

AclitolTM Cozycap

Aclidinium Bromide INN 400 mcg and Formoterol Fumarate Dihydrate EP 12 mcg

Composition

AclitolTM Cozycap: Each Cozycap contains Aclidinium Bromide INN 400 mcg and Formoterol Fumarate Dihydrate EP 12 mcg.

Indication

It is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Description

Aclidinium bromide:

Aclidinium bromide is a long-acting anti-muscarinic agent, which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of M3 receptors at the smooth muscle leading to bronchodilation. The competitive and reversible nature of antagonism was shown with human and animal origin receptors and isolated organ preparations. In preclinical, in vitro as well as in vivo studies, prevention of acetylcholine-induced bronchoconstriction effects was dose-dependent and lasted longer than 24 hours. The clinical relevance of these findings is unknown. The bronchodilation following inhalation of aclidinium bromide is predominantly a site-specific effect.

Formoterol fumarate:

Formoterol fumarate is a long-acting selective beta2-adrenergic receptor agonist (LABA) (beta 2-agonist). Inhaled formoterol fumarate acts locally in the lung as a bronchodilator. The pharmacologic effects of beta 2-adrenoceptor agonist drugs, including formoterol, 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.

Dosage & Administration

- For oral inhalation only. Should be taken by **revolizerTM**
- 400 mcg/12 mcg, twice daily (One Cozycap in the morning and one Cozycap in the evening).
- Do not take more than one inhalation twice daily.

Contraindication

- Use of a long-acting beta2-adrenergic agonist (LABA), including formoterol fumarate, one of the active ingredients in this combination, without an inhaled corticosteroid is contraindicated in patients with asthma.
- Hypersensitivity to aclidinium bromide or formoterol fumarate or to any component of this product.

Adverse reaction

Most common adverse reactions (incidence \geq 3% and more common than with placebo) include: upper respiratory tract infection and headache.

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Precautions

- Asthma-related death: Long-acting beta2-adrenergic agonists as monotherapy (without an inhaled corticosteroid) for asthma increase the risk of serious asthma-related events.
- Do not initiate in acutely deteriorating COPD or to treat acute symptoms.
- Do not use in combination with an additional medicine containing a LABA because of risk of overdose.
- If paradoxical bronchospasm occurs, discontinue this combination and institute alternative therapy.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus and ketoacidosis.
- Be alert to hypokalemia and hyperglycemia.
- Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a physician immediately if symptoms occur.
- Worsening urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to consult a physician immediately if symptoms occur.

Drug Interaction

- Use of other adrenergic by any route may potentiate the effect of this combination. Use with caution.
- Xanthine derivatives, steroids, diuretics or non-potassium sparing diuretics may potentiate hypokalemia or ECG changes. Use with caution.
 - Diuretics: Electrocardiographic changes and/or hypokalemia associated with non-potassium sparing diuretics may worsen with concomitant beta2-agonists. 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 this combination with other anticholinergic-containing drugs.

Use in Pregnancy and Lactation

Pregnancy

There are no adequate and well-controlled studies of **AclitolTM** or its individual components, formoterol fumarate or aclidinium bromide, in pregnant women to inform drug associated risks.

Lactation

There are no available data on the effects of aclidinium bromide, or formoterol fumarate on the breastfed child or on milk production or presence in human milk.

Storage

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

Pharmaceutical Precaution

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

How Supplied

AclitolTM Cozycap: Each box contains 20 Cozycaps in Alu-Alu blister.