ArmonAir® Digihaler™ (fluticasone propionate) – New formulation approval

- On February 24, 2020, Teva announced the FDA approval of ArmonAir Digihaler (fluticasone propionate) inhalation powder, for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.
    - ArmonAir Digihaler is NOT indicated for the relief of acute bronchospasm.
- ArmonAir Digihaler contains a built-in electronic module that records and stores information about inhaler events. ArmonAir Digihaler may be used with, and transmits information to a mobile App. Use of the App is not required for administration of ArmonAir Digihaler.
- The efficacy of ArmonAir Digihaler was based primarily on the dose-ranging trials and the confirmatory trials for ArmonAir RespiClick®.
    - ArmonAir RespiClick was approved in 2017; however it was subsequently withdrawn from the market by Teva.
- ArmonAir Digihaler is contraindicated for the primary treatment of status asthmaticus or other acute episodes of asthma 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 ArmonAir Digihaler include local effects of inhaled corticosteroids; acute asthma episodes; immunosuppression; transferring patients from systemic corticosteroid therapy; hypercorticism and adrenal suppression; hypersensitivity reactions, including anaphylaxis; reduction in bone mineral density; effect on growth; glaucoma and cataracts; paradoxical bronchospasm; drug interactions with strong cytochrome P450 3A4 inhibitors; and eosinophilic conditions and Churg-Strauss syndrome.
- The most common adverse reactions (≥ 3%) with ArmonAir Digihaler use were upper respiratory tract infection, nasopharyngitis, oral candidiasis, headache, and cough.
- The recommended starting dosage for ArmonAir Digihaler is based on asthma severity and current asthma drug therapy and strength. ArmonAir Digihaler should be administered as one inhalation twice daily (approximately 12 hours apart at the same time every day) by the orally inhaled route.
    - ArmonAir Digihaler should not be used more than two times every 24 hours.
    - The highest recommended dose of ArmonAir Digihaler is 232 mcg twice daily.
    - Refer to the ArmonAir Digihaler drug label for complete dosing and administration recommendations.
- Teva plans to launch ArmonAir Digihaler later this year. ArmonAir 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.

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