Duaklir Pressair (aclidinium bromide and formoterol fumarate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Duaklir Pressair
- **Generic name:** Aclidinium bromide and formoterol fumarate
- **Pharmacological class:** Anticholinergic + long-acting beta-2 agonist (LABA)
- **Strength and Formulation:** 400mcg/12mcg per actuation; dry powder for oral inhalation
- **Manufacturer:** Circassia Pharmaceuticals
- **How supplied:** Dry powder inhaler—30, 60 doses
- **Legal Classification:** Rx

Duaklir Pressair

Indication

- Maintenance treatment of patients with chronic obstructive pulmonary disease (**COPD**)

Limitations of Use

- Not indicated for the relief of acute bronchospasm or for the treatment of asthma

Dosage and Administration

Adults:

- One inhalation twice daily (in the AM + PM)
- Max 1 inhalation twice daily

Considerations for Special Populations

- **Pregnancy:** not enough data to inform drug-associated risks
- **Nursing mothers**: no available data on the effects on the breastfed child or on milk production or presence in human milk
- **Pediatric**: not indicated for use in children
- **Geriatric:** no adjustment of dosage warranted
- **Hepatic impairment:** no adjustment of dosage warranted
- **Renal impairment:** no adjustment of dosage warranted

Contraindications

- Use of LABA without inhaled corticosteroid (ICS) in asthma
- Milk protein sensitivity

Warnings/Precautions

- LABA as monotherapy (without ICS) for asthma can increase risk of asthma-related events
- Do not initiate in acute deteriorating COPD
- Not for relief of acute symptoms
- Prescribe a short-acting β2-agonist for acute symptoms; monitor for increased need
- Do not exceed recommended dose
- 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
- Hyperglycemia
- Narrow-angle glaucoma
- Urinary retention
- Prostatic hyperplasia
- Bladder-neck obstruction

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
- **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

- **Most common (≥3%)**: upper respiratory tract infection, headache
- **Others:** back pain, paradoxical bronchospasm, hypersensitivity reactions, cardiovascular effects

Mechanism of Action

- Duaklir Pressair contains 2 bronchodilators: aclidinium, a long-acting muscarinic antagonist, and formoterol, a long-acting beta$_2$-adrenergic agonist
- In the airways, aclidinium bromide exhibits pharmacological effects through inhibition of M_3 receptors at the smooth muscle leading to bronchodilation
- Inhaled formoterol fumarate acts locally in the lung as a bronchodilator

Clinical Trials

- The safety and efficacy of Duaklir Pressair was evaluated in a clinical development program that included 3 dose ranging trials, 1 active and 2 placebo-controlled lung function trials of 24 weeks duration; and one 28-week long-term safety extension study
- Efficacy was primarily based on 1 dose ranging trial in 128 subjects with COPD and the three 6-month duration confirmatory trials in 5015 patients with COPD, including chronic bronchitis and emphysema

Clinical Trials

- The 24-week trials included 4,977 patients >40 years old that had a clinical diagnosis of COPD, with a smoking history ≥10 pack-years, a post-albuterol FEV_1< 80% of predicted normal values, and a ratio of FEV_1/FVC of less than 0.7
- Results showed that treatment with Duaklir Pressair led to a statistically significant increase in mean change from baseline in trough FEV_1 and change from baseline in 1-hour post-dose FEV_1 at Week 24 (co-primary end points) relative to formoterol fumarate 12mcg and aclidinium 400mcg, respectively

Clinical Trials

Least Squares Mean Change From Baseline in 1-hour Morning Post Dose FEV_1 at 24 Weeks Compared With Aclidinium 400mcg

- *Trial 1*
  - Difference: 0.125L (95% CI: 0.090, 0.160)
- *Trial 2*
  - Difference: 0.108L (95% CI: 0.073, 0.144)
- *Trial 3*
  - Difference: 0.084L (95% CI: 0.051, 0.117)

Clinical Trials

Least Squares Mean Change From Baseline in Trough FEV_1 at 24 Weeks Compared With Formoterol Fumarate 12mcg

- *Trial 1*
  - Difference: 0.085L (95% CI: 0.051, 0.119)
- *Trial 2*
  - Difference: 0.045L (95% CI: 0.011, 0.079)
- *Trial 3*
  - Difference: 0.055L (95% CI: 0.023, 0.088)

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/duaklir-pressair/