Bevespi Aerosphere

(glycopyrrolate, formoterol fumarate)

New Product Slideshow

MPR

Introduction

- **Brand name:** Bevespi Aerosphere
- **Generic name:** Glycopyrrolate, formoterol fumarate
- **Pharmacological class:** Anticholinergic + long-acting beta2-agonist
- **Strength and Formulation:** Glycopyrrolate 9mcg, formoterol fumarate 4.8mcg; per inhalation; metered-dose inhaler
- **Manufacturer:** AstraZeneca
- **How supplied:** Inhalation aerosol—10.7g (120 inhalations)
- **Legal Classification:** Rx

Bevespi Aerosphere

Indications

- Long-term maintenance treatment of airflow obstruction in **COPD**, including chronic bronchitis and/or emphysema

Limitations of Use

- **Not** for the relief of acute bronchospasm
- **Not** for the treatment of asthma

Dosage & Administration

- **Adult:** 2 inhalations twice daily (in the AM + PM)

- Max 2 inhalations twice daily

Considerations for Special Populations

- **Pregnancy:** Category C
- **Nursing mothers:** Not recommended
- **Pediatric:** <18 years: not established
- **Elderly:** Exercise caution
- **Hepatic impairment:** Monitor closely
- **Renal impairment:** Severe impairment (CrCl ≤30mL/min/1.73m^2) or ESRD requiring dialysis: use if benefit outweighs risk

Contraindications

- LABA use in asthma patients without use of long-term control medication

Warnings/Precautions

- LABAs increase risk of asthma-related death
- Not recommended for treating asthma
- Do not initiate during acutely deteriorating or potentially life-threatening COPD episodes
- Not for treating acute symptoms
- Prescribe a short-acting β2-agonist for acute symptoms; monitor for increased need
- Discontinue immediately and treat if paradoxical bronchospasm or immediate hypersensitivity reactions occur; use alternative therapy

Warnings/Precautions

- Cardiovascular disorders (eg, coronary insufficiency, cardiac arrhythmias, hypertension)
- Convulsive disorders
- Thyrotoxicosis
- Hyperresponsiveness to sympathomimetics
- Diabetes
- Ketoacidosis
- Hypokalemia

Warnings/Precautions

- Hyperglycemia
- Narrow-angle glaucoma
- Urinary retention
- Prostatic hyperplasia
- Bladder-neck obstruction
- Hepatic disease; monitor
- Labor & delivery

Interactions

- **Not for use** with other drugs containing LABAs
- **Caution** with concomitant adrenergic drugs; may potentiate sympathetic effects
- Concomitant xanthine derivatives, steroids, or diuretics may potentiate hypokalemia
- Caution with non-K^+-sparing diuretics

Interactions

- Extreme caution with MAOIs, TCAs, or others that prolong QTc interval
- Antagonized by β-blockers; if needed, use cardioselective agents if no acceptable alternatives
- Additive effects with concomitant other anticholinergic-containing drugs; avoid

Adverse Reactions

- Urinary tract infection
- Cough
- Paradoxical bronchospasm
- Hypersensitivity reactions
- Cardiovascular effects

Mechanism of Action

- **Glycopyrrolate** is a long-acting antimuscarinic agent (anticholinergic) that inhibits the muscarinic receptor M3 in the smooth muscle in the airways, resulting in brochodilation

- **Formoterol fumarate** is a long-acting selective beta2-adrenergic agonist that stimulates the production of cAMP and rapidly causes relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells

Clinical Trials

- Bevespi Aerosphere was evaluated in 8 dose-ranging trials and 2 placebo-controlled lung function trials of 24-weeks duration that included a 28-week extension study to evaluate safety over 1 year

- Its efficacy is based on the dose ranging trials in 822 patients with COPD and the 2 placebo-controlled confirmatory trials in 3,705 patients with COPD

Clinical Trials

- Trial 1 and Trial 2 were randomized, double-blind, placebo-controlled, parallel-group, 24-week studies in patients with moderate to very severe COPD (n=3,699)

- Patients were aged 40-80 years, had smoking history of ≥10 pack-years, post-albuterol FEV_1<80% of predicted normal, and FEV_1/FVC<0.7

Clinical Trials

- Trials 1 and 2 evaluated Bevespi Aersophere 18mcg/9.6mcg, glycopyrrolate 18mcg, formoterol fumarate 9.6mcg, and placebo given twice daily

- The primary endpoint was change from baseline in trough FEV_1 at Week 24 compared with placebo, glycopyorrolate 18mcg twice daily and formoterol fumarate 9.6mcg twice daily

Clinical Trials

- At Week 24 Bevespi Aerosphere showed a larger increase in mean change in trough FEV_1 from baseline compared to placebo, glycopyrrolate 18mcg, or formoterol fumarate 9.6mcg
- **Trial 1:**
  - Least square (LS) mean change vs. placebo: 150mL (95% CI: 114, 186)
  - LS mean change vs. glycopyrrolate: 59mL (95% CI: 31, 88)
  - LS mean change vs. formoterol fumarate: 64mL (95% CI: 36, 92)

Clinical Trials

- **Trial 2:**
  - Least square (LS) mean change vs. placebo: 130mL (95% CI: 67, 140)
  - LS mean change vs. glycopyrrolate: 54mL (95% CI: 25, 83)
  - LS mean change vs. formoterol fumarate: 56mL (95% CI: 27, 85)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/bevespi-aerosphere/drug/34613/