

FIRST TIME GENERIC APPROVAL

Brand Name	fluticasone propionate
Generic Name	fluticasone propionate
Drug Manufacturer	Prasco Laboratories

New Drug Approval

TYPE OF CLINICAL UPDATE

First time generic

FDA APPROVAL DATE

November, 2021

LAUNCH DATE

May 24, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

N/A

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Fluticasone propionate HFA is an inhaled corticosteroid indicated for maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older.

Limitations of use: Not indicated for relief of acute bronchospasm.

MECHANISMS OF ACTION

Fluticasone propionate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Fluticasone propionate has been shown in vitro to exhibit a binding affinity for the human glucocorticoid receptor that is 18 times that of dexamethasone, almost twice that of beclomethasone-17-monopropionate (BMP), the active metabolite of beclomethasone dipropionate, and over 3 times that of budesonide. Data from the McKenzie vasoconstrictor assay in man are consistent with these results. The clinical significance of these findings is unknown.

Inflammation is an important component in the pathogenesis of asthma. Corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. These anti-inflammatory actions of corticosteroids contribute to their efficacy in asthma.

DOSE FORM AND STRENGTH

44 mcg; 110 mcg and 220 mcg Fluticasone propionate per actuation.

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DOSE & ADMINISTRATION

- Fluticasone Propionate HFA should be administered by the orally inhaled route only.
- The starting dosage is based on previous asthma therapy and asthma severity, including consideration of patients' current control of asthma symptoms and risk of future exacerbation.
 - **Adult and Adolescent Patients Aged 12 Years and Older:** The recommended starting dosage for patients aged 12 years and older who are not on an inhaled corticosteroid (ICS): 88 mcg (2 inhalations of 44 mcg fluticasone propionate) twice daily by oral inhalation, approximately 12 hours apart. The maximum recommended dosage for patients aged 12 years and older is 880 mcg twice daily.
 - **Pediatric Patients Aged 4 to 11 Years:** The recommended dosage for patients aged 4 to 11 years: 88 mcg (2 inhalations of 44 mcg fluticasone propionate) twice daily by oral inhalation, approximately 12 hours apart.

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