

Vilanti™ Cozycap

Vilanterol & Fluticasone Furoate

Composition:

Vilanti™ 100 Cozycap: Each cozycap contains Vilanterol 25 micrograms (as Vilanterol Trifenatate INN) and Fluticasone Furoate INN 100 micrograms.

Vilanti™ 200 Cozycap: Each cozycap contains Vilanterol 25 micrograms (as Vilanterol Trifenatate INN) and Fluticasone Furoate INN 200 micrograms.

Indication:

• Long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

• Once-daily treatment of asthma in patients aged 18 years and older.

Description:

This preparation contains both fluticasone furoate and vilanterol, the mechanisms of action described below for the individual components. These drugs represent 2 different classes of medications (a synthetic corticosteroid and a LABA) that have different effects on clinical and physiological aspects.

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

Dosage & Administration

Should be administered as 1 inhalation once daily by the orally inhaled route only.

For COPD: **Vilanti™ 100 cozycap** 1 inhalation once daily. Should be taken by **revolizer™**.

For Asthma: **Vilanti™ 100 cozycap** or **Vilanti™ 200 cozycap** 1 inhalation once daily. The maximum recommended dosage is 1 inhalation of Vilanti 200 cozycap once daily. Should be taken by **revolizer™**.

Contraindication & Precautions:

- Primary treatment of status asthmaticus or acute episodes of COPD or asthma requiring intensive measures.
- Severe hypersensitivity to milk proteins or any ingredients.
- Hypersensitivity to the active substances or to any of the excipients.
- 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 an additional medicine 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.
- Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infections; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.

Side effects:

Common side effects in COPD: Most common adverse reactions (incidence $\geq 3\%$) are nasopharyngitis, upper respiratory tract infection, headache, oral candidiasis, back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, influenza, pharyngitis, and pyrexia.

Common side effects in Asthma: Most common adverse reactions (incidence $\geq 2\%$) are nasopharyngitis, oral candidiasis, headache, influenza, upper respiratory tract infection, bronchitis, sinusitis, oropharyngeal pain, dysphonia, and cough.

Drug interactions:

- Other adrenergic drugs may potentiate effect. Use with caution.
- Xanthine derivatives, steroids, diuretics or non-potassium sparing diuretics may potentiate hypokalemia or EDG changes. Use with caution.
- Diuretics: Use with caution.
- Monoamine oxidase inhibitors and tricyclic antidepressants: Use with extreme caution. May potentiate effect of formoterol fumarate on cardiovascular system.
- Beta-Blockers: Use with caution and only when medically necessary.
- Anticholinergics: May interact additively with concomitantly used anticholinergic medications. Avoid administrations of Beviprex 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: It can be used at the recommended dose in elderly patients.

Renal impairment: No dosage adjustment is required in patients with renal impairment.

Hepatic impairment: Caution should be observed in patients with moderate or severe hepatic impairment.

Pediatric population: The safety and efficacy of this combination in children have not been established. No data are available.

Storage Condition:

Store below 25° C. Protect from light & moisture. Keep out of the reach of children.

Pharmaceutical Precaution:

Vilanti™ Cozycap must not be swallowed. Only to be used with **revolizer™** device. Remove **Vilanti™ Cozycap** capsule from the blister pack only immediately before use it in the **revolizer™**.

How supplied:

Vilanti™ 100 Cozycap: Each box contains 20 Cozycaps in Alu-Alu blister.

Vilanti™ 200 Cozycap: Each box contains 20 Cozycaps in Alu-Alu blister.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH