

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	fluticasone furoate and vilanterol
<b>Generic Name</b>	fluticasone furoate and vilanterol
<b>Drug Manufacturer</b>	Prasco Laboratories

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First time generic

#### FDA APPROVAL DATE

July, 2021

#### LAUNCH DATE

May 25, 2022

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

N/A

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION FOR USE

Fluticasone furoate/vilanterol is a combination of fluticasone furoate, an inhaled corticosteroid (ICS), and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for:

- 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.

**Limitation of use:** Not indicated for the relief of acute bronchospasm.

#### MECHANISMS OF ACTION

**Fluticasone Furoate:** Fluticasone furoate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Fluticasone furoate has been shown in vitro to exhibit a binding affinity for the human glucocorticoid receptor that is approximately 29.9 times that of dexamethasone and 1.7 times that of fluticasone propionate. The clinical relevance of these findings is unknown.

**Vilanterol:** Vilanterol is a LABA. In vitro tests have shown the functional selectivity of vilanterol was similar to salmeterol. The clinical relevance of this in vitro finding is unknown. Although beta2-receptors are the predominant

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adrenergic receptors in bronchial smooth muscle and beta1-receptors are the predominant receptors in the heart, there are also beta2-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 beta2-agonists may have cardiac effects. 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.

### DOSE FORM AND STRENGTH

Inhalation powder: Inhaler containing 2 foil blister strips of powder formulation for oral inhalation. One strip contains fluticasone furoate 100 or 200 mcg per blister and the other contains vilanterol 25 mcg per blister.

### DOSE & ADMINISTRATION

Fluticasone furoate/vilanterol should be administered as 1 inhalation once daily by the orally inhaled route only.

#### **Maintenance treatment of Chronic Obstructive Pulmonary Disease:**

- Fluticasone furoate/vilanterol 100/25 mcg should be administered as 1 inhalation once daily.
- The maximum recommended dosage is 1 inhalation of fluticasone furoate/vilanterol 100/25 mcg once daily.

#### **Treatment of Asthma:**

- The recommended starting dosage is fluticasone furoate/vilanterol 100/25 mcg or fluticasone furoate/vilanterol 200/25 mcg administered as 1 inhalation once daily.
- The maximum recommended dosage is 1 inhalation of fluticasone furoate/vilanterol 200/25 mcg once daily.

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