

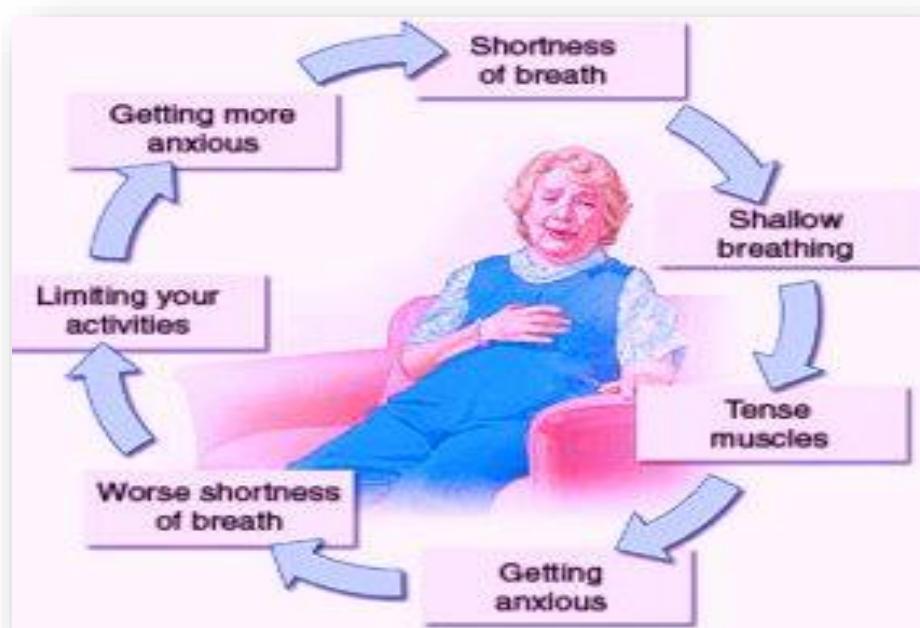
# US FDA approves YUPELRI (Reverfenacin) a new drug to treat chronic lung condition (COPD) on 9<sup>th</sup> Nov 2018



# COPD Disease Burden

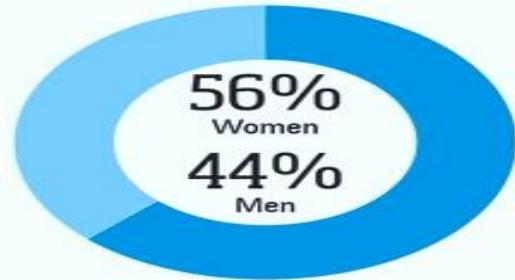
## What is COPD?

- 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:**

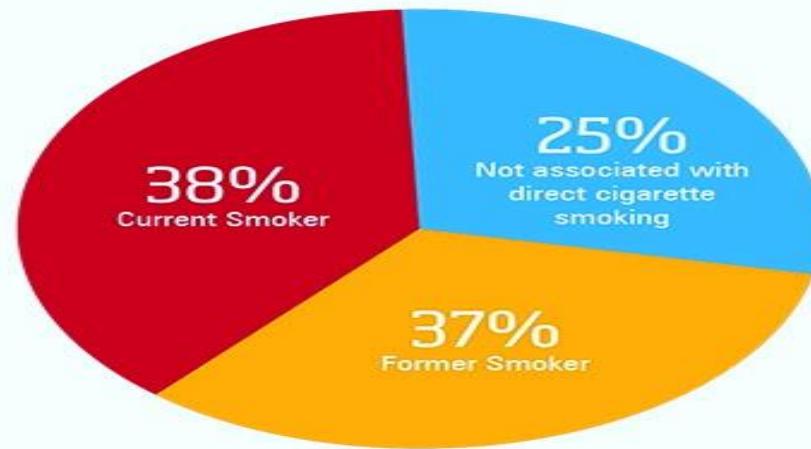


## Facts and Figures (1)

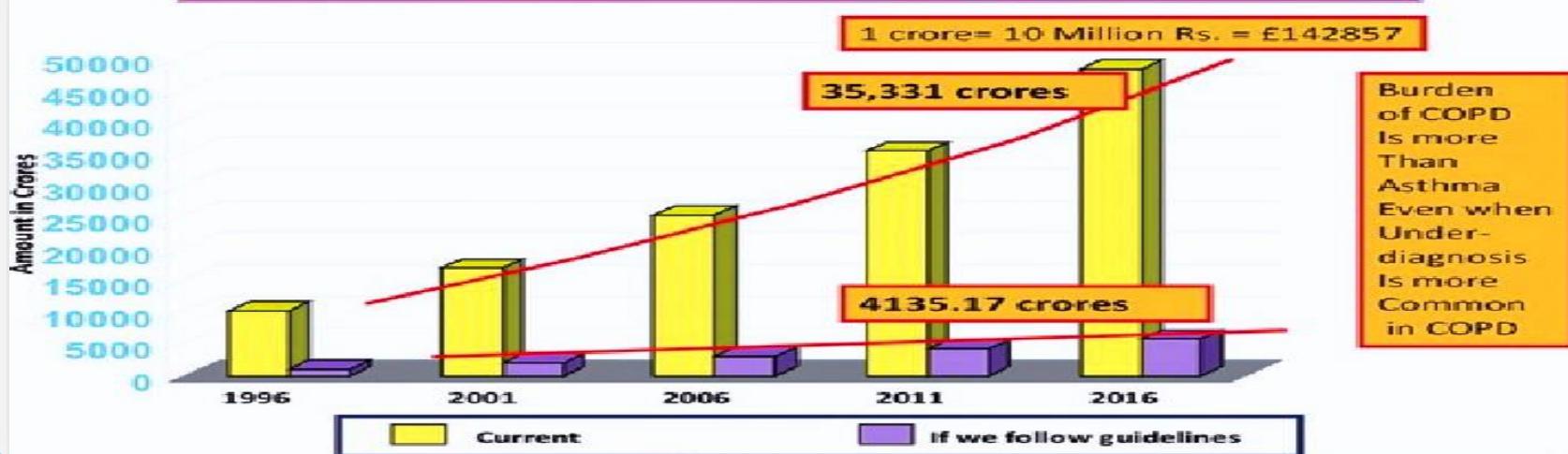
- The reported **prevalence** rates of COPD have ranged from 2 to 22% in men and from 1.2 to 19% in women in India.
- The economic impact of COPD among LMICs (**Low – Middle Income Countries**) is expected to increase to £1.7 trillion by 2030.
- India and China account for 66% of the global COPD mortality.



# Who Has COPD?



## ECONOMIC BURDEN OF COPD IN INDIA



## 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



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



**EVERY  
FOUR  
MINUTES  
SOMEONE  
DIES OF  
COPD**

#GoOrange



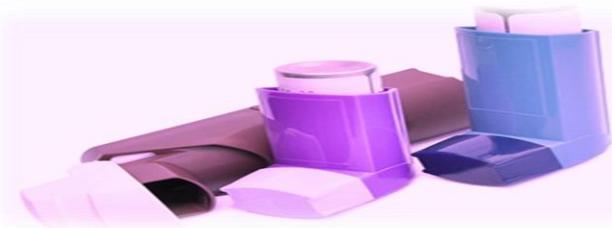
# About YUPELRI (Reverfenacin) (1)

## 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 Reverfenacin through other dosage forms; like - **a metered dose inhaler or dry powder inhaler (MDI/DPI), and the rights to nebulized Reverfenacin in China**
- According to data; from the two 12-week efficacy trials- in which 1055 patients participated, Reverfenacin → 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-reverfenacin-in-Adults-with-Chronic-Obstructive-Pulmonary-Disease>

<https://www.pharmacytimes.com/news/ondaily-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 (Reverfenacin) (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

- Reverfenacin 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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