AirDuo ® Digihaler™ (fluticasone propionate/salmeterol) – New formulation approval

- On July 15, 2019, Teva announced the FDA approval of AirDuo (fluticasone propionate/salmeterol) inhalation powder, for the treatment of asthma in patients aged 12 years and older.
    - AirDuo Digihaler should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long acting beta$_2$ adrenergic agonist.
    - AirDuo Digihaler is NOT indicated for the relief of acute bronchospasm.

- AirDuo Digihaler contains a built-in electronic module which detects, records, and stores data on inhaler events, including peak inspiratory flow rate, for transmission to the mobile App where inhaler events are categorized. Use of the App is not required for administration of fluticasone propionate and salmeterol to the patient.
    - There is no evidence the use of the App leads to improved clinical outcomes, including safety and effectiveness.

- The efficacy of AirDuo Digihaler was based primarily on the dose-ranging trials and the confirmatory trials for AirDuo RespiClick®.

- AirDuo Digihaler is contraindicated for the primary treatment of status asthmaticus or acute episodes of asthma-related events and in patients with known severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to fluticasone propionate or any of the excipients.

- Warnings and precautions for AirDuo Digihaler include serious asthma-related events-hospitalizations, intubations, death; deterioration of disease and acute episodes; excessive use of AirDuo Digihaler and use with other long-acting beta$_2$-agonists; local effects of inhaled corticosteroids; immunosuppression; transferring patients from systemic corticosteroid therapy; hypercorticism and adrenal suppression; drug interactions with strong cytochrome P450 3A4 inhibitors; paradoxical bronchospasm and upper airway symptoms; hypersensitivity reactions, including anaphylaxis; cardiovascular and central nervous system effects; reduction in bone mineral density; effect on growth; glaucoma and cataracts; eosinophilic conditions and Churg-Strauss Syndrome; coexisting conditions; and hypokalemia and hyperglycemia.

- The most common adverse reactions (≥ 3%) with AirDuo Digihaler use were nasopharyngitis, oral candidiasis, headache, cough and back pain.

- The recommended starting dosage for AirDuo Digihaler is based on asthma severity and current inhaled corticosteroid use and strength. AirDuo Digihaler should be administered as one inhalation twice daily (approximately 12 hours apart at the same time every day) by the orally inhaled route.
    - AirDuo Digihaler should not be used more than two times every 24 hours. More frequent administration or a greater number of daily inhalations (more than one inhalation twice daily) is not recommended as some patients are more likely to experience adverse reactions with higher salmeterol dosages.
    - Concomitant use of other long acting beta$_2$ adrenergic agonists should be avoided.
    - Refer to the AirDuo Digihaler drug label for additional dosing and administration recommendations.

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- Teva plans to launch AirDuo Digihaler in 2020. ProAir Digihaler will be available as multidose dry powder inhalers with an electronic module that meters 55 mcg, 113 mcg, or 232 mcg of fluticasone propionate with 14 mcg of salmeterol.