

ProAir® RespiClick — New Formulation Approval

- 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.



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