Lonhala Magnair

(glycopyrrolate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Lonhala Magnair
- **Generic name:** Glycopyrrolate
- **Pharmacological class:** Long-acting anticholinergic
- **Strength and Formulation:** 25mcg/mL; oral solution for inhalation
- **Manufacturer:** Sunovion
- **How supplied:** Kit—60 vials (w. Magnair device)
- **Legal Classification:** Rx

Indications

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

Lonhala Magnair

Dosage & Administration

- For oral inhalation use only with Magnair device
- Administer at the same time of the day (AM + PM)
- Inhale contents of one vial (25mcg) twice daily

Considerations for Special Populations

- **Pregnancy:** Use only if expected benefit outweighs potential risk to fetus
- **Nursing mothers:** Consider clinical need and potential adverse effects
- **Pediatric:** Not established
- **Elderly:** No dose adjustment needed

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

- Narrow-angle glaucoma
- Urinary retention
- Prostatic hyperplasia
- Bladder-neck obstruction
- Labor & delivery

Interactions

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

Adverse Reactions

- Dyspnea
- Urinary tract infection
- Wheezing
- Upper respiratory tract infection
- Nasopharyngitis
- Peripheral edema
- Fatigue
- Paradoxical bronchospasm
- Hypersensitivity reactions

Mechanism of Action

- **Glycopyrrolate** exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation
- The bronchodilation is predominantly a site-specific effect

Clinical Studies

- The safety and efficacy of Lonhala Magnair were evaluated in 2 dose-ranging studies, 2 placebo-controlled confirmatory studies (12-week studies), and a 48-week long-term safety study

Clinical Studies

- **Study 1** (N=435) and **Study 2** (N=426) were randomized, double-blind, placebo-controlled, parallel-group, 12-week studies that evaluated Lonhala Magnair 25mcg and 50mcg twice daily vs placebo twice daily

Clinical Studies

- **The primary endpoint** was change from baseline in trough FEV_1 at Day 84 vs placebo

Clinical Studies

- Lonhala Magnair 25mcg twice daily resulted in a larger increase in mean change from baseline in **trough FEV_1** vs placebo
  - **Study 1:** 0.089 vs -0.008 (treatment difference 0.096, 95% CI, 0.059, 0.133)
  - **Study 2:** 0.092 vs 0.011 (treatment difference 0.081, 95% CI, 0.042, 0.120)

Clinical Studies

- Lonhala Magnair 50mcg **did not** provide sufficient additional benefit on various endpoints, including FEV_1, to support use of higher doses

Clinical Studies

- Mean peak FEV_1 improvement from baseline on Day 1 and Day 84 in a subset of patients was **0.228L** and **0.214L**, respectively (Study 1)

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/lonhala-magnair/drug/34807/