

# Trelanti™ Cozycap

Vilanterol 25 mcg, Umeclidinium 62.5 mcg & Fluticasone Furoate 100 mcg

## Composition:

**Trelanti™** Cozycap: Each cozycap contains Vilanterol 25 microgram (as Vilanterol Trifenatate INN), Umeclidinium 62.5 microgram (as Umeclidinium Bromide INN) and Fluticasone Furoate INN 100 microgram.

## Indication:

- For the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
- For the maintenance treatment of asthma in patients aged 18 years and older.

## Description:

**Trelanti™** Cozycap is an inhalation powder drug product for delivery of a combination of fluticasone furoate (an ICS), umeclidinium (an anticholinergic), and vilanterol (a LABA) to patients by oral inhalation. The pharmacologic effects of beta2-adrenoceptor agonist drugs, including vilanterol, are at least in part attributable to stimulation of intracellular adenylyl cyclase, the enzyme that catalyzes the conversion of adenosine triphosphate (ATP) to cyclic-3, 5 -adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

The precise mechanism through which fluticasone furoate affects COPD and asthma symptoms is not known. Inflammation is an important component in the pathogenesis of COPD and asthma. Corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. Umeclidinium is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptors M<sub>1</sub> to M<sub>5</sub>. In the airways, it exhibits pharmacological effects through inhibition of M<sub>3</sub> receptor at the smooth muscle leading to bronchodilation.

## Dosage & Administration:

Adults: 18 years or older: For oral inhalation only. Should be taken by **revolizer™**. Should be used at the same time every day, not more than 1 time every 24 hours. If shortness of breath or other asthma symptoms arise in the period between doses, an inhaled SABA should be taken for immediate relief.

- Maintenance treatment of COPD: 1 inhalation of **Trelanti™** cozycap once daily.
- Maintenance treatment of asthma: 1 inhalation of **Trelanti™** cozycap once daily.

Limitation of use: Not indicated for relief of acute bronchospasm.

## Contraindication:

- Primary treatment of status asthmaticus or acute episodes of COPD or asthma requiring intensive measures
- Severe hypersensitivity to milk proteins or any ingredients.

## Warnings & Precautions:

- LABA monotherapy increases the risk of serious asthma-related events.
- Do not initiate in acutely deteriorating COPD or asthma. Do not use to treat acute symptoms.
- Do not use in combination with additional therapy containing a LABA because of risk of overdose.
- Candida albicans infection of the mouth and pharynx may occur. Monitor patients periodically. Advise the patient to rinse his/her mouth with water without swallowing after inhalation to help reduce the risk.
- Increased risk of pneumonia in patients with COPD. Monitor patients for signs and symptoms of pneumonia.
- If paradoxical bronchospasm occurs, discontinue and institute alternative therapy.
- Use with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation.
- Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.

## Adverse effect:

COPD: Most common adverse reactions (incidence ≥1%) are upper respiratory tract infection, pneumonia, bronchitis, oral candidiasis, headache, back pain, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, dysgeusia, constipation, urinary tract infection, diarrhea, gastroenteritis, oropharyngeal pain, cough, and dysphonia.

Asthma: Most common adverse reactions (incidence ≥2%) are pharyngitis/nasopharyngitis, upper respiratory tract infection/viral upper respiratory tract infection, bronchitis, respiratory tract infection/viral respiratory tract infection, sinusitis/acute sinusitis, urinary tract infection, rhinitis, influenza, headache, and back pain.

## Drug interactions:

- Strong cytochrome P450 3A4 inhibitors (e.g., ketoconazole): Use with caution. May cause systemic corticosteroid and cardiovascular effects.
- Monoamine oxidase inhibitors and tricyclic antidepressants: Use with extreme caution. May potentiate effect of vilanterol on vascular system.
- Beta-blockers: Use with caution. May block bronchodilatory effects of beta-agonists and produce severe bronchospasm.
- Diuretics: Use with caution. Electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.
- Anticholinergics: May interact additively with concomitantly used anticholinergic medications. Avoid administration of Trelanti with other anticholinergic containing drugs.

## Use in Pregnancy and Lactation:

Insufficient data on the use of this preparation in pregnant women and lactating mother

Use in specific population:

Elderly population: Based on available data, no adjustment of the dosage in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

Renal impairment: It has not been studied in subjects with renal impairment.

Hepatic impairment: It has not been studied in subjects with hepatic impairment.

Pediatric population: It is not indicated for use in children and adolescents. The safety and efficacy in pediatric patients (aged 17 years and younger) have not been established.

## Storage Condition:

Store below 25° C, protect from light & moisture. Keep out of reach of children.

## Pharmaceutical Precaution:

**Trelanti™** Cozycap must not be swallowed. Only to be used with **revolizer™** device. Remove **Trelanti™** Cozycap capsule from the blister pack only immediately before use it in the **revolizer™**. After inhalation, rinse mouth with water without swallowing to reduce the risk of oropharyngeal candidiasis.

## How Supplied:

**Trelanti™** Cozycap: Each box contains 10 cozycaps in Alu-Alu blister.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH