FIRST TIME GENERIC APPROVAL

Brand Name	Perforomist®
Generic Name	formoterol fumarate
Drug Manufacturer	Teva Pharmaceuticals USA, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

June 22, 2021

LAUNCH DATE

June 23, 2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 091141

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Formoterol fumarate inhalation solution is a long-acting beta-adrenergic agonist (beta-agonist) indicated for: Long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Important limitations of use:

- Not indicated to treat acute deteriorations of chronic obstructive pulmonary disease.
- Not indicated to treat asthma.

MECHANISMS OF ACTION

Formoterol fumarate is a long-acting, beta-adrenergic receptor agonist (beta-agonist). Inhaled formoterol fumarate acts locally in the lung as a bronchodilator. In vitro studies have shown that formoterol has more than 200-fold greater agonist activity at beta-receptors than at beta-receptors. Although beta-receptors are the predominant adrenergic receptors in bronchial smooth muscle and beta-receptors are the predominant receptors in the heart, there are also beta-receptors in the human heart comprising 10% to 50% of the total beta-adrenergic receptors. The precise function of these receptors has not been established, but they raise the possibility that even highly selective beta-agonists may have cardiac effects.

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The pharmacologic effects of beta-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.

In vitro tests show that formoterol is an inhibitor of the release of mast cell mediators, such as histamine and leukotrienes, from the human lung. Formoterol also inhibits histamine-induced plasma albumin extravasation in anesthetized guinea pigs and inhibits allergen-induced eosinophil influx in dogs with airway hyper-responsiveness. The relevance of these in vitro and animal findings to humans with COPD is unknown.

DOSE FORM AND STRENGTH

Inhalation Solution (unit dose vial for nebulization); 20 mcg/2 mL solution.

DOSE & ADMINISTRATION

- For oral inhalation only. One 20 mcg/2 mL vial every 12 hours.
- For use with a standard jet nebulizer (with a facemask or mouthpiece) connected to an air compressor.