

BufocortTM Cozycap

Budesonide BP and Formoterol Fumarate Dihydrate BP

COMPOSITION

BufocortTM 200 Cozycap : Each Cozycap contains Budesonide BP 200 mcg and Formoterol 6 mcg as Formoterol Fumarate Dihydrate BP. **BufocortTM 400** Cozycap : Each Cozycap contains Budesonide BP 200 mcg and Formoterol 12 mcg as Formoterol Fumarate Dihydrate BP

DESCRIPTION

BufocortTM Cozycaps are a combination of Budesonide BP and Formoterol Fumarate Dihydrate BP. Budesonide BP is a potent glucocorticoid that binds with high affinity to the glucocorticoid receptor. Formoterol Fumarate Dihydrate BP is a very potent, long-acting β_2 - adrenoceptor agonist with a high intrinsic activity and a rapid onset of action.

PHARMACOLOGY

Pharmacodynamics: **BufocortTM** Cozycap contain both Budesonide BP and Formoterol Fumarate Dihydrate BP; therefore, the mechanism of action described below for the individual components apply to **BufocortTM** Cozycap.

Budesonide BP: It is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity. Inflammation is an important component in the pathogenesis of asthma. Corticosteroids have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes and cytokines) involved in allergic and non-allergic-mediated inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in asthma.

Formoterol Fumarate Dihydrate BP: It is a long-acting, selective β_2 - adrenergic agonist with a rapid onset of action. Inhaled Formoterol Fumarate Dihydrate BP acts locally in the lungs as a bronchodilator. The pharmacological effects of β_2 -adrenoceptor agonist drugs are attributable to the stimulation of intracellular adenylyl cyclase, the enzyme that catalyses the conversion of adenosine triphosphate (ATP) to cyclic AMP. Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibit the release of mediators of immediate hypersensitivity from the cells, especially from mast cells.

INDICATIONS

BufocortTM Cozycaps are indicated in the regular treatment of asthma. They are also indicated in the symptomatic treatment of severe chronic obstructive pulmonary disease (COPD), with a history of repeated exacerbations despite regular therapy with long-acting bronchodilators.

DOSAGE AND ADMINISTRATION

Asthma

Dosage is individual and should be adjusted according to disease severity. When control has been achieved, the dose should be titrated to the lowest effective dose.

For **BufocortTM** there are two treatment approaches:

(A) Maintenance Therapy: Patients should be advised to have their separate rapid acting bronchodilator available for rescue use at all times.

Adults (18 Years and Older)

BufocortTM 200 Cozycap: 1-2 Cozycaps, twice daily, maximum dose is 4 Cozycaps, twice daily.

BufocortTM 400 Cozycap: 1 Cozycaps, twice daily, maximum dose is 2 Cozycaps, twice daily.

Adolescents (12-17 Years)

BufocortTM 200 Cozycap, 1-2 Cozycaps, twice daily.

BufocortTM 400 Cozycap, 1 Cozycap, twice daily.

Children (6-11 Years)

BufocortTM 200 Cozycap, 1 Cozycap, twice daily.

(B) Single Maintenance and Reliever Therapy (For **BufocortTM 200** Cozycap only) Patients take a daily maintenance dose of **BufocortTM** and in addition take **BufocortTM** as needed in response to symptoms. Patients should be advised to always have

BufocortTM available for use.

Adults (18 years and older): The recommended maintenance dosage is 2 inhalations per day as maintenance therapy (either one Cozycap twice daily, or two Cozycaps in either the morning or the evening), although some patients may require two Cozycaps twice daily.

Patients should take 1 additional Cozycap as needed in response to symptoms. If symptoms persist after a few minutes, an additional Cozycap should be taken. Not more than 6 Cozycaps should be taken on any single occasion.

A total daily dose of more than 8 Cozycaps is not normally needed; however, a total daily dose of up to 12 Cozycaps could be used for a limited period. Patients using more than 8 Cozycaps daily should be strongly recommended to seek medical advice.

COPD (Chronic Obstructive Pulmonary Disease)

BufocortTM 200 Cozycap : 2 Cozycaps , twice daily.

CONTRAINDICATION

BufocortTM Cozycaps are contraindicated in patients with a history of hypersensitivity to any of the components of the drug product.

PRECAUTION

Budesonide BP and Formoterol Fumarate Dihydrate BP Cozycap should be administered with caution in patients with severe cardiovascular disorders, including heart rhythm abnormalities, diabetes mellitus, untreated hypokalaemia, or thyrotoxicosis. Paradoxical bronchospasm may occur. In such cases, Budesonide BP and Formoterol Fumarate Dihydrate BP Cozycap should be discontinued immediately.

PREGNANCY AND LACTATION

Administration of **BufocortTM** Cozycaps in pregnant women and lactating mother should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

SIDE EFFECT

Budesonide BP: Hoarseness, and candidiasis (thrush) of the mouth and throat can occur in some patients. Cutaneous hypersensitivity reactions have been reported.

Formoterol Fumarate Dihydrate BP: Tremor, palpitations and headache have been reported. Cardiac arrhythmias, muscle cramps and hypersensitivity reactions, including rash, oedema and angio-oedema, may occur in some patients.

HOW TO USE

BufocortTM Cozycaps are recommended to be used with SQUARE's **revolizerTM**.

WARNING

BufocortTM Cozycaps must not be swallowed. Don't exceed the recommended dose. Store below 25^o C, protected from light & moisture. Insert the Cozycap in the **revolizerTM** just prior use, as Cozycap exposed to moisture may not tear easily.

HOW SUPPLIED

BufocortTM 200 Cozycap : Each pack contains 30 Cozycaps in alu-alu blister. **BufocortTM 400** Cozycap : Each pack contains 30 Cozycaps in alu-alu blister.

Manufactured by

