APPLICATION NUMBER:
75-358

APPROVED DRAFT LABELING
Albuterol Sulfate Inhalation Solution, 0.083% *

2.5 mg/3 mL*

*Potency expressed as albuterol

FOR ORAL INHALATION ONLY
Prediluted with Normal Saline

60 x 3 mL Sterile Unit Dose

©Bausch & Lomb Pharmaceuticals, Inc.
Albuterol Sulfate Inhalation Solution, 0.083%*  
2.5 mg/3 mL*  
*Potency expressed as albuterol

Each milliliter contains albuterol sulfate equivalent to 0.83 mg of albuterol.

Equivalent to 0.5 mL albuterol sulfate 0.5%* diluted to 3 mL with normal saline.
*Potency expressed as albuterol.

Attention Pharmacist: Detach "Patient's Instructions for Use" from package insert and dispense with solution.

Please consult your physician before use. Do not exceed recommended dosage.

Usual Dosage: See package insert for Dosage and Administration.

STORAGE: Store in a refrigerator between 2°-8°C (36°-46°F). PROTECT FROM LIGHT. Albuterol sulfate inhalation solution may be held at room temperature for up to 2 weeks before use. (The vials must be used within 2 weeks of removal from refrigerator; record date the vials are removed from the refrigerator in the space provided on the product carton). Discard if solution becomes discolored. (Note: Albuterol sulfate inhalation solution is colorless).

Rx only

Date removed from refrigerator

Bausch & Lomb Pharmaceuticals, Inc.  
Tampa, FL 33637

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Rx only

60 x 3 mL Sterile Unit Dose

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XZ94322 R.10/98-8J AB37460
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NDC 24208-374-28

Albuterol Sulfate Inhalation Solution, 0.083%*

2.5 mg/3 mL*

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Rx only

28 x 3 mL Sterile Unit Dose

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©Bausch & Lomb Pharmaceuticals, Inc.
XZ94323 R.10/98-8J AB37405
Albuterol Sulfate Inhalation Solution, 0.083%*  
2.5 mg/3 mL*  
*Potency expressed as albuterol

Bausch & Lomb Pharmaceuticals, Inc.  
Tampa, FL 33637  
©Bausch & Lomb Pharmaceuticals, Inc.

28 x 3 mL Sterile Unit Dose

Date removed from refrigerator ——

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Storage: Store in a refrigerator between 2°-8°C (36°-46°F). Protect from light.
A buterol sulfate inhalation solution may be held at room temperature for up to 2 weeks before use. (The solution must be used within 2 weeks of removal from refrigerator; record date the vials are removed from the refrigerator in the space provided on the product carton. Discard if solution becomes discolored. (Note: Albuterol sulfate inhalation solution is colorless).

Rx only
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2.5 mg/3 mL*

*Potency expressed as albuterol

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Tampa, FL 33637
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28 x 3 mL Sterile Unit Dose

**Ventolin Nebules® is a registered trademark of Glaxo Wellcome Inc.
**Pharmacist — Detach Instructions for Patient**

**Albuterol Sulfate Inhalation Solution. 0.083%**

*Potency expressed as albuterol for oral inhalation only*

Rx only

**DESCRIPTION**

Albuterol Sulfate Inhalation Solution is a synthetic sympathomimetic amine of the β-adrenergic receptor activating type. CLINICAL PHARMACOLOGY

Absorption: After aerosol administration, albuterol is rapidly absorbed from the lungs into the systemic circulation. About 50% of the drug is absorbed within 5 minutes. The mean absolute bioavailability is approximately 50%.

Distribution: Albuterol is distributed to the systemic circulation and is extensively bound to plasma proteins. The binding is concentration-dependent with a mean binding of about 90% at therapeutic plasma concentrations.

Metabolism: Albuterol is extensively metabolized in the liver with the major metabolite being an N-glucuronide conjugate. The metabolites are excreted in the urine and feces.

Elimination: The elimination half-life of albuterol is approximately 3 hours in the elderly and 2 hours in young subjects.

**INDICATIONS AND USAGE**

Albuterol sulfate inhalation solution is indicated for the relief of bronchospasm in patients 3 years of age and older with reversible obstructive airway disease and as an adjunct to bronchodilator therapy.

**CONTRAINDICATIONS**

Albuterol sulfate inhalation solution is contraindicated in patients with a history of hypersensitivity to albuterol or any of its components.

**WARNINGS**

For aerosolized bronchodilators: Albuterol sulfate inhalation solution can produce paradoxical bronchospasm, which may be life-threatening. If paradoxical bronchospasm occurs, albuterol sulfate inhalation solution should be discontinued immediately and another therapy substituted. It should be remembered that paradoxical bronchospasm, when it occurs, is not alleviated by increasing the dose of albuterol sulfate inhalation solution.

Tracheoesophageal Fistula: Albuterol sulfate inhalation solution should not be used in patients with tracheoesophageal fistula because the drug may enter the thoracic cavity.

**PRECAUTIONS**

General: Albuterol sulfate inhalation solution should be used with caution in patients with cardiovascular disease, especially those with angina pectoris or coronary insufficiency, cardiac arrhythmias, hypertension, or hyperthyroidism.

**ADVERSE REACTIONS**

**CLINICAL EFFICACY AND SAFETY:**

Clinical efficacy and safety studies have shown that albuterol sulfate inhalation solution is effective in the treatment of reversible obstructive airway disease. The clinical efficacy and safety studies were conducted under controlled conditions and are not necessarily indicative of what will happen in actual practice.

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