ARMONAIR RESPICLICK

(fluticasone propionate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** ArmonAir RespiClick
- **Generic name:** Fluticasone propionate
- **Pharmacological class:** Steroid
- **Strength and Formulation:** 55mcg, 113mcg, 232mcg; per actuation; dry pwd for oral inh with a dose counter
- **Manufacturer:** Teva Pharmaceuticals
- **How supplied:** RespiClick (60 actuations)—1
- **Legal Classification:** Rx

ArmonAir RespiClick

Indications

- Maintenance treatment of asthma as prophylactic therapy

Limitations of Use

- Not for the relief of acute bronchospasm

Dosage & Administration

- Allow approximately 12hrs between doses
- Take at same time each day
- Rinse mouth after each dose
- **Not previously on inhaled steroid:** 1 inh of 55mcg twice daily
- **Already on inhaled steroid:** see full labeling

Dosage & Administration

- If insufficient response after 2 weeks, use next higher strength
- Max 1 inh of 232mcg twice daily
- Titrate to lowest effective dose after stability achieved

Considerations for Special Populations

- **Pregnancy:** Monitor closely
- **Nursing mothers:** Consider benefits with potential adverse effects
- **Pediatric:** <12yrs: not established
- **Elderly:** No overall differences in safety or efficacy were observed
- **Hepatic impairment:** Monitor closely

Contraindications

- Primary treatment of status asthmaticus or other acute episodes of asthma requiring intensive measures
- Severe milk protein hypersensitivity

Warnings/Precautions

- Do not exceed recommended dose
- Prescribe a short-acting, inhaled β_2-agonist for acute symptoms; monitor for increased need
- Immunosuppressed
- Tuberculosis
- Systemic infection

Warnings/Precautions

- Ocular herpes simplex
- If exposed to chickenpox or measles, consider immune globulin or antiviral prophylactic therapies
- Monitor for signs/symptoms of adrenal insufficiency when transferring from systemic steroids

Warnings/Precautions

- May need supplemental systemic corticosteroids during periods of stress or a severe asthma attack
- May unmask previously suppressed allergic conditions
- Reevaluate periodically

Warnings/Precautions

- Monitor for hypercorticism and HPA axis suppression (if occurs, discontinue gradually), growth in children, visual changes, or with a history of increased intraocular pressure, glaucoma and/or cataracts
- Discontinue if paradoxical bronchospasm occurs; use alternative therapy

Warnings/Precautions

- Eosinophilic conditions
- Assess bone mineral density if risk factors exist (eg, prolonged immobilization, osteoporosis, or chronic use of drugs that can reduce bone mass [eg, anticonvulsants, oral steroids])
- Do not use with spacers or volume holding chambers

Interactions

- Concomitant **strong CYP3A4 inhibitors** (eg, ketoconazole, itraconazole, ritonavir, atazanavir, clarithromycin, indinavir, nefazodone, nelfinavir, saquinavir, telithromycin): not recommended

Adverse Reactions

- Nasopharyngitis
- Upper respiratory tract infection
- Oral candidiasis
- Headache
- Cough
- Hypersensitivity reactions
- Adrenal suppression
- Immunosuppression
- Churg-Strauss syndrome
- Bronchospasm

Mechanism of Action

- Fluticasone propionate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity
- Corticosteroids have been shown to have a wide range of actions on multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (eg, histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation

Clinical Studies

- ArmonAir RespiClick was evaluated in 2,130 patients with asthma in 2 confirmatory trials of 12 weeks duration, a 26-week safety trial, and 2 dose-ranging trials of 12 weeks

Clinical Studies

- In Trial 1, patients were randomized as follows:
  - Placebo (n=130)
  - ArmonAir RespiClick 55mcg (n=129)
  - ArmonAir RespiClick 113mcg (n=130)
  - Airduo RespiClick 55/14mcg (n=129)
  - Airduo RespiClick 113/14mcg (n=129)

Clinical Studies

- The **primary endpoints** were the change from baseline in trough FEV_1 at Week 12 for all patients and standardized baseline-adjusted FEV_1 $AUEC_{0\text{-}12h}$ at Week 12 for a subset (n=312) who underwent post-dose serial spirometry

Clinical Studies

- Patients in the ArmonAir arms had significantly greater improvements in trough FEV_1 vs. placebo
- Estimated mean differences between ArmonAir 55mcg and 113mcg vs. placebo were **0.119L** (95% CI: 0.025, 0.212) and **0.151L** (95% CI: 0.057, 0.244), respectively

Clinical Studies

- In Trial 2, patients were randomized as follows:
  - Placebo (n=145)
  - ArmonAir RespiClick 113mcg (n=146)
  - ArmonAir RespiClick 232mcg (n=146)
  - AirDuo RespiClick 113/14mcg (n=145)
  - AirDuo RespiClick 232/14mcg (n=146)

Clinical Studies

- The **primary endpoints** were the change from baseline in trough FEV_1 at Week 12 for all patients and standardized baseline-adjusted FEV_1 $AUEC_{0\text{-}12h}$ at Week 12 for a subset (n=312) who underwent post-dose serial spirometry

Clinical Studies

- Patients in the ArmonAir arms had significantly greater improvements in trough FEV_1 vs. placebo
- Estimated mean differences between ArmonAir 113mcg and 232mcg vs. placebo were **0.123L** (95% CI: 0.038, 0.208) and **0.183L** (95% CI: 0.098, 0.268), respectively

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/armonair-respiclick/drug/34748/