Dear Healthcare Professional,

At MPR we strive to bring you important drug information in a concise and timely fashion. In keeping with this goal, we are pleased to bring you this CLINICAL ALERT about ProAir® HFA (albuterol sulfate) Inhalation Aerosol, a product of Teva Respiratory, LLC.

ProAir HFA is the number one dispensed quick-relief inhaler. The product design offers a complete package of helpful features for the management of bronchospasm in patients with reversible obstructive airway disease, such as asthma, exercise-induced bronchospasm, and chronic obstructive pulmonary disease. With a built-in dose counter, your patients will know how many puffs are left in the canister and when it’s time to refill their prescription. ProAir HFA may also give patients more time to inhale each puff with its longer-duration plume, and offers up to 24 months expiration dating.

In this CLINICAL ALERT you will learn more about all the helpful features of ProAir HFA.

Indications
ProAir HFA Inhalation Aerosol is indicated in patients 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

Important Safety Information
- Inhaled albuterol sulfate can produce paradoxical bronchospasm that may be life-threatening. It should be recognized that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister.
- Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma.
- ProAir HFA, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders (especially coronary insufficiency, cardiac arrhythmias, and hypertension), convulsive disorders, hyperthyroidism, and diabetes.
- Potential drug interactions can occur with beta-blockers, diuretics, digoxin, or monoamine oxidase inhibitors, and tricyclic antidepressants.
- Do not exceed the recommended dose.
- Adverse events, which occurred at an incidence rate of at least 3% with ProAir HFA, include headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis.

Please see the full Prescribing Information for ProAir HFA.

Sincerely,

Madonna Krawczyk, PharmD
Director of Clinical Communications
MPR Custom Programs

REFERENCE
ProAir® HFA
(albuterol sulfate) Inhalation Aerosol

Company: Teva Respiratory.
Pharmacologic class: β₂-agonist.
Active Ingredients: Albuterol sulfate 108 mcg/inhalation metered-dose aerosol.
Indications: For the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm, in patients 4 years of age and older.
Dosing: <4yrs: not recommended. ≥4yrs: 2 inhalations every 4–6 hrs as needed; 1 inhalation every 4 hrs may suffice. Exercise-induced bronchospasm: 2 inhalations 15–30 minutes before exercise.
Warnings & Precautions: Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Need for more doses may be a sign of deterioration of asthma; reevaluate therapy. Consider adding anti-inflammatory agents (eg, corticosteroids) to therapeutic regimen. Caution in patients with cardiovascular disease (eg, coronary insufficiency, arrhythmias, hypertension). Avoid excessive use. Caution in patients sensitive to sympathomimetic drugs; discontinue immediately if immediate hypersensitivity occurs. Monitor for hypokalemia and changes in blood glucose.
Interactions: Oral sympathomimetics: not recommended. Antagonized by β-blockers. Caution with other drugs that may lower serum potassium (eg, diuretics). Monitor digoxin. Avoid MAOIs, tricyclics within 14 days (increased cardiovascular effects).
Adverse reactions: Headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis.
How Supplied: Inhalation aerosol—8.5 g (200 inhalations)

Guidelines for short-acting β₂-agonist use

- Short-acting β₂-agonists (SABAs) are indicated for the treatment or prevention of bronchospasm with reversible obstructive pulmonary disease
  - Reversible obstructive pulmonary disease includes asthma, exercise-induced bronchospasm (EIB), and chronic obstructive pulmonary disorder (COPD).
  - SABAs bind to β₂-adrenergic receptors to relax smooth muscle after adenylate cyclase activation and increase cyclic AMP to antagonize further bronchoconstriction
- Currently, SABAs are the most effective type of medication for relieving acute bronchospasm
  - The guidelines of the National Heart, Lung, and Blood Institute (NHLBI) recommends SABAs as the preferred treatment of acute asthma symptoms and exacerbations (Evidence Level A)
  - In addition, the NHLBI guidelines recommend the use of SABAs prior to exercise for the prevention of EIB (Evidence Level A)

The NHLBI guidelines recommend that patients with asthma and EIB should have a SABA inhaler available at all times.

Please see full Prescribing Information and the last page for additional Important Safety Information.
The #1 dispensed quick-relief inhaler³

ProAir® HFA (albuterol sulfate) offers a complete package of helpful features for the management of asthma, EIB, and COPD

ProAir HFA has a built-in dose counter⁴ (Figure 1)

- Patients will know
  - How many puffs are left in the canister
  - When it is time to refill their prescription

ProAir HFA may give patients more time to inhale each puff (Figure 2)

- ProAir HFA delivers a warmer, lower-impact, longer-duration plume⁵
- The ProAir HFA plume is 55% less forceful and lasts nearly 2.5 times longer than that of Ventolin HFA⁵

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Selected Safety Information

- Potential drug interactions can occur with beta-blockers, diuretics, digoxin, or monoamine oxidase inhibitors, and tricyclic antidepressants
- Do not exceed the recommended dose

Please see full Prescribing Information and the last page for additional Important Safety Information.
Reduce wasted medication by providing more time to use all 200 puffs\(^6,7\) (Figure 3)

- ProAir\(^\text{®}\) HFA (albuterol sulfate) provides long expiration dating (up to 24 months)\(^6\)
- Patients get consistent dosing for up to 2 years or 200 doses\(^6\)
- Patients who use their inhaler infrequently may need fewer refills

Offers more features through inhaler design

<table>
<thead>
<tr>
<th>Comparing Quick-Relief Inhalers</th>
<th>ProAir(^\text{®}) HFA</th>
<th>Proventil(^\text{®}) HFA</th>
<th>Ventolin(^\text{®}) HFA</th>
<th>Xopenex HFA(^\text{®})</th>
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<tbody>
<tr>
<td>Dose counter</td>
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<td>Flexible storage</td>
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<td>Fewest sprays wasted during priming</td>
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<td>3 sprays to prime, instead of 4</td>
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<td>No need to reprime if dropped</td>
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<td>Extended expiration</td>
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Sources: ProAir HFA [prescribing information]\(^4\); Data on file\(^6\); Ventolin HFA [prescribing information]\(^7\); Proventil HFA [prescribing information]\(^8\); Xopenex HFA [prescribing information]\(^9\)

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(continued on next page)
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