ProAir® Digihaler™ (albuterol sulfate) – New drug approval

- On December 21, 2018, Teva announced the FDA approval of ProAir Digihaler (albuterol sulfate) inhalation powder, for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for prevention of exercise-induced bronchospasm in patients 4 years of age and older.

- ProAir Digihaler is the first digital inhaler with built-in sensors that detect when the inhaler is used and measure inspiratory flow. This inhaler-use data is then sent to the companion mobile app using Bluetooth® Wireless Technology so patients can review their data over time, and if desired, share it with their healthcare professionals.

- The approval of ProAir Digihaler was based upon adequate and well-controlled efficacy studies in adults and pediatric patients of albuterol sulfate inhalation powder (ProAir RespiClick®).

- ProAir Digihaler is contraindicated in patients with albuterol hypersensitivity and patients with severe hypersensitivity to milk.

- Warnings and precautions of ProAir Digihaler include paradoxical bronchospasm, deterioration of asthma, use of anti-inflammatory agents, cardiovascular effects, do not exceed recommended dose, immediate hypersensitivity reactions, coexisting conditions, and hypokalemia.

- The most common adverse reactions (≥ 1% and > placebo) of ProAir Digihaler use were back pain, pain, gastroenteritis viral, sinus headache, urinary tract infection, nasopharyngitis, oropharyngeal pain, and vomiting.

- The recommended dose of ProAir Digihaler for the treatment of acute episodes of bronchospasm or prevention of symptoms associated with bronchospasm is 2 inhalations repeated every 4 to 6 hours.

    - More frequent administration or a larger number of inhalations is not recommended. In some patients, 1 inhalation every 4 hours may be sufficient.

- The recommended dose of ProAir Digihaler for prevention of exercise-induced bronchospasm is 2 inhalations 15 to 30 minutes before exercise.

- ProAir Digihaler contains a built-in electronic module which detects, records, and stores data on inhaler events, including peak inspiratory flow rate (L/min), for transmission to the mobile App where inhaler events are categorized.

    - Use of the App is not required for administration of ProAir Digihaler to the patient.
    - There is no evidence the use of the App leads to improved clinical outcomes, including safety and effectiveness.

- Teva plans to launch ProAir Digihaler in 2019 through a small number of “Early Experience” Programs, which will be conducted in partnership with healthcare systems and in limited geographies, in order to gather real-world experience. A national launch is planned for 2020.

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- ProAir Digihaler will be available as a dry powder inhaler that meters 117 mcg of albuterol sulfate (equivalent to 97 mcg of albuterol base) from the device reservoir and delivers 108 mcg of albuterol sulfate (equivalent to 90 mcg of albuterol base) from the mouthpiece per actuation.