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Albuterol Sulfate Inhalation Solution 0.083% (albuterol sulfate) - Drug Summary

Mylan Pharmaceuticals Inc.

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Albuterol Inhalation Solution 0.083% (albuterol sulfate)

THERAPEUTIC CLASS

Beta₂ agonist

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Bronchospasm

Relief of bronchospasm in patients w/ reversible obstructive airway disease and acute attacks of bronchospasm

Usual: 2.5mg (1 vial) tid-qid by nebulization

PEDIATRIC DOSAGE & INDICATIONS

Bronchospasm

Relief of bronchospasm in patients w/ reversible obstructive airway disease and acute attacks of bronchospasm

≥15kg:

Usual: 2.5mg (1 vial) tid-qid by nebulization

Children weighing <15kg who require <2.5mg/dose should use albuterol inh sol 0.5% instead

ADMINISTRATION

Oral inh route

To Administer 2.5mg of Albuterol:

- 1. Administer the entire contents of 1 sterile unit dose vial (3mL) by nebulization.
- 2. Flow rate is regulated to suit the particular nebulizer so that sol will be delivered over approx 5-15 min.

HOW SUPPLIED

Sol, Inh: 0.083% [3mL]

WARNINGS/PRECAUTIONS

May produce paradoxical bronchospasm, which can be life threatening; d/c immediately and institute alternative therapy if this occurs. Fatalities reported w/ excessive use of inhaled sympathomimetic drugs and w/ the home use of nebulizers. Immediate hypersensitivity reactions may occur. May have a clinically significant cardiac effect. Caution w/ cardiovascular (CV) disorders (especially coronary insufficiency, cardiac arrhythmias, and HTN), convulsive disorders, hyperthyroidism, diabetes mellitus (DM), and in patients unusually responsive to sympathomimetic amines. Aggravation of preexisting DM and ketoacidosis reported w/ large doses of IV albuterol. May produce significant hypokalemia.

ADVERSE REACTIONS

Tremors, dizziness, nervousness, headache, nausea, bronchospasm, cough, bronchitis, insomnia.

DRUG INTERACTIONS

Do not use w other sympathomimetic aerosol bronchodilators or epinephrine. Use extreme caution w MAOIs or TCAs; action of albuterol on the vascular system may be potentiated. β -blockers and albuterol inhibit the effect of each other

PREGNANCY AND LACTATION

Pregnancy: Category C.

Lactation: Not for use in nursing.

MECHANISM OF ACTION

 β_2 -agonist; stimulates adenyl cyclase, the enzyme which catalyzes the formation of cAMP from ATP. The cAMP thus formed mediates the cellular responses.

PHARMACOKINETICS

Absorption: (3mg) C_{max}=2.1ng/mL, T_{max}=0.5 hr. Elimination: Urine. (4mg, oral administration) T_{1/2}=5-6 hrs.

ASSESSMENT

Assess for history of drug hypersensitivity, CV disorders, convulsive disorders, hyperthyroidism, DM, pregnancy/nursing status, and possible drug interactions. Assess use in patients unusually responsive to sympathomimetic amines.

MONITORING

Monitor for paradoxical bronchospasm, CV effects, deterioration of asthma, immediate hypersensitivity reactions, hypokalemia, and other adverse effects.

PATIENT COUNSELING

Instruct not to use more frequently than recommended; advise not to increase dose or frequency w/o consulting physician. Instruct to seek medical attention immediately if symptoms get worse or if a previously effective dose fails to provide the usual relief. Inform that other anti-asthma medicines should not be used unless prescribed.

STORAGE

 $2\text{-}25^{\circ}\text{C}$ (36-77°F). Protect from light. Store in pouch until time of use.

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