Utibron Neohaler

(indacaterol, glycopyrrolate)

New Product
Slideshow

MPR

Introduction

- **Brand name:** Utibron Neohaler
- **Generic name:** Indacaterol, glycopyrrolate
- **Pharmacological class:** Long-acting beta2-agonist (LABA) + anticholinergic
- **Strength and Formulation:** 27.5mcg/15.6mcg; per capsule; dry powder for oral inhalation for use with Neohaler device; contains lactose
- **Manufacturer:** Novartis
- **How supplied:** Blister pack—6, 60 (w. one Neohaler device)
- **Legal Classification:** Rx

UTIBRON NEOHALER

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 or for the treatment of asthma

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 (27.5mcg/15.6mcg) twice daily

Considerations for Special Populations

- **Pregnancy:** Category C
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Geriatric:** No overall differences in efficacy or safety
- **Renal impairment:** Severe impairment or ESRD requiring dialysis: use if benefit outweighs potential risk
- **Hepatic impairment:** Severe impairment: not studied

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 in patients during acutely deteriorating or potentially life-threatening COPD episodes
- Not for treating acute symptoms
- Prescribe a short-acting β_2-agonist for acute symptoms; monitor for increased need

Warnings/Precautions

- Do not exceed recommended dose
- **Discontinue** immediately and treat if paradoxical bronchospasm or immediate hypersensitivity reactions occur; use alternative therapy
- Severe milk protein hypersensitivity
- Cardiovascular disorders (eg, coronary insufficiency, cardiac arrhythmias, hypertension)
- Convulsive disorders
- Thyrotoxicosis

Warnings/Precautions

- Hyperresponsiveness to sympathomimetics
- Diabetes, ketoacidosis
- Narrow-angle glaucoma
- Urinary retention
- Prostatic hyperplasia
- Bladder-neck obstruction
- Hypokalemia
- Hyperglycemia
- Labor & delivery

Interactions

- Caution with concomitant other 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, tricyclics, 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

- Nasopharyngitis
- Hypertension
- Back pain
- Oropharyngeal pain
- Paradoxical bronchospasm
- Hypersensitivity reactions

Mechanism of Action

- **Indacaterol**, a LABA, stimulates intracellular adenyl cyclase for the conversion of ATP to cyclic AMP, increasing its levels which then causes bronchial smooth muscle relaxation and inhibition of release of mediators of immediate hypersensitivity from mast cells
- **Glycopyrrolate**, a long-acting muscarinic antagonist, inhibits M3 receptor at the smooth muscle in the airways leading to bronchodilation

Clinical Trials

- The safety and efficacy of Utibron Neohaler were evaluated in 3 dose-ranging trials, two 12-week (placebo- and active-controlled) lung function trials, and a 12-month long-term safety trial
- Results from the individual components' dose-ranging trials supported the evaluation of indacaterol 27.5mcg twice daily (BID) and glycopyrrolate 15.6mcg BID in the confirmatory COPD trials

Clinical Trials

- The confirmatory trials (Trials 1 and 2), evaluated Utibron Neohaler in 2,038 COPD subjects
- The **primary endpoint** was the change from baseline in FEV_1 $AUC_{0\text{-}12h}$ following the morning dose at Day 85 compared to placebo, glycopyrrolate 15.6mcg BID and indacaterol 27.5mcg BID

Clinical Trials

- In both trials, Utibron Neohaler demonstrated a larger increase in mean change from baseline in FEV_1 $AUC_{0\text{-}12h}$ compared to placebo, indacaterol, and glycopyrrolate
  - **Trial 1:** 0.262L (0.224, 0.300), 0.112L (0.075, 0.149), 0.079L (0.042, 0.116)
  - **Trial 2:** 0.231L (0.192, 0.271), 0.094L (0.055, 0.133), 0.098L (0.059, 0.137)
- 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/utibron-neohaler/drugproduct/404/