On April 1, 2015, Teva announced the FDA approval of ProAir RespiClick (albuterol sulfate) for the treatment or prevention of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease, and for the prevention of exercise-induced bronchospasm (EIB) in patients 12 years of age and older.

Asthma is a chronic lung disease characterized by airway inflammation and defined by a history of respiratory symptoms. Common symptoms include wheezing, shortness of breath, chest tightness, and cough. According to the National Heart, Lung, and Blood Institute, over 22 million people in the U.S. are known to have asthma.

ProAir RespiClick is a new breath-actuated, dry powder inhaler (DPI) formulation of ProAir® HFA (albuterol sulfate), an inhalation aerosol. There are no other DPI rescue inhalers approved by the FDA. The DPI formulation eliminates the need for hand-breath coordination during inhalation.

— Other inhaled albuterol aerosols include Proventil® HFA (albuterol sulfate) and Ventolin® HFA (albuterol sulfate). ProAir HFA, Proventil HFA, and Ventolin HFA are all indicated for treatment or prevention of bronchospasm and for the prevention of EIB in patients 4 years of age and older.

The safety and efficacy of ProAir RespiClick were based on placebo controlled trials in patients (n = 354) with asthma or EIB.

— In two 12-week trials in patients with asthma, two inhalations of ProAir RespiClick produced significantly greater improvement in the mean change of forced expiratory volume in 1 second (FEV₁) over the pre-treatment value compared with placebo.

— In a single trial in patients with EIB, two inhalations of ProAir RespiClick taken 30 minutes before exercise prevented EIB for the hour following exercise in 97% of patients compared to 42% with placebo.

ProAir RespiClick is contraindicated in patients with sensitivity to albuterol or milk proteins.

Warnings and precautions of ProAir RespiClick include paradoxical bronchospasm, deterioration of asthma, use of anti-inflammatory agents, cardiovascular effects, excessive use, immediate hypersensitivity reactions, coexisting conditions, and hypokalemia.

The most common adverse events (≥ 1% and > placebo) with ProAir RespiClick use were back pain, pain, gastroenteritis viral, sinus headache, and urinary tract infection.

The recommended dose of ProAir RespiClick for the treatment or prevention of bronchospasm is 2 inhalations (90 mcg of albuterol per inhalation) every 4 to 6 hours. In some patients, 1 inhalation every 4 hours may be sufficient. The recommended dose for prevention of EIB is 2 inhalations 15 to 30 minutes before exercise.

— ProAir RespiClick does not require priming.

— It should not be used with a spacer or volume holding chamber.

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Routine maintenance of the inhaler is not required.

- Teva plans to launch ProAir RespiClick as an inhaler containing 200 doses during the second quarter of 2015.