

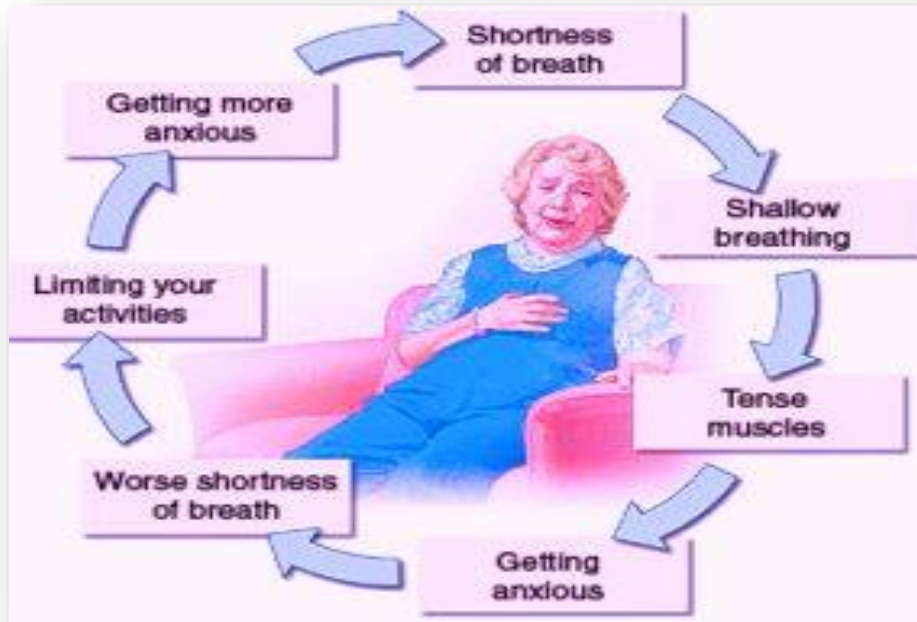
# US FDA approves YUPELRI (Revefenacin) a new drug to treat chronic lung condition (COPD) on 9<sup>th</sup> Nov 2018



# 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:**

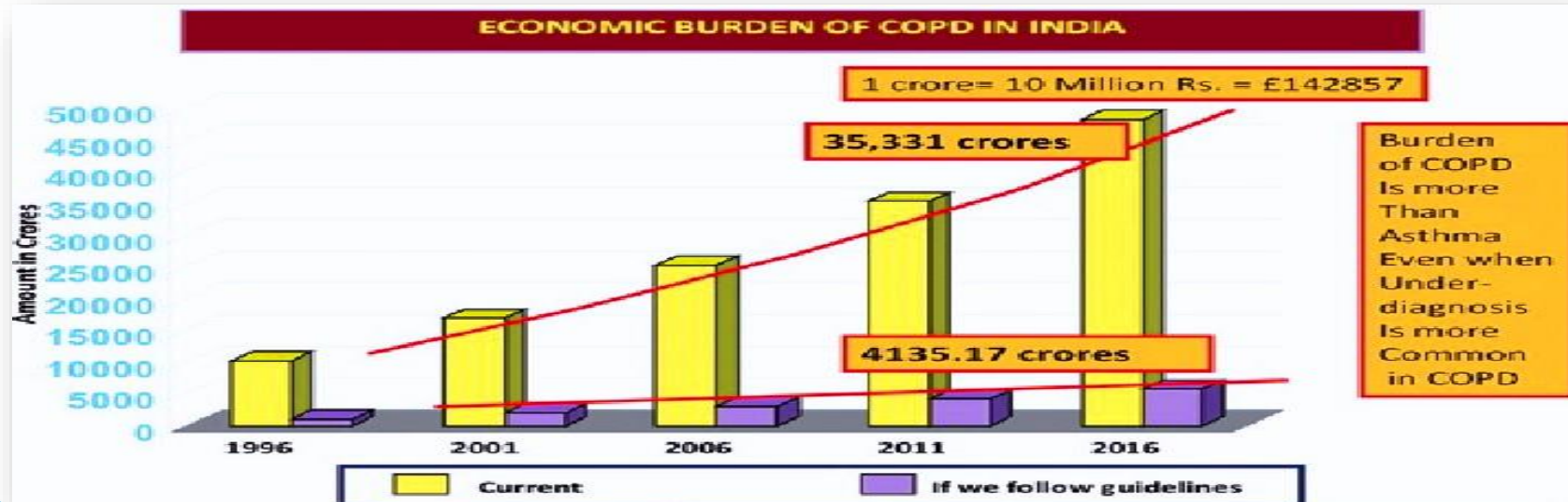
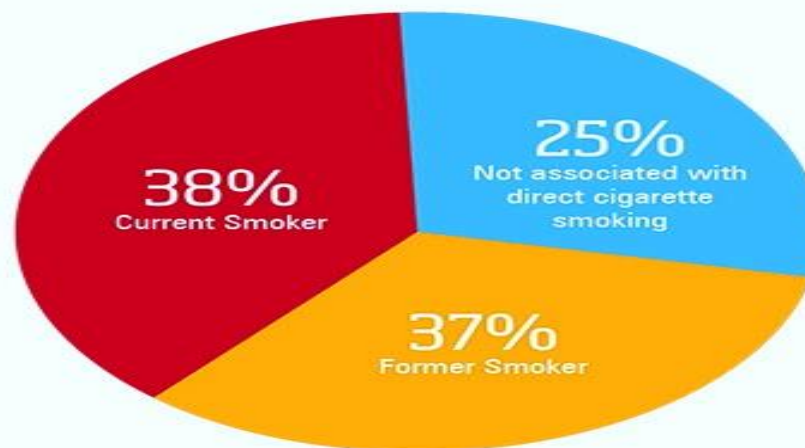


## Facts and Figures (1)

- 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.



# Who Has COPD?



## THE GLOBAL BURDEN OF COPD



Currently the **4<sup>th</sup>** leading cause of death in the world  
Estimated to become the **3<sup>rd</sup>** 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

#GoOrange  
for COPD Awareness Month

**ORANGE**  
IS THE OFFICIAL COLOR OF  
COPD AWARENESS

EVERY  
**FOUR**  
MINUTES  
SOMEONE  
DIES OF  
COPD

#GoOrange





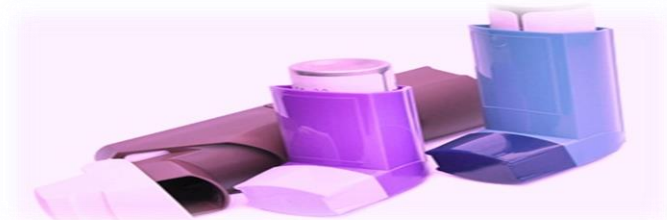
# About YUPELRI (Revefenacin) (1)

## 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 Inhalational 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 Yupelri or any other component of this solution.



Source: <http://newsroom.mylan.com/2018-11-09-Theravance-Biopharma-and-Mylan-Receive-FDA-Approval-for-YUPELRI-TM-revefenacin-in-Adults-with-Chronic-Obstructive-Pulmonary-Disease>

<https://www.pharmacytimes.com/news/onedaily-nebulized-therapy-for-copd-gets-fda-approval>

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/210508s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210508s000lbl.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**



# 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.





[www.pharmastate.com](http://www.pharmastate.com)

For Any Feedback or Suggestions mail at: [info@pharmastate.com](mailto:info@pharmastate.com)



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