

# ROFLUREN™

Roflumilast 500 mcg Tablets

## DESCRIPTION :

- ❖ ROFLUREN is orally available anti-inflammatory drug contains roflumilast 500 mcg. It is used in reducing the risk of flare-ups and worsened breathing problems in certain patients with severe chronic obstructive pulmonary disease (COPD), symptoms of chronic bronchitis, and a history of frequent exacerbations
- ❖ COPD is a progressive lung disease that may lead to death. Worldwide, COPD kills one person every 15 seconds and the World Health Organization predicts that it will be the third leading cause of death by 2030. The pathophysiology of COPD involves a complex series of chronic inflammatory processes that progressively destroy the pulmonary vasculature and lung parenchyma
- ❖ Roflumilast produces a statistically significant and clinically relevant reduction in exacerbations and improvement in lung function in patients with moderate to severe COPD. It can be used as add on therapy to standard bronchodilators

## INDICATIONS :

- ❖ Chronic Obstructive Pulmonary Disorder (COPD)
- ❖ Chronic Bronchitis
- ❖ Asthma

## MODE OF ACTION :

Roflumilast and its active metabolite (Roflumilast N-oxide) is potent and selective second generation phosphodiesterase (PDE-4) inhibitor, with an improved therapeutic index compared with the weak, nonselective PDE inhibitors. Inhibition of PDE4 (a major cyclic-3',5'-adenosine monophosphate (cyclic AMP)-metabolizing enzyme in lung tissue) leads to accumulation of intracellular cyclic AMP within localized immune cells and lung tissue leading to subsequent inhibition of pro-inflammatory cells and mediators

## DOSAGE :

One Tablet Daily or as prescribed by Registered Medical Practitioner

## PRESENTATION :

ROFLUREN Tablet is available in Blister of 10 tablets

### La Renon Healthcare

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Call me on: \_\_\_\_\_  
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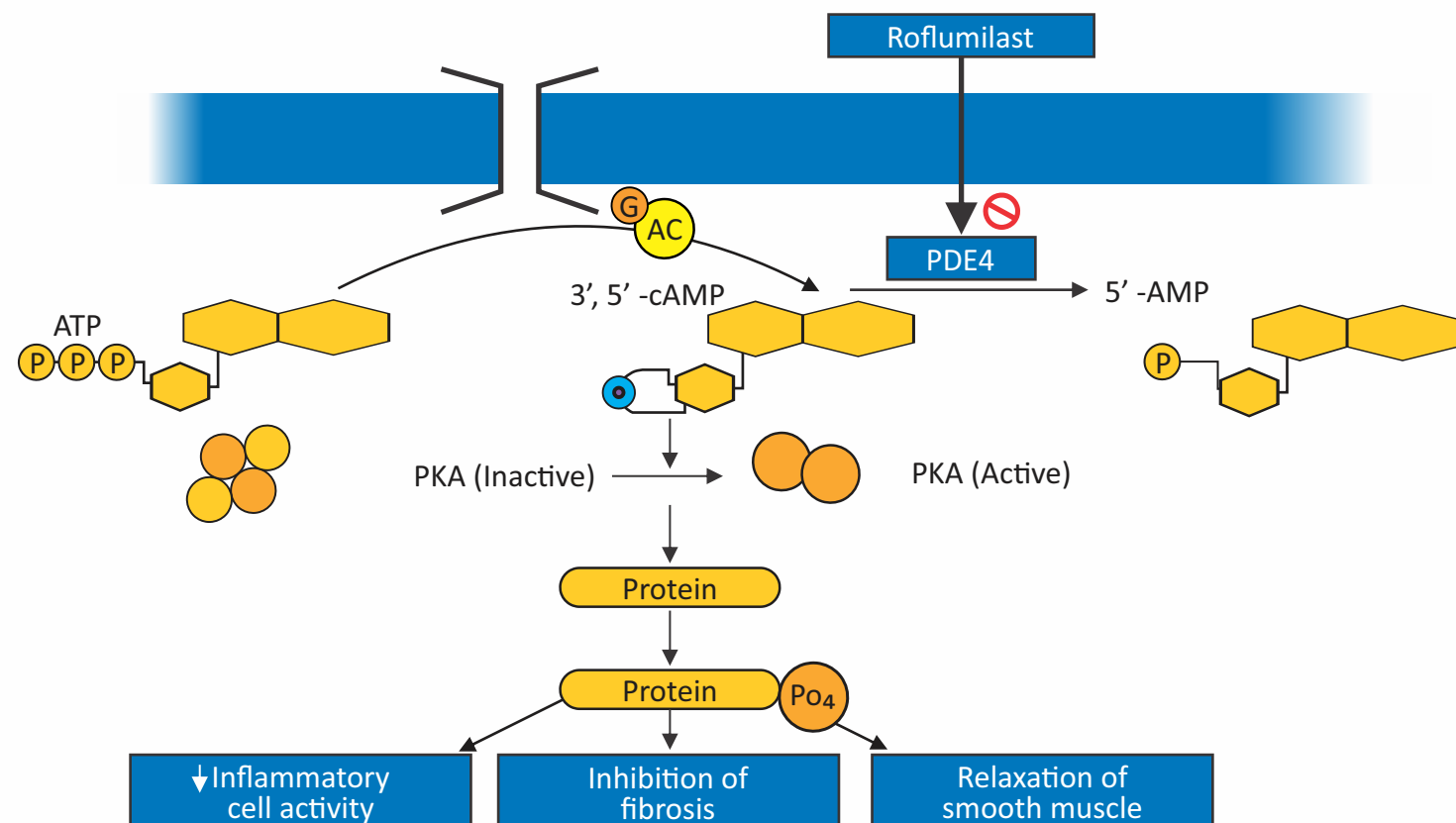
# TARGETED OUTCOME

# ROFLUREN™

Roflumilast 500 mcg Tablets

La Renon®

## PDE4 Is a Key Enzyme Involved in Modulating Production of Inflammatory Mediators by Immune Cells :



**Figure:** PDE4 inhibitors increase levels of cyclic adenosine monophosphate (cAMP) through inhibition of its metabolism. The resulting increase in protein kinase A (PKA) activation stimulates increased protein phosphorylation, with subsequent inhibition of pro-inflammatory cells and mediators and inhibition of fibrosis.

## CLINICAL EVIDANCE :

Sr. No.	Patients	Treatment
1	N= 1523 Bronchitis symptoms and a history of exacerbation	Roflumilast 500 mcg OD for 1 year
2	N= 1568 Bronchitis symptoms and a history of exacerbation	Roflumilast 500 mcg OD for 1 year
3	N=933 COPD Patients	Roflumilast 500 mcg OD for 24 weeks in addition to salmeterol 50 mcg twice a day
4	N=743 COPD Patients	Roflumilast 500 mcg OD for 24 weeks in addition to Tiotropium 18 mcg ounce a day

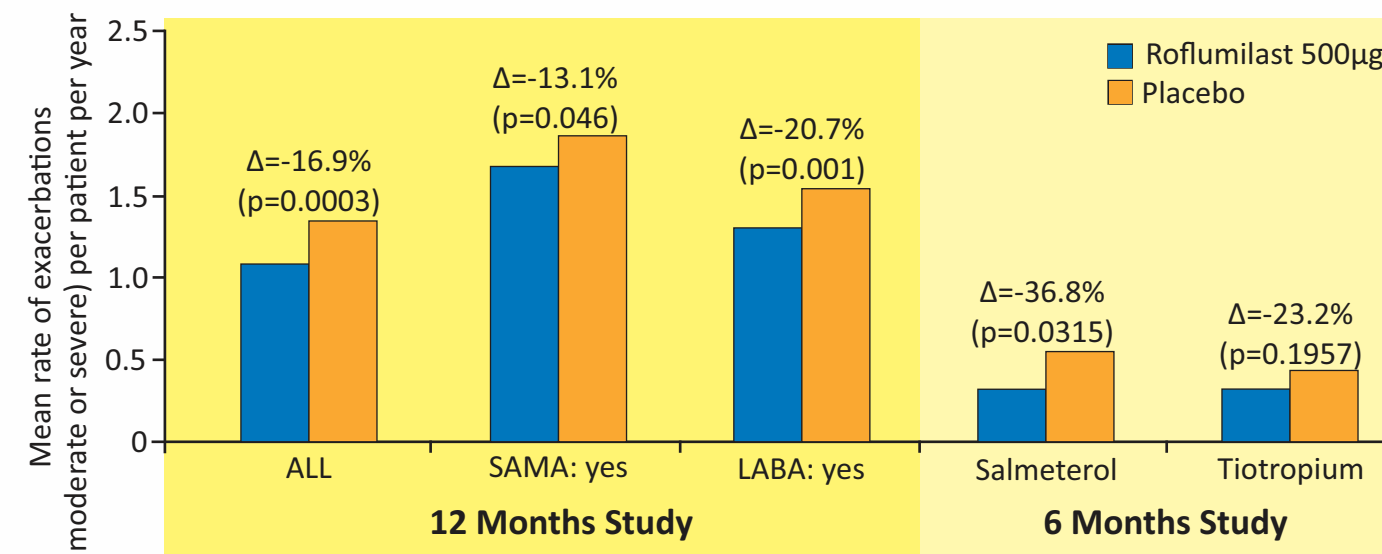
Roflumilast is effective when used concomitantly with all forms of bronchodilator and even in patients treated with ICS. Thus it represents an important addition to current therapeutic options for COPD patients with chronic bronchitis, including those who remain symptomatic despite treatment.

### Reference:

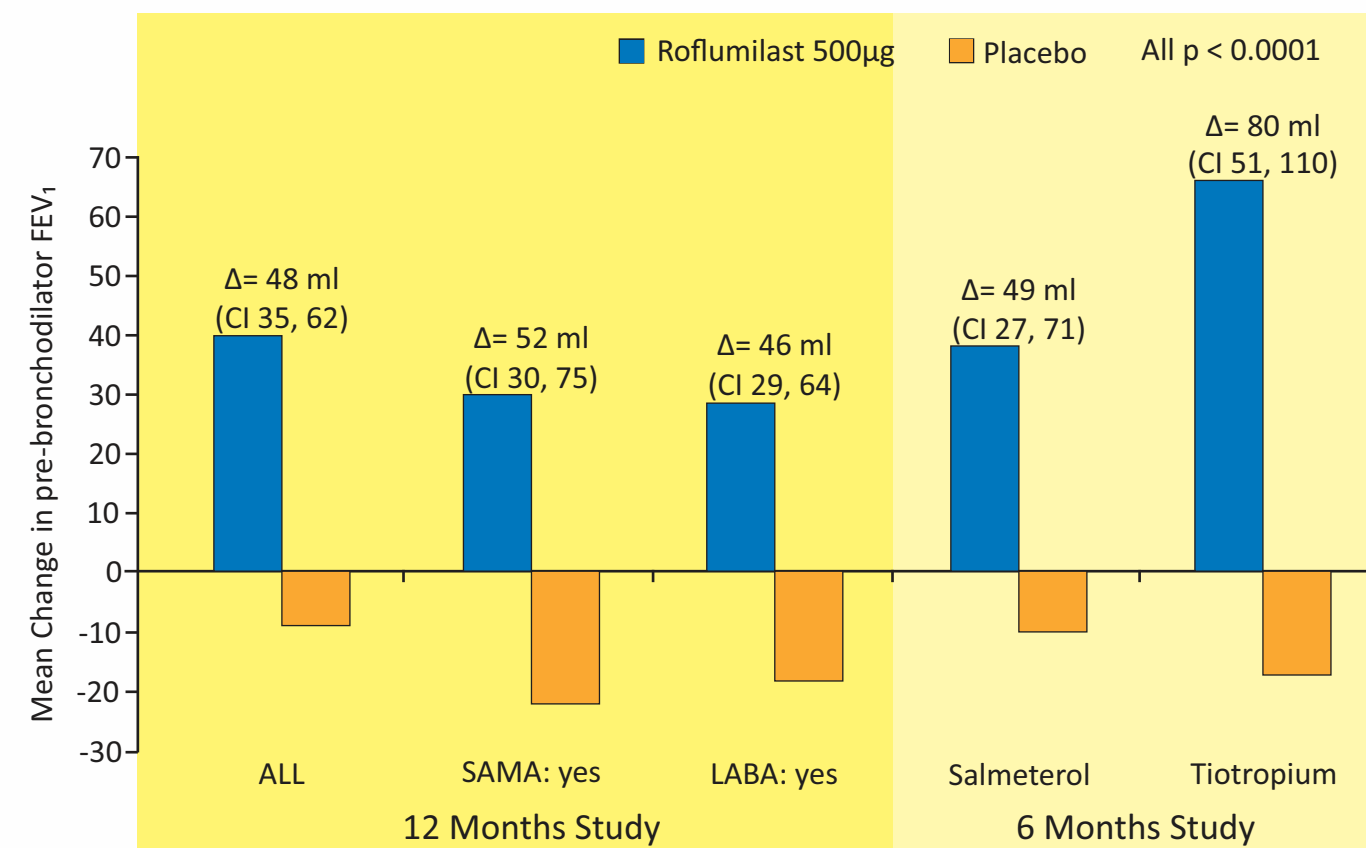
- 1) Klaus F. Rabe; British Journal of Pharmacology, (2011) 163 53–67 53.
- 2) The Lancet; Roflumilast in symptomatic chronic obstructive pulmonary disease: two randomised clinical trials, 2009; 374: 685–94.
- 3) Rennard SI et al. The effect of roflumilast treatment on exacerbations in patients with COPD; Am J Respir Crit Care Med. 2008;177:A963.
- 4) Calverley PMA (2010a); Roflumilast in the treatment of COPD: a pooled safety analysis. Eur Respir J Suppl 36 (Suppl. 54): P4001.

## RESULTS :

### 1) Mean Rate of Exacerbations:



### 2) Mean Change in pre-bronchodilator FEV<sub>1</sub>:



### Key Findings from above Charts:

#### 1) 12-Months studies:

Pre-bronchodilator **FEV<sub>1</sub> increased** in the roflumilast group by 48 mL, but was almost unchanged (8 mL increase) in the placebo group (CI 35, 62). There was also **16.9% reduction in the exacerbation rate** in the roflumilast group vs placebo (P = 0.0003).

#### 2) 6-Months studies:

Compared with placebo, roflumilast consistently improved mean pre-bronchodilator FEV<sub>1</sub> by 49 mL & 80 mL (P < 0.0001) in patients treated with Salmeterol and Tiotropium.