Seebri Neohaler

(glycopyrrolate)

New Product
Slideshow

MPR

Introduction

- **Brand name:** Seebri Neohaler
- **Generic name:** Glycopyrrolate
- **Pharmacological class:** Long-acting anticholinergic
- **Strength and Formulation:** 15.6mcg per capsule; dry powder for oral inhalation for use with Neohaler device; contains lactose
- **Manufacturer:** Novartis
- **How supplied:** Blister pack—60 (with one Neohaler device)
- **Legal Classification:** Rx

Indications

- Long-term maintenance treatment of airflow obstruction due to **chronic obstructive pulmonary disease (COPD)**, including chronic bronchitis and/or emphysema

Dosage & Administration

- For oral inhalation use only with Neohaler device; do not swallow caps
- Administer at the same time of the day (AM + PM)
- Inhale contents of one capsule (15.6mcg) twice daily

Considerations for Special Populations

- **Pregnancy:** Category C
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Geriatric:** No dose adjustment warranted
- **Renal or hepatic impairment:** No dose adjustment warranted

Warnings/Precautions

- Do not initiate in patients during acutely deteriorating or potentially life-threatening COPD episodes
- Not for treating acute symptoms
- Do not exceed recommended dose
- Discontinue immediately and treat if paradoxical bronchospasm or immediate hypersensitivity reactions occur; use alternative therapy

Warnings/Precautions

- Severe milk protein hypersensitivity
- Narrow-angle glaucoma
- Urinary retention
- Prostatic hyperplasia
- Bladder-neck obstruction
- Severe renal impairment, including ESRD requiring dialysis

Interactions

- Additive effects with concomitant other anticholinergic-containing drugs; avoid

Adverse Reactions

- Upper respiratory tract infection
- Nasopharyngitis
- Urinary tract infection
- Sinusitis
- Oropharyngeal pain
- Paradoxical bronchospasm
- Hypersensitivity reactions

Mechanism of Action

- Glycopyrrolate is a long-acting muscarinic antagonist (anticholinergic) with similar affinity to muscarinic receptor subtypes M1-M5
- In the airways, glycopyrrolate exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation
- Following inhalation of glycopyrrolate, the bronchodilation is predominantly a site-specific effect

Pharmacokinetics

- **Metabolism:** Oxidative biotransformation via multiple CYP isoenzymes

- **Elimination:** Renal (major)

Clinical Trials

- The safety and efficacy of Seebri Neohaler were evaluated in two dose-ranging trials, four 12-week efficacy and safety trials, and a 52-week long-term safety trial
- The dose-ranging trial was a 28-day, randomized, double-blind, placebo-controlled, 2-period, crossover study that supported the dose selection of glycopyrrolate in chronic obstructive pulmonary disease (COPD)

Clinical Trials

- Seven doses of glycopyrrolate (15.6mcg, 31.2mcg, 62.4mcg, 124.8mcg once-daily and 15.6mcg, 31.2mcg, 62.4mcg twice-daily) were evaluated compared to placebo in 388 subjects with COPD

Clinical Trials

- The differences in trough FEV_1 from baseline after 28 days for -glycopyrrolate 15.6mcg, 31.2mcg, 62.4mcg, 124.8mcg once-daily and 15.6mcg, 31.2mcg, 62.4mcg twice-daily vs. placebo were 0.083L (95% CI: 0.030, 0.136), 0.098L (0.048, 0.148), 0.090L (0.038, 0.142), 0.176L (0.132, 0.220), 0.139L (0.089, 0.189), 0.167L (0.115, 0.219), and 0.177L (0.132, 0.222), respectively
- These results supported the evaluation of the glycopyrrolate 15.6mcg twice daily dose in the confirmatory COPD trials

Clinical Trials

- The confirmatory trials included two (Trials 1 and 2) similar 12-week, randomized, double-blind, placebo-controlled, parallel-group studies that evaluated glycopyrrolate 15.6mcg twice daily and placebo twice daily in 867 subjects with COPD

Clinical Trials

- The primary endpoint was the change from baseline in FEV1 $AUC_{0–12h}$ after the morning dose at Day 85 compared with placebo
- In both trials, Seebri Neohaler demonstrated a larger increase in mean change from baseline in FEV_1 $AUC_{0–12h}$ vs. placebo, with a treatment difference of 0.139L (95% CI: 0.095, 0.184) in Trial 1 and 0.123L (95% CI: 0.081, 0.165) in Trial 2

Clinical Trials

- Both trials also showed that patients treated with Seebri Neohaler used less daily rescue albuterol during the trial compared to placebo patients

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the complete product monograph available at:

http://www.empr.com/seebri-neohaler/drugproduct/411/