other Albuterol Sulfate Inhalation Aerosol Components.

#### WARNINGS AND PRECAUTIONS

- Life-threatening paradoxical bronchospasm may occur. Discontinue Albuterol Sulfate Inhalation Aerosol immediately and treat with alternative therapy.
- Need for more doses of Albuterol Sulfate Inhalation Aerosol than usual may be a sign of deterioration of asthma and requires reevaluation of treatment.
- Albuterol Sulfate Inhalation Aerosol is not a substitute for corticosteroids.
- Cardiovascular effects may occur. Use with caution in patients sensitive to sympathomimetic drugs and patients with cardiovascular or convulsive disorders.
- Excessive use may be fatal. Do not exceed recommended dose.

- Immediate hypersensitivity reactions may occur. Discontinue Albuterol Sulfate Inhalation Aerosol immediately.
- Hypokalemia and changes in blood glucose may occur.

#### ADVERSE REACTIONS

Most common adverse reactions ( $\geq 3.0\%$  and  $>$ placebo) are headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis.

**To report SUSPECTED ADVERSE REACTIONS, contact Armstrong Pharmaceuticals, Inc. at 1-800-423-4136 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

#### DRUG INTERACTIONS

- Other short-acting sympathomimetic aerosol bronchodilators and adrenergic drugs: May potentiate effect.
- Beta-blockers: May decrease effectiveness of Albuterol Sulfate and produce severe bronchospasm. Patients with asthma should not normally be treated with beta-blockers.
- Diuretics, or non-potassium sparing diuretics: May potentiate hypokalemia or ECG changes. Consider monitoring potassium levels.
- Digoxin: May decrease serum digoxin levels. Consider monitoring digoxin levels.
- Monoamine oxidase (MAO) inhibitors and tricyclic antidepressants: May potentiate effect of albuterol on the cardiovascular system. Consider alternative therapy in patients taking MAOs or tricyclic antidepressants.