RXADVANCE
2 Park Central Drive
Southborough, MA 01772

CLINICAL UPDATE

Brand Name	ArmonAir® Digihaler™
Generic Name	fluticasone propionate
Drug Manufacturer	Teva Pharmaceuticals

Clinical Update

TYPE OF CLINICAL UPDATE

New formulation approval – FDA approval of ArmonAir® Digihaler™ 55,113,232 mcg/actuation (fluticasone propionate) inhalation powder.

FDA APPROVAL DATE

September 18, 2020

LAUNCH DATE

September 21, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Type 4 - New Combination
SUPPL-7 - Labeling-Package Insert

DISPENSING RESTRICTIONS

None

Overview

INDICATION(S) FOR USE

ArmonAir® Digihaler™ is indicated for the maintenance treatment of asthma in patients 12 years and older. It is not indicated for the relief of acute bronchospasm. An estimated 25 million people in the United States live with asthma, a chronic disease of the lungs' bronchial tubes (airways). The condition can cause swelling, tightening, and scarring of the airways, making it difficult to breathe. Asthma attacks may be triggered by exposure to irritants and allergens in the environment. Fluticasone propionate, the active ingredient in ArmonAir® Digihaler™, is a corticosteroid used to reduce swelling in the bronchial tubes.

MECHANISMS OF ACTION

Fluticasone propionate is a synthetic trifluorinated corticosteroid with anti-inflammatory effects that acts as a human glucocorticoid receptor agonist with an affinity for the receptor that is 18 times greater than that of dexamethasone, almost twice that of beclomethasone-17-monopropionate, and over 3 times that of budesonide. Although its exact mechanism is unknown, glucocorticoids have been shown to inhibit mast cells, eosinophils, basophils, lymphocytes, macrophages, and neutrophils. Glucocorticoids also inhibit production or secretion of cell mediators such as histamine, leukotrienes, cytokines, and eicosanoids

CLINICAL UPDATE

DOSAGE FORM(S) AND STRENGTH(S)

ArmonAir® Digihaler™ with e-module: Inhalation powder containing 55 mcg, 113 mcg, or 232 mcg of fluticasone propionate per actuation.

DOSE & ADMINISTRATION

1 inhalation twice daily (approximately 12 hours apart at the same time every day) by the orally inhaled route.

EFFICACY

In two placebo-controlled, 12-week, clinical studies (Trial 1 and Trial 2) [see Clinical Studies (14)] a total of 822 adolescent and adult patients with persistent symptomatic asthma despite ICS or ICS/LABA therapy were treated twice daily with either placebo; or fluticasone propionate MDPI 55 mcg, 113 mcg, or 232 mcg. Sixty percent of patients were female and 80% of patients were white. The average duration of exposure was 82 days in the fluticasone propionate MDPI groups compared with 75 days in the placebo group. Table 1 displays the incidence of most common adverse reactions in pooled Trials 1 and 2.

Table 1: Adverse Reactions with ≥ 3% Incidence with Fluticasone Propionate MDPI, and More Common than Placebo in Subjects with Asthma

Adverse Reaction	Fluticasone Propionate MDPI 55 mcg (n=129) %	Fluticasone Propionate MDPI 113 mcg (n=274) %	Fluticasone Propionate MDPI 232 mcg (n=146) %	Placebo (n=273) %
URTI	5.4	4.7	5.5	4.8
Nasopharyngitis	5.4	5.8	4.8	4.4
Oral candidiasis*	3.1	2.9	4.8	0.7
Headache	1.6	7.3	4.8	4.4
Cough	1.6	1.8	3.4	2.6

* Oral candidiasis includes oropharyngeal candidiasis, oral fungal infection, oropharyngitis fungal
URTI = upper respiratory tract infection