

# Bufocort<sup>®</sup> HFA MDI

Budesonide Ph. Eur. and Formoterol Fumarate Dihydrate Ph. Eur.

## COMPOSITION

**Bufocort<sup>®</sup>** 160 HFA MDI: Each puff delivers Budesonide Ph. Eur. 160 mcg and Formoterol Fumarate Dihydrate Ph. Eur. 4.5 mcg.

## DESCRIPTION

**Bufocort<sup>®</sup>** HFA MDI are a combination of Budesonide and Formoterol Fumarate Dihydrate. Budesonide is a potent glucocorticoid that binds with high affinity to the glucocorticoid receptor. Formoterol Fumarate Dihydrate is a very potent, long-acting  $\beta_2$  - adrenoceptor agonist with a high intrinsic activity and a rapid onset of action.

## PHARMACOLOGY

Pharmacodynamics: **Bufocort<sup>®</sup>** HFA MDI contains both Budesonide and Formoterol Fumarate Dihydrate; therefore, the mechanism of action described below for the individual components apply to **Bufocort<sup>®</sup>** HFA MDI. Budesonide: 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 & COPD. 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 & COPD.

Formoterol Fumarate Dihydrate: It is a long-acting, selective  $\beta_2$  – 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  $\beta_2$ -adrenoceptor agonist drugs are attributable to the stimulation of intracellular adenylyl cyclase, the enzyme that catalyzes 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

**Bufocort<sup>®</sup>** HFA MDI is 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

- Treatment of asthma in patients 12 years and older: 2 puffs of Bufocort<sup>®</sup> 160 HFA MDI twice daily. Starting dosage is based on asthma severity.
- Maintenance treatment in COPD: 2 puffs of Bufocort<sup>®</sup> 160 HFA MDI twice daily.

## CONTRAINDICATION

Budesonide and Formoterol Fumarate Dihydrate HFA MDIs are contraindicated in patients with a history of hypersensitivity to any of the components of the drug product.

## WARNING & PRECAUTION

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

## SIDE EFFECT

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

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

## PREGNANCY AND LACTATION

Administration of Budesonide and Formoterol Fumarate Dihydrate HFA MDIs 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 fetus.

## STORAGE

Keep out of the reach of children. Store below 30°C. Protect from direct sunlight and heat. Keep away from contact of eyes.

## HOW SUPPLIED

**Bufocort<sup>®</sup>** 160 HFA MDI: Each Inhaler delivers 120 puffs.

Manufactured by-



**SQUARE**  
**PHARMACEUTICALS PLC.**  
Bangladesh

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