Supplemental Approvals

Generic Name (Trade Name—Company) | Uses/Notes
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Fluticasone propionate and salmeterol inhalation powder, fluticasone propionate inhalation powder | Teva announced FDA approval of two BX-rated generic products for adolescent and adult patients with asthma: fluticasone propionate and salmeterol inhalation powder (AirDuo RespiClick) and fluticasone propionate inhalation powder (ArmonAir RespiClick).

(AirDuo RespiClick, ArmonAir RespiClick—Teva) | AirDuo RespiClick, a fixed-dose combination product containing the same active ingredients as Advair, is a corticosteroid and long-acting beta2-adrenergic agonist indicated for treatment of asthma in patients aged 12 years and older.

Two new generic maintenance inhalers approved for treatment of asthma | ArmonAir RespiClick, an inhaled corticosteroid containing the same active ingredient as Flovent, is indicated for maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older.

These BX generics cannot be substituted for Advair without permission of the prescriber.

The medications are delivered via Teva’s RespiClick breath-activated, multidose dry powder inhaler.

Both products, approved in three strengths each, are expected to become available to patients later in 2017. Approved strengths of AirDuo RespiClick are 55/14 mcg, 113/14 mcg, and 232/14 mcg administered as one inhalation twice daily. Approved strengths of ArmonAir RespiClick are 55 mcg, 113 mcg, and 232 mcg administered as one inhalation twice daily.

Approval was based on data from three Phase III trials evaluating the efficacy and safety of the treatments in adolescent and adult patients with asthma.

In the two double-blind studies, both therapies showed clinically relevant and greater benefit compared with placebo in improvement of lung function after 12 weeks of treatment as measured by forced expiratory volume in one second (FEV$_1$).