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
Indication

- Maintenance treatment of COPD
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
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 nebulizer
  - 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
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 FEV₁ 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
For more information view the product monograph available at:

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