US FDA approves YUPELRI (Revefenacin) a new drug to treat chronic lung condition (COPD) on 9th Nov 2018
COPD Disease Burden

What is COPD?

➢ It is a lung disease characterized by chronic obstruction of lung airflow that interferes with normal breathing and is not fully reversible.

➢ **Signs and Symptoms:**

![Image showing signs and symptoms of COPD]

Facts and Figures (1)

➢ The reported *prevalence* rates of COPD have ranged from 2 to 22% in men and from 1.2 to 19% in women in India.

➢ The economic impact of COPD among LMICs (Low – Middle Income Countries) is expected to increase to £1.7 trillion by 2030.

➢ India and China account for 66% of the global COPD mortality.

Source: [https://www.google.com/search?ei=hBJtW7iGB4_drQHDrL6oCg&q=definition+of+COPD+&oq=defination+of+COPD+&gs_l=psy-ab.3...35i304i39k1j0i13k1j7j0i13i30k1.5006.7591.0.8377.19.12.0.0.0.292.1841.0j5.9.0....0...0l6.0j4j5.9.lYPTyC1PCk](https://www.google.com/search?ei=hBJtW7iGB4_drQHDrL6oCg&q=definition+of+COPD+&oq=defination+of+COPD+&gs_l=psy-ab.3...35i304i39k1j0i13k1j7j0i13i30k1.5006.7591.0.8377.19.12.0.0.0.292.1841.0j5.9.0....0...0l6.0j4j5.9.lYPTyC1PCk)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5921960/...https://bmjopen.bmj.com/content/7/5/e015211
Who Has COPD?

- 65% Non-Hispanic White
- 15% American Indian/Alaska Native
- 8% Non-Hispanic Black
- 6% Hispanic
- 2% Other
- 1% Asian

56% Women
44% Men

38% Current Smoker
25% Not associated with direct cigarette smoking
37% Former Smoker

ECONOMIC BURDEN OF COPD IN INDIA

1 crore = 10 Million Rs. = £142857

- 35,331 crores
- 4135.17 crores

Burden of COPD is more than Asthma. Even when under-diagnosis is more common in COPD.
THE GLOBAL BURDEN OF COPD

Currently the 4th leading cause of death in the world
Estimated to become the 3rd leading cause of death by 2020
More than 3 million people die of COPD annually

300 million
INDIVIDUALS WORLDWIDE HAVE COPD
AND WORLDWIDE DEATHS ARE EXPECTED TO INCREASE MORE THAN
30% IN THE NEXT 10 YEARS

ORANGE
IS THE OFFICIAL COLOR OF
COPD AWARENESS

EVERY FOUR MINUTES
SOMEONE DIES OF
COPD

#GoOrange
for COPD Awareness Month
About YUPELRI (Revefenacin) (1)

About Theravance Biopharma and Mylan

- Mylan is responsible for ex-US development and commercialization of Yupelri.
- Theravance Biopharma will receive up to $220 million in development and sales payments, as well as a profit-sharing arrangement with Mylan on US sales.
- Theravance Biopharma retains worldwide rights to deliver Revefenacin through other dosage forms; like a metered dose inhaler or dry powder inhaler (MDI/DPI), and the rights to nebulized Revefenacin in China.
- According to data; from the two 12-week efficacy trials-in which 1055 patients participated, Revefenacin COPD exacerbations from 15% to 18% in moderate-to-very-severe COPD for up to 52 weeks.

Brief on Yupelri

- **DOSAGE FORM:** Oral Inhalation solution
- **INDICATIONS AND USAGE:** It is an inhalation anticholinergic solution indicated for the treatment of COPD.
- **DOSE AND ADMINISTRATION:**
  - One 175 mcg vial /3 mL once daily.
  - It is an Inhalational nebulization solution
- **CONTRAINDICATIONS:**
  - It is contraindicated in patients who are Hypersensitive to Yupeleri or any other component of this solution.

[https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210598s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210598s000lbl.pdf)
About YUPELRI (Revefenacin) (2)

Product information

➢ WARNINGS AND PRECAUTIONS:
Stop Yupelri treatment immediately if patient start receiving below conditions:
• Paradoxical Bronchospasm,
• Worsening of narrow-angle glaucoma and
• Worsening of urinary retention.
• Patients with Hepatic Impairment

➢ ADVERSE REACTIONS:
• Cough
• Nasopharyngitis
• Upper respiratory tract infection
• Headache
• Back pain

➢ DRUG INTERACTIONS:
• Rifampicin
• Cyclosporine
• Also avoid taking other Anti-Cholinergic drugs

Mechanism of action

➢ Revefenacin is a long-acting muscarinic antagonist,
 ➢ It has similar affinity to the subtypes of muscarinic receptors M1 to M5.
➢ In the airways,
  Yupelri exhibits pharmacological effects through

Inhibition of M3 receptor at the Smooth Muscle

Leading to bronchodilation

Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210598s000lbl.pdf
Market Overview - COPD

Current Treatment options

- **Bronchodilators:**
  - Short-Acting: Levalbuterol, Ipratropium
  - Long-Acting: Tiotropium, salmeterol

- **Inhaled steroids:**
  - Fluticasone
  - Budesonide

- **Combination inhalers**
  - Salmeterol and fluticasone
  - Formoterol and budesonide

- **Phosphodiesterase-4 inhibitors**
  - Roflumilast

- **Theophylline**

- **Antibiotics**

- **Lung therapies**

- **Surgery**

Top Competitive landscape for YUPELRI

- **Lonhala Magnair**: Sunovion Pharmaceutical’s nebulized LAMA

  - It can be taken twice-daily and is administered for three minutes during each dosing period.

Source:
- [Mayo Clinic](https://www.mayoclinic.org/diseases-conditions/copd/diagnosis-treatment/drc-20353685)
- [PharmaSalmanac](https://www.pharmasalmanac.com/articles/mylan-and-theravance-will-receive-fda-decision-on-copd-drug-by-november)
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