Yupelri (revefenacin)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Yupelri
- **Generic name:** Revefenacin
- **Pharmacological class:** Long-acting anticholinergic
- **Strength and Formulation:** 175mcg/3mL; solution for inhalation
- **Manufacturer:** Mylan, Inc.
- **How supplied:** Vials (3mL)—7, 30
- **Legal Classification:** Rx

Yupelri


NDC 49502-806-93
Rx only
YUPELRI™
(revefenacin) inhalation solution
175 mcg/3 mL
For Oral Inhalation Only
PHARMACIST: Dispense the enclosed Medication Guide to each patient.
Theravance Biopharma
Mylan
30 sterile unit-dose vials
OPEN HERE
NDC 49502-806-32 Rx only
YUPELRI™
(revefenacin)
inhalation solution
175 mcg/3 mL
For Oral Inhalation Only
Contents:
Each vial contains 175 mcg of revefenacin in an isotonic, sterile aqueous solution containing sodium chloride, citric acid and sodium citrate.
Storage:
Store YUPELRI (revefenacin) inhalation solution in the protective foil pouch. Store at room temperature from 68°F to 77°F (20°C to 25°C); excursions permitted from 59°F to 86°F (15°C to 30°C) [See USP Controlled Room Temperature]. Protect from direct sunlight and excessive heat. The YUPELRI unit-dose vial should only be removed from the foil pouch and opened IMMEDIATELY BEFORE USE. The vial and any residual content should be discarded after use. Discard any solution that is not clear and colorless. Use only as directed by your healthcare provider.
Keep out of reach of children.
Please read accompanying Medication Guide for dosage and administration.
Made in USA
Licensed from: Theravance Biopharma Ireland Limited
Manufactured for: Mylan Specialty L.P.
Morgantown, WV 26505 USA
Theravance Biopharma
Mylan

Indication

- Maintenance treatment of COPD

Dosage & Administration

- Administer by the orally inhaled route via standard jet nebulizer connected to an air compressor
- Inhale 1 vial (175mcg) once daily (using a mouthpiece)

Considerations for Special Populations

- **Pregnancy:** No adequate and well-controlled studies in pregnant women
- **Nursing mothers:** Consider mother's clinical need and potential adverse effects on breastfed infant
- **Pediatric:** Not indicated for use
- **Renal impairment:** Severe: monitor for antimuscarinic adverse effects
- **Hepatic impairment:** Not recommended

Warnings/Precautions

- **Do not initiate** in patients during acutely deteriorating or potentially life-threatening COPD episodes
- **Not** for treating acute symptoms
- Prescribe a **short-acting β2-agonist** for acute symptoms; monitor for increased need
- Do not exceed recommended dose

Warnings/Precautions

- **Discontinue immediately** and treat if paradoxical bronchospasm or immediate hypersensitivity reactions occur; use alternative therapy
- Narrow-angle glaucoma
- Urinary retention
- Prostatic hyperplasia
- Bladder-neck obstruction

Interactions

- **Additive effects** with concomitant other anticholinergic-containing drugs; avoid
- Concomitant **OATP1B1 and OATP1B3 inhibitors** (eg, rifampicin, cyclosporine): not recommended

Adverse Reactions

- Cough
- Nasopharyngitis
- Upper respiratory tract infection
- Headache
- Back pain
- Paradoxical bronchospasm

Mechanism of Action

- Revefenacin has similar affinity to the subtypes of muscarinic receptors M1 to M5
- In the airways, it inhibits the M3 receptor at the smooth muscle leading to bronchodilation
- Bronchodilation following revefenacin inhalation is predominantly a site-specific effect

Clinical Studies

- The efficacy and safety of Yupelri 175mcg once daily were evaluated in 2 dose-ranging trials, two replicate 12-week, phase 3 confirmatory trials, and a 52-week safety trial
- The efficacy of Yupelri was primarily based on the two replicate 12-week phase 3 trials (N=1229)

Clinical Studies

- The 2 replicate, randomized, double-blind, placebo-controlled, multiple dose, parallel-group confirmatory trials **(Trial 1 and Trial 2)** enrolled patients aged 40 years or older with moderate to very severe COPD and compared Yupelri vs placebo once daily

Clinical Studies

- Of the total 1229 patients, 395 received Yupelri 175mcg via a standard jet nbulizer
  - 37% of total patients were taking a LABA or ICS/LABA at study entry and remained on this during the study
- The **primary endpoint** was change from baseline in trough FEV_1 at day 85

Clinical Studies

- In both trials, Yupelri 175mcg showed **significant improvement in lung function** (mean change from baseline in trough FEV_1) vs placebo
  - **Trial 1:** 127mL vs -19mL (difference from placebo 146mL, 95% CI, 103.7, 188.8)
  - **Trial 2:** 102mL vs -45mL (difference from placebo 147mL, 95% CI, 97.0, 197.1)

Clinical Studies

- Serial spirometry over 24 hours was performed in a subset of patients in Trial 1 (N=89) and in Trial 2 (N=83)
- Mean peak FEV_1 improvement on day 1 vs placebo was **133mL** in Trial 1 and **129mL** in Trial 2

Clinical Studies

- In **Trial 1,** the SGRQ responder rate for the Yupelri arm was 49% vs 34% for placebo (odds ratio [OR] 2.11, 95% CI, 1.14, 3.92)
- In **Trial 2,** the SGRQ responder rate for the Yupelri arm was 45% vs 39% for placebo (OR 1.31, 95% CI, 0.72, 2.38)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/yupelri/drug/34904/