

- itchy skin
- swelling beneath your skin or in your throat
- rash
- worsening trouble breathing
- **worsening of other medical problems in people who also use PROAIR RESPICLICK including increases in blood sugar**
- **low potassium levels in your blood**

The most common side effects of PROAIR RESPICLICK include:

- back pain
- pain
- upset stomach
- sinus headache
- urinary tract infection
- your heart feels like it is pounding or racing (palpitations)
- chest pain
- fast heart rate
- shakiness
- nervousness
- headache
- dizziness
- sore throat
- runny nose
- vomiting

These are not all of the possible side effects of PROAIR RESPICLICK.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PROAIR RESPICLICK?

- Store PROAIR RESPICLICK at room temperature between 59°F and 77°F (15°C and 25°C).
- Avoid exposure to extreme heat, cold, or humidity.
- Keep the cap on the inhaler closed during storage.
- Keep your PROAIR RESPICLICK inhaler dry and clean at all times.
- **Do not wash or put any part of your PROAIR RESPICLICK inhaler in water.** Replace your inhaler if washed or placed in water.

Keep PROAIR RESPICLICK and all medicines out of the reach of children.

General information about the safe and effective use of PROAIR RESPICLICK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use PROAIR RESPICLICK for a condition for which it was not prescribed. Do not give PROAIR RESPICLICK to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or doctor for information about PROAIR RESPICLICK that was written for health professionals.

For more information, go to www.MyProAir.com or call 1-888-482-9522.

What are the ingredients in PROAIR RESPICLICK?

Active ingredient: albuterol sulfate

Inactive ingredients: lactose (may contain milk proteins)

Distributed by:

Teva Pharmaceuticals USA, Inc.

Parsippany, NJ 07054

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PRORPL-005

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 09/2020

Instructions for Use
PROAIR® RESPICLICK® (prō´ār res-pē-klik)
(albuterol sulfate)
inhalation powder

Your PROAIR RESPICLICK Inhaler

When you are ready to use PROAIR RESPICLICK for the first time, remove the PROAIR RESPICLICK inhaler from the foil pouch.

There are 2 main parts of your PROAIR RESPICLICK inhaler including:

- the white inhaler with the mouthpiece. **See Figure A.**
- the red cap that covers the mouthpiece of the inhaler. **See Figure A.**

There is a dose counter in the back of the inhaler with a viewing window that shows you how many doses of medicine you have left. **See Figure A.**

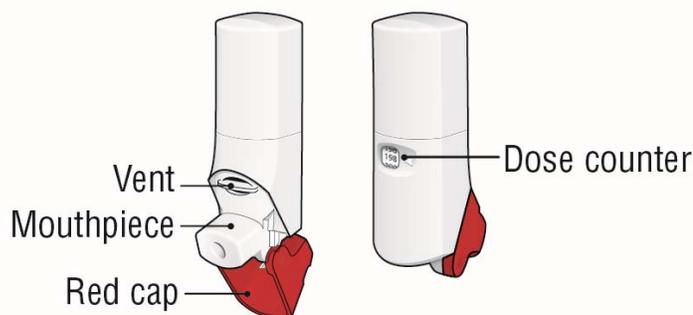


Figure A

- Your PROAIR RESPICLICK inhaler contains 200 doses (inhalations). **See Figure B.**
- The dose counter shows the number of doses left in your inhaler.
- When there are 20 doses left, the dose counter will change to red, and you should refill your prescription or ask your doctor for another prescription.
- When the dose counter displays '0,' your inhaler is empty, and you should stop using the inhaler and throw it away. **See Figure B.**

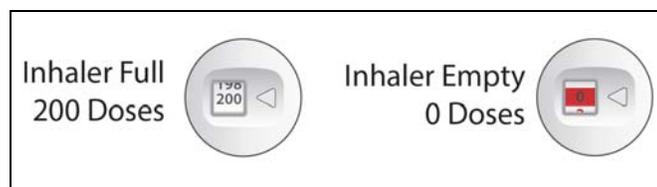


Figure B

IMPORTANT:

- **Always close the cap after each inhalation so your inhaler will be ready for you to take your next dose.** Do not open the cap unless you are ready for your next dose.
- You will hear a “click” sound when the cap is opened fully. If you do not hear the “click” sound the inhaler may not be activated to give you a dose of medicine.
- **PROAIR RESPICLICK does not have an activation button or medicine canister.** When you open the cap, a dose of PROAIR will be activated for delivery of the medicine.
- In general, the technique for administering PROAIR RESPICLICK to children is similar to that for adults. Children should use PROAIR RESPICLICK under adult supervision, as instructed by the patient’s physician.
- Do not use a spacer or volume holding chamber with PROAIR RESPICLICK. PROAIR RESPICLICK does not need priming.

Using your PROAIR RESPICLICK inhaler:

Important: Make sure the red cap is closed before you start using your inhaler.

Step 1. Open

- Hold the inhaler upright and open the red cap fully until you feel and hear a “click”. **See Figure C.**
- Each time you open the red cap and it “clicks”, a dose of PROAIR RESPICLICK is ready to be inhaled.

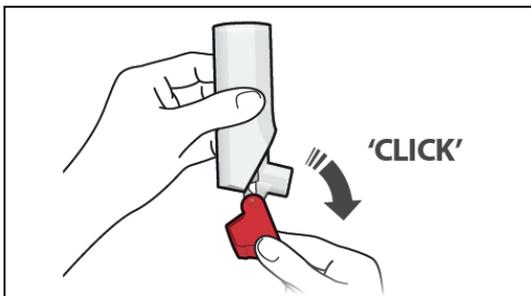


Figure C

Remember:

- For the correct use of PROAIR RESPICLICK, **hold the inhaler upright** as you open the red cap. **See Figure D.**
- **Do not** hold the inhaler in any other way as you open the red cap.
- **Do not** open the red cap until you are ready to take a dose of PROAIR RESPICLICK.

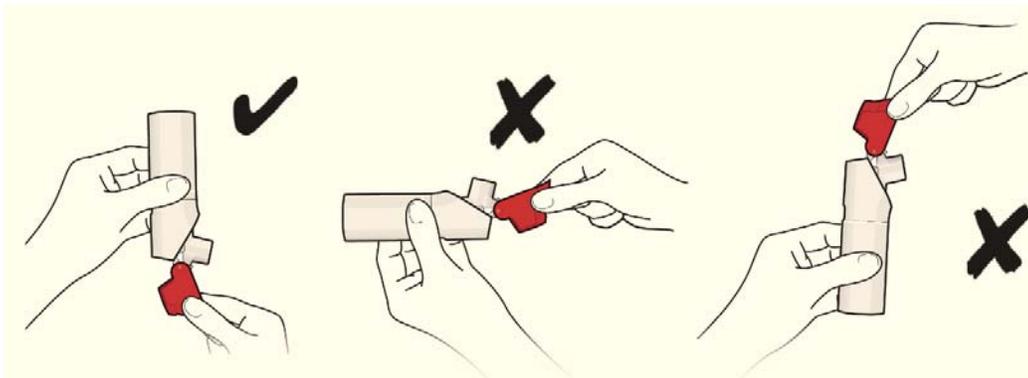
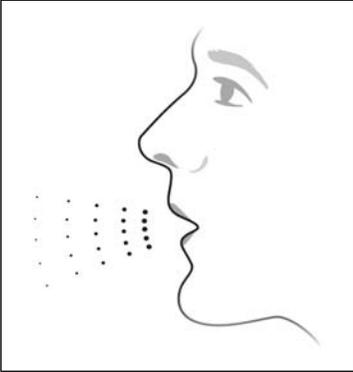


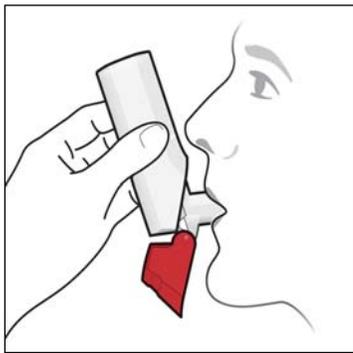
Figure D

Step 2. Inhale



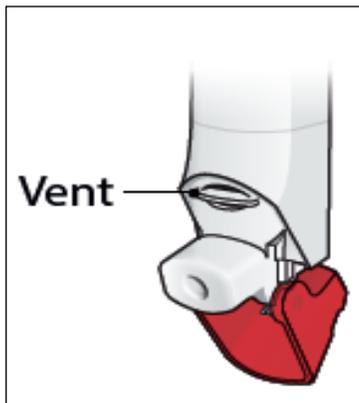
- Before you inhale, breathe out (exhale) through your mouth and push as much air from your lungs as you can. **See Figure E.**
- **Do not** exhale into the inhaler mouthpiece.

Figure E



- Put the mouthpiece in your mouth and close your lips tightly around it. **See Figure F.**

Figure F



- **Do not** block the vent above the mouthpiece with your lips or fingers. **See Figure G.**

Figure G

- **Breathe in quickly and deeply through your mouth, to deliver the dose of medicine to your lungs.**
- Remove the inhaler from your mouth.
- Hold your breath for about 10 seconds or for as long as you comfortably can.
- Your PROAIR RESPICLICK inhaler delivers your dose of medicine as a very fine powder that you may or may not taste or feel. **Do not** take an extra dose from the inhaler even if you do not taste or feel the medicine.

Step 3. Close

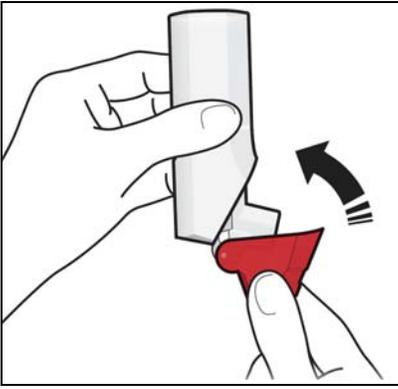


Figure H

- Close the red cap firmly over the mouthpiece. **See Figure H.**
- Make sure you close the red cap after each inhalation so that the inhaler will be ready for your next dose.
- **If you need another dose** close the red cap and then repeat steps 1-3.



Storing your PROAIR RESPICLICK inhaler

- Store PROAIR RESPICLICK at room temperature between 59°F and 77°F (15°C and 25°C).
- Avoid exposure to extreme heat, cold, or humidity.
- Keep the red cap on the inhaler closed during storage.
- Keep your PROAIR RESPICLICK inhaler dry and clean at all times.
- **Do not wash or put any part of your PROAIR RESPICLICK inhaler in water.** Replace your inhaler if washed or placed in water.
- **Keep your PROAIR RESPICLICK inhaler and all medicines out of the reach of children.**

Cleaning your PROAIR RESPICLICK inhaler

- **Do not wash or put any part of your PROAIR RESPICLICK inhaler in water.** Replace your inhaler if washed or placed in water.
- PROAIR RESPICLICK contains a powder and must be kept clean and dry at all times.
- If the mouthpiece needs cleaning, gently wipe it with a dry cloth or tissue.

Replacing your PROAIR RESPICLICK inhaler

- The dose counter on the back of your inhaler shows how many doses you have left. Do not try to change the numbers for the dose counter.
- When there are 20 doses left, the dose counter color will change to red, and you should refill your prescription or ask your doctor for another prescription.

- When the dose counter displays '0' your PROAIR RESPICLICK inhaler is empty, and you should stop using the inhaler and throw it away.
- Throw away your PROAIR RESPICLICK inhaler 13 months after removing it from the foil pouch for the first time, when the dose counter displays '0', or after the expiration date on the package, whichever comes first.

Important information

- Do not open the red cap unless you are taking a dose. Repeatedly opening and closing the cap without inhaling a dose will waste the medicine and may damage your inhaler.
- Your PROAIR RESPICLICK inhaler contains dry powder so it is important that you do not blow or breathe into it.
- **Do not** take the inhaler apart.

Support

- If you have any questions about PROAIR RESPICLICK or how to use your inhaler, go to www.ProAir.com or call 1-888-482-9522.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Parsippany, NJ 07054
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The Teva logo consists of the word "teva" in a bold, lowercase, sans-serif font. The letters are black and have a slightly irregular, hand-drawn appearance.

PRORIFU-005

Revised September 2020

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROAIR DIGIHALER safely and effectively. See full prescribing information for PROAIR DIGIHALER.

PROAIR® DIGIHALER® (albuterol sulfate) inhalation powder, for oral inhalation use

Initial U.S. Approval: 1981

INDICATIONS AND USAGE

ProAir Digihaler is a beta₂-adrenergic agonist indicated for:

- Treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease. (1.1)
- Prevention of exercise-induced bronchospasm in patients 4 years of age and older. (1.2)

DOSAGE AND ADMINISTRATION

For oral inhalation only

- Treatment or prevention of bronchospasm in adults and children 4 years of age and older: 2 inhalations every 4 to 6 hours by oral inhalation. In some patients, 1 inhalation every 4 hours may be sufficient. (2.1)
- Prevention of exercise-induced bronchospasm in adults and children 4 years of age and older: 2 inhalations 15 to 30 minutes before exercise by oral inhalation. (2.2)
- ProAir Digihaler does not require priming. (2.3)
- Do not use with a spacer or volume holding chamber. (2.3)
- Keep the inhaler clean and dry at all times. Routine maintenance is not required. If the mouthpiece needs cleaning, gently wipe the mouthpiece with a dry cloth or tissue as needed. Never wash or put any part of the inhaler in water. (2.3)
- Discard 13 months after opening the foil pouch, when the dose counter displays 0, or after the expiration date on the product, whichever comes first. (2.3)
- ProAir Digihaler contains a built-in electronic module which detects, records, and stores data on inhaler events for transmission to the mobile App. Use of the App is not required for administration of medication to the patient. (2.3)

DOSAGE FORMS AND STRENGTHS

Inhalation powder: dry powder inhaler 108 mcg of albuterol sulfate (equivalent to 90 mcg of albuterol base) from the mouthpiece per actuation. The inhaler is supplied for 200 inhalation doses. ProAir Digihaler includes a built-in electronic module. (3)

FULL PRESCRIBING INFORMATION: CONTENTS*

HIGHLIGHTS OF PRESCRIBING INFORMATION

FULL PRESCRIBING INFORMATION: CONTENTS

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- 1.1 Bronchospasm
- 1.2 Exercise-Induced Bronchospasm

2 DOSAGE AND ADMINISTRATION

- 2.1 Recommended Dosage for Bronchospasm
- 2.2 Recommended Dosage for Exercise-Induced Bronchospasm
- 2.3 Administration and Maintenance Information
- 2.4 Dose Counter
- 2.5 Storage of Data on Inhaler Events

3 DOSAGE FORMS AND STRENGTHS

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5 WARNINGS AND PRECAUTIONS

- 5.1 Paradoxical Bronchospasm
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- 5.4 Cardiovascular Effects
- 5.5 Do Not Exceed Recommended Dose
- 5.6 Immediate Hypersensitivity Reactions
- 5.7 Coexisting Conditions
- 5.8 Hypokalemia

6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

7 DRUG INTERACTIONS

CONTRAINDICATIONS

- Patients with hypersensitivity to albuterol. (4)
- Patients with severe hypersensitivity to milk proteins. (4)

WARNINGS AND PRECAUTIONS

- Life-threatening paradoxical bronchospasm may occur. Discontinue ProAir Digihaler immediately and treat with alternative therapy. (5.1)
- Need for more doses of ProAir Digihaler than usual may be a sign of deterioration of asthma and requires reevaluation of treatment. (5.2)
- ProAir Digihaler is not a substitute for corticosteroids. (5.3)
- Cardiovascular effects may occur. Use with caution in patients sensitive to sympathomimetic drugs and patients with cardiovascular or convulsive disorders. (5.4, 5.7)
- Excessive use may be fatal. Do not exceed recommended dose. (5.5)
- Immediate hypersensitivity reactions may occur. Discontinue ProAir Digihaler immediately. (5.6)
- Hypokalemia and changes in blood glucose may occur. (5.7, 5.8)

ADVERSE REACTIONS

Most common adverse reactions ($\geq 1\%$ and $>$ placebo) are back pain, pain, gastroenteritis viral, sinus headache, urinary tract infection, nasopharyngitis, oropharyngeal pain and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Teva Respiratory, LLC at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Other short-acting sympathomimetic aerosol bronchodilators and adrenergic drugs: May potentiate effect. (7)
- Beta-blockers: May decrease effectiveness of ProAir Digihaler and produce severe bronchospasm. Patients with asthma should not normally be treated with beta-blockers. (7.1)
- Diuretics, or non-potassium sparing diuretics: May potentiate hypokalemia or ECG changes. Consider monitoring potassium levels. (7.2)
- Digoxin: May decrease serum digoxin levels. Consider monitoring digoxin levels. (7.3)
- Monoamine oxidase (MAO) inhibitors and tricyclic antidepressants: May potentiate effect of albuterol on the cardiovascular system. Consider alternative therapy in patients taking MAOs or tricyclic antidepressants. (7.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 09/2020

7.1 Beta-Blockers

7.2 Diuretics

7.3 Digoxin

7.4 Monoamine Oxidase Inhibitors or Tricyclic Antidepressants

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Bronchospasm

ProAir[®] Digihaler[®] is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

1.2 Exercise-Induced Bronchospasm

ProAir Digihaler is indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage for Bronchospasm

The recommended dosage is 2 inhalations every 4 to 6 hours by oral inhalation. More frequent administration or a larger number of inhalations is not recommended. In some patients, 1 inhalation every 4 hours may be sufficient.

2.2 Recommended Dosage for Exercise-Induced Bronchospasm

The recommended dosage is 2 inhalations 15 to 30 minutes before exercise by oral inhalation.

2.3 Administration and Maintenance Information

Administer ProAir Digihaler by oral inhalation only. ProAir Digihaler inhaler does not require priming. Do not use ProAir Digihaler with a spacer or volume holding chamber.

Keep the inhaler clean and dry at all times. Never wash or put any part of your inhaler in water. Routine maintenance is not required. If the mouthpiece needs cleaning, gently wipe the mouthpiece with a dry cloth or tissue as needed.

2.4 Dose Counter

ProAir Digihaler inhaler has a dose counter attached to the actuator. When the patient receives the inhaler, the number 200 will be displayed. The dose counter will count down each time the inhaler is actuated. When the dose counter reaches 20, the color of the numbers will change to red to remind the patient to contact their pharmacist for a refill of medication or consult their physician for a prescription refill. When the dose counter reaches 0, the background will change to solid red. Discard ProAir Digihaler 13 months after opening the foil pouch, when the dose counter displays 0 or after the expiration date on the product, whichever comes first [*see Patient Counseling Information (17)*].

2.5 Storage of Data on Inhaler Events

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 albuterol sulfate to the patient. There is no evidence the use of the App leads to improved clinical outcomes, including safety and effectiveness [*see How Supplied/Storage and Handling (16)*].

3 DOSAGE FORMS AND STRENGTHS

Inhalation Powder: multi-dose breath-actuated dry powder inhaler that delivers 108 mcg of albuterol sulfate (equivalent to 90 mcg of albuterol base) from the mouth piece per actuation. Each inhaler is supplied for 200 inhalations. [*see How Supplied/Storage and Handling (16)*].

4 CONTRAINDICATIONS

ProAir Digihaler is contraindicated in patients with a history of hypersensitivity to albuterol and/or severe hypersensitivity to milk proteins. Rare cases of hypersensitivity reactions, including urticaria, angioedema, and rash have been reported after the use of albuterol sulfate. There have been reports of anaphylactic reactions in patients using inhalation therapies containing lactose [see *Warnings and Precautions (5.6)*].

5 WARNINGS AND PRECAUTIONS

5.1 Paradoxical Bronchospasm

ProAir Digihaler can produce paradoxical bronchospasm that may be life threatening. If paradoxical bronchospasm occurs, ProAir Digihaler should be discontinued immediately and alternative therapy instituted.

5.2 Deterioration of Asthma

Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses of ProAir Digihaler, this may be a marker of destabilization of asthma and requires re-evaluation of the patient and treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.

5.3 Use of Anti-Inflammatory Agents

The use of beta-adrenergic-agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids, to the therapeutic regimen.

5.4 Cardiovascular Effects

ProAir Digihaler, like other beta-adrenergic agonists, can produce clinically significant cardiovascular effects in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of ProAir Digihaler at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T-wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. Therefore, ProAir Digihaler, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

5.5 Do Not Exceed Recommended Dose

Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma. The exact cause of death is unknown, but cardiac arrest following an unexpected development of a severe acute asthmatic crisis and subsequent hypoxia is suspected.

5.6 Hypersensitivity Reactions including Anaphylaxis

Immediate hypersensitivity reactions may occur after administration of albuterol sulfate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema. ProAir Digihaler contains small amounts of lactose, which may contain trace levels of milk proteins. Hypersensitivity reactions including anaphylaxis, angioedema, pruritus, and rash have been reported with the use of therapies containing lactose (lactose is an inactive ingredient in ProAir Digihaler). The potential for hypersensitivity must be considered in the clinical evaluation of patients who experience immediate hypersensitivity reactions while receiving ProAir Digihaler.

5.7 Coexisting Conditions

ProAir Digihaler, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders,

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Albuterol sulfate is a beta₂-adrenergic agonist. The pharmacologic effects of albuterol sulfate are attributable to activation of beta₂-adrenergic receptors on airway smooth muscle. Activation of beta₂-adrenergic receptors leads to the activation of adenylyl cyclase and to an increase in the intracellular concentration of cyclic-3',5'-adenosine monophosphate (cyclic AMP). This increase of cyclic AMP is associated with the activation of protein kinase A, which in turn inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in muscle relaxation. Albuterol relaxes the smooth muscle of all airways, from the trachea to the terminal bronchioles. Albuterol acts as a functional antagonist to relax the airway irrespective of the spasmogen involved, thus protecting against all bronchoconstrictor challenges. Increased cyclic AMP concentrations are also associated with the inhibition of release of mediators from mast cells in the airway. While it is recognized that beta₂-adrenergic receptors are the predominant receptors on bronchial smooth muscle, data indicate that there are beta-receptors in the human heart, 10% to 50% of which are cardiac beta₂-adrenergic receptors. The precise function of these receptors has not been established [*see Warnings and Precautions (5.4)*].

Albuterol has been shown in most controlled clinical trials to have more effect on the respiratory tract, in the form of bronchial smooth muscle relaxation, than isoproterenol at comparable doses while producing fewer cardiovascular effects. However, inhaled albuterol, like other beta-adrenergic agonist drugs, can produce a significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure, symptoms, and/or electrocardiographic changes [*see Warnings and Precautions (5.4)*].

12.2 Pharmacodynamics

In a pharmacodynamic (PD) trial conducted in 47 patients, the PD and safety profiles were similar for albuterol sulfate MDPI and ProAir HFA. Comparable changes from baseline in the PD measures (serum glucose and potassium concentrations, QTcB, QTcF, heart rate, systolic blood pressure, and diastolic blood pressure) were observed following cumulative dose administration up to 1440 mcg of both albuterol sulfate MDPI and ProAir HFA. The overall safety, efficacy and PD profile of albuterol sulfate MDPI and ProAir HFA were comparable.

Following 90 or 180 mcg single-dose inhalation, the bronchodilatory effect of albuterol sulfate MDPI was significantly greater than placebo and comparable to that of ProAir HFA in patients 12 years of age and older (N=71) and pediatric patients 4 to 11 years of age (N=61) with persistent asthma.

Cardiac Electrophysiology

As with other beta₂-adrenergic agonists, albuterol sulfate MDPI prolonged QT intervals following a 1440 mcg cumulative dose. The prolongation was comparable to that of ProAir HFA.

12.3 Pharmacokinetics

Absorption

Albuterol was rapidly absorbed into the systemic circulation with peak plasma concentrations occurring at half an hour following single- or multiple-dose oral inhalation(s) of albuterol sulfate MDPI. In a cumulative dose study, the AUC_{0-t} was comparable between albuterol sulfate MDPI group and ProAir HFA group; C_{max} value was approximately one-third higher in albuterol sulfate MDPI group than ProAir HFA group.

Distribution

The volume of distribution has not been determined for albuterol sulfate MDPI. Published literature suggests that albuterol exhibits low *in vitro* plasma protein binding (10%).

Elimination

The accumulation ratio (~1.6 fold) was observed following one week QID dosing. The corresponding effective half-life was approximately 5 hours, which was consistent with the elimination half-life following both single- or multiple-dose administration.

Metabolism

Information available in the published literature suggests that the primary enzyme responsible for the metabolism of albuterol in humans is SULT1A3 (sulfotransferase). When racemic albuterol was administered either intravenously or via inhalation after oral charcoal administration, there was a 3- to 4-fold difference in the area under the concentration-time curves between the (R)- and (S)-albuterol enantiomers, with (S)-albuterol concentrations being consistently higher. However, without charcoal pretreatment, after either oral or inhalation administration the differences were 8- to 24-fold, suggesting that the (R)-albuterol is preferentially metabolized in the gastrointestinal tract, presumably by SULT1A3.

Excretion

The primary route of elimination of albuterol is through renal excretion (80% to 100%) of either the parent compound or the primary metabolite. Less than 20% of the drug is detected in the feces. Following intravenous administration of racemic albuterol, between 25% and 46% of the (R)-albuterol fraction of the dose was excreted as unchanged (R)-albuterol in the urine.

Specific Populations

No pharmacokinetic studies for ProAir Digihaler have been conducted in neonates or elderly subjects. The systemic exposure in children 6 to 11 years of age is similar to that of adults following 180 mcg single dose inhalation of albuterol sulfate MDPI. The influence of gender or race on the pharmacokinetics of ProAir Digihaler has not been studied.

Patients with Renal Impairment: The effect of renal impairment on the pharmacokinetics of albuterol was evaluated in 5 subjects with creatinine clearance of 7 to 53 mL/min, and the results were compared with those from healthy volunteers. Renal disease had no effect on the half-life, but there was a 67% decline in albuterol clearance. Caution should be used when administering high doses of ProAir Digihaler to patients with renal impairment [see *Use in Specific Populations* (8.5)].

Patients with Hepatic Impairment: The effect of hepatic impairment on the pharmacokinetics of ProAir Digihaler has not been evaluated.

Drug Interaction Studies: In vitro and in vivo drug interaction studies have not been conducted with ProAir Digihaler. Known clinically significant drug interactions are outlined in *Drug Interactions* (7).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year study in Sprague-Dawley rats, albuterol sulfate caused a dose-related increase in the incidence of benign leiomyomas of the mesovarium at and above dietary doses of 2 mg/kg (approximately 15 times and 6 times the maximum recommended daily inhalation dose (MRHDID) for adults and children, respectively, on a mg/m² basis). In another study this effect was blocked by the coadministration of propranolol, a non-selective beta-adrenergic antagonist. In an 18-month study in CD-1 mice, albuterol sulfate showed no evidence of tumorigenicity at dietary doses of up to 500 mg/kg (approximately 1,900 times and 740 times the MRHDID for adults and children, respectively, on a mg/m² basis). In a 22-month study in Golden Hamsters, albuterol sulfate showed no evidence of tumorigenicity at dietary doses of up to 50 mg/kg (approximately 250 times and 100 times the MRHDID for adults and children, respectively, on a mg/m² basis).

Albuterol sulfate was not mutagenic in the Ames test or a mutation test in yeast. Albuterol sulfate was not clastogenic in a human peripheral lymphocyte assay or in an AH1 strain mouse micronucleus assay.

Reproduction studies in rats demonstrated no evidence of impaired fertility at oral doses up to 50 mg/kg (approximately 380 times the MRHDID for adults on a mg/m² basis).

13.2 Animal Toxicology and/or Pharmacology

Preclinical: Intravenous studies in rats with albuterol sulfate have demonstrated that albuterol crosses the blood-brain barrier and reaches brain concentrations amounting to approximately 5% of the plasma concentrations. In structures outside the blood-brain barrier (pineal and pituitary glands), albuterol concentrations were found to be 100 times those in the whole brain.

Studies in laboratory animals (minipigs, rodents, and dogs) have demonstrated the occurrence of cardiac arrhythmias and sudden death (with histologic evidence of myocardial necrosis) when β -agonists and methylxanthines were administered concurrently. The clinical significance of these findings is unknown.

14 CLINICAL STUDIES

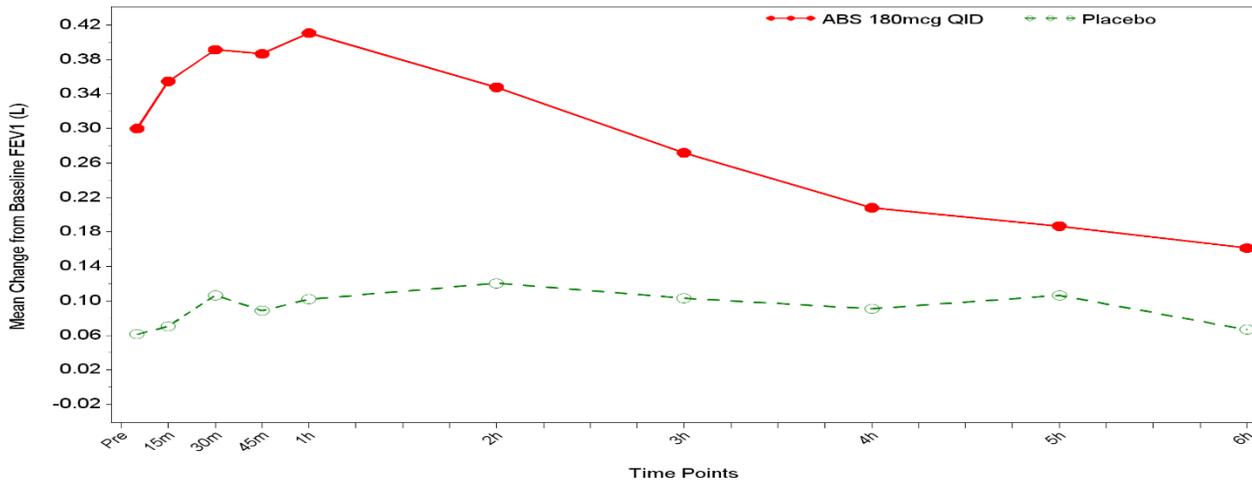
14.1 Overview of Clinical Studies

The safety and effectiveness of ProAir Digihaler has been established in the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and in the prevention of exercise-induced bronchospasm in patients 4 years of age and older. The use of ProAir Digihaler for these indications is supported by adequate and well-controlled studies in adults and pediatric patients of albuterol sulfate inhalation powder (ProAir RespiClick hereafter referred to as albuterol sulfate MDPI) [see *Use in Specific Populations (8.4), Clinical Studies (14.2, 14.3)*].

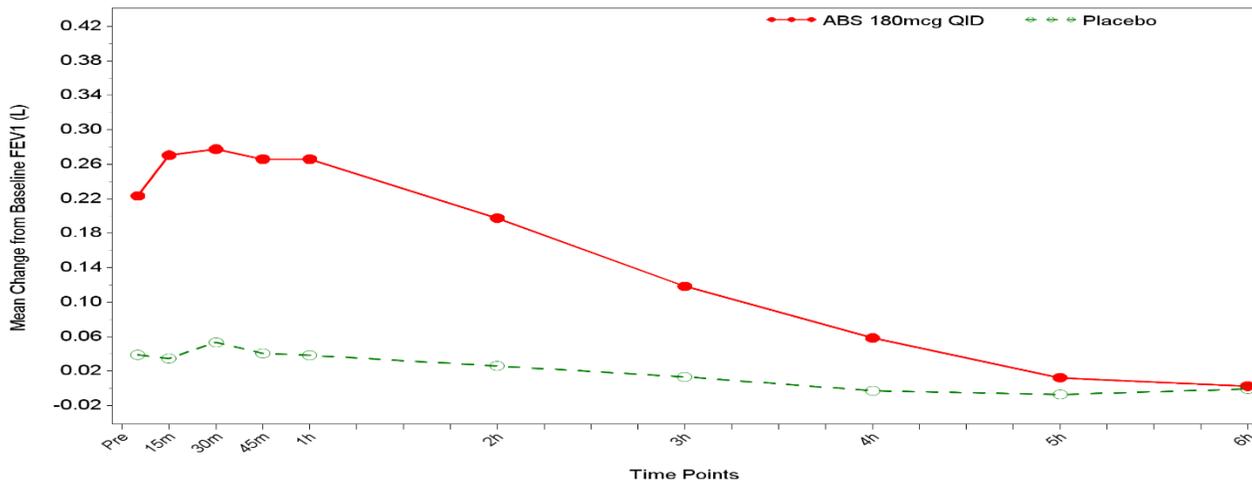
14.2 Bronchospasm Associated with Asthma

Adult and Adolescent Patients 12 Years of Age and Older

In two 12-week, randomized, double-blind, placebo-controlled studies of identical design (Study 1 and Study 2), albuterol sulfate MDPI (153 patients) was compared to a matched placebo dry powder inhaler (163 patients) in asthmatic patients 12 to 76 years of age at a dose of 180 mcg albuterol four times daily. Patients were maintained on inhaled corticosteroid treatment. Serial FEV₁ measurements, shown below in Figure 1 as average of the mean changes from test-day baseline at Day 1 and Day 85, demonstrated that two inhalations of albuterol sulfate MDPI produced significantly greater improvement in FEV₁ AUC_{0-6hr} over the pre-treatment value than placebo in Study 1. Consistent results were observed in Study 2.



Day 1



Day 85

Figure 1: FEV₁ as Mean Change from Test-Day, Pre-Dose Baseline in a 12-Week Clinical Trial (Study 1)

In Study 1, 44 of 78 patients treated with albuterol sulfate MDPI achieved a 15% increase in FEV₁ within 30 minutes post-dose on Day 1. The median time to onset was 5.7 minutes, and median duration of effect as measured by a 15% increase was approximately 2 hours. Consistent results were observed in Study 2. In a double-blind, randomized, placebo-controlled, single-dose crossover study evaluating albuterol sulfate MDPI and ProAir HFA in 71 adult and adolescent subjects ages 12 and older with persistent asthma, ProAir RespiClick had bronchodilator efficacy that was significantly greater than placebo at administered doses of 90 and 180 mcg.

Pediatric Patients 4 to 11 Years of Age

In a 3-week, randomized, double-blind, placebo-controlled trial, albuterol sulfate MDPI (92 patients) was compared to a matched placebo (92 patients) in asthmatic children 4 to 11 years of age at a dose of 180 mcg albuterol four times daily. Serial FEV₁ measurements, expressed as the baseline-adjusted percent-predicted FEV₁ AUC_{0-6h} over the 3-week treatment period, demonstrated that 2 inhalations of albuterol sulfate MDPI produced significantly greater improvement in FEV₁ over the pre-treatment value than the matched placebo.

In this study, 48 of 92 patients treated with albuterol sulfate MDPI achieved a 15% increase in FEV₁ within 30 minutes post-dose on Day 1. The median time to onset was 5.9 minutes, and the median duration of effect as measured by a 15% increase was approximately 1 hour.

In a placebo-controlled, single-dose, crossover study in 61 patients 4 to 11 years of age, albuterol sulfate MDPI, administered at albuterol doses of 90 and 180 mcg, was compared with a matched placebo and with albuterol HFA MDI. Albuterol sulfate MDPI provided similar bronchodilation when administered as one or two inhalations (baseline-adjusted

percent-predicted serial FEV₁ observed over 6 hours post-dose), whereas two inhalations from albuterol HFA MDI provided significantly greater bronchodilation compared to a single inhalation.

14.3 Exercise-Induced Bronchospasm

In a randomized, single-dose, crossover study in 38 adult and adolescent patients with exercise-induced bronchospasm (EIB), two inhalations of albuterol sulfate MDPI taken 30 minutes before exercise prevented EIB for the hour following exercise (defined as the maintenance of FEV₁ within 80% of post-dose, pre-exercise baseline values) in 97% (37 of 38) of patients as compared to 42% (16 of 38) of patients when they received placebo.

Patients who participated in these clinical trials were allowed to use concomitant steroid therapy.

16 HOW SUPPLIED/STORAGE AND HANDLING

ProAir Digihaler inhalation powder is supplied as a white inhaler with a red cap, in a sealed foil pouch, one pouch per carton.

Actuations	Net Contents	NDC
200	0.65 g	59310-117-20

Store at room temperature (between 15°C and 25°C; 59°F and 77°F). Avoid exposure to extreme heat, cold, or humidity.

Keep out of reach of children.

ProAir Digihaler inhaler has a dose counter. Patients should never try to alter the numbers for the dose counter. Discard the inhaler 13 months after opening the foil pouch, when the counter displays 0, or after the expiration date on the product, whichever comes first. The labeled amount of medication in each actuation cannot be assured after the counter displays 0, even though the inhaler is not completely empty and will continue to operate [see *Dosage and Administration (2.4)*, *Patient Counseling Information (17)*].

ProAir Digihaler contains a QR code and a built-in electronic module which automatically detects, records, and stores data on inhaler events, including peak inspiratory flow rate (L/min). ProAir Digihaler may pair with and transmit data to the mobile App via Bluetooth® wireless technology where inhaler events are categorized.

ProAir Digihaler contains a lithium-manganese dioxide battery and should be disposed of in accordance with state and local regulations.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use). Patients should be given the following information:

Frequency of Use

The action of ProAir Digihaler should last for 4 to 6 hours. Instruct patients to not use ProAir Digihaler more frequently than recommended. Instruct patients to not increase the dose or frequency of doses of ProAir Digihaler without consulting the physician. If patients find that treatment with ProAir Digihaler becomes less effective for symptomatic relief, symptoms become worse, and/or they need to use the product more frequently than usual, they should seek medical attention immediately [see *Warnings and Precautions (5.2)*].

Use of ProAir Digihaler Electronic Module and Mobile App

Direct the patient to the Instructions for Use (IFU) on how to download the App and use the inhaler. Advise the patient that pairing of the inhaler to the App, having Bluetooth turned on, or being near their smartphone is not required for delivery of the medication from the inhaler or for normal use of the product [see *Dosage and Administration (2.5)*].

Caring for and Storing the Inhaler

Instruct patients to not open their inhaler unless they are taking a dose. Repeated opening and closing the cover without taking medication will waste medication and may damage the inhaler.

Advise patients to keep their inhaler dry and clean at all times. Never wash or put any part of the inhaler in water. Patient should replace inhaler if washed or placed in water.

Routine maintenance is not required. If the mouthpiece needs cleaning, instruct patients to gently wipe the mouthpiece with a dry cloth or tissue as needed.

Instruct patients to store the inhaler at room temperature and to avoid exposure to extreme heat, cold, or humidity.

Instruct patients to never take the inhaler apart.

Inform patients that ProAir Digihaler has a dose counter. When the patient receives the inhaler, the number 200 will be displayed. The dose counter will count down each time the mouthpiece cap is opened and closed. The dose counter window displays the number of actuations left in the inhaler in units of two (e.g., 200, 198, 196, etc.). When the counter displays 20, the color of the numbers will change to red to remind the patient to contact their pharmacist for a refill of medication or consult their physician for a prescription refill. When the dose counter reaches 0, the background will change to solid red. Inform patients to discard ProAir Digihaler when the dose counter displays 0 or after the expiration date on the product, whichever comes first [see *Dosage and Administration (2.3), (2.4)*].

Paradoxical Bronchospasm

Inform patients that ProAir Digihaler can produce paradoxical bronchospasm. Instruct patients to discontinue ProAir Digihaler if paradoxical bronchospasm occurs [see *Warnings and Precautions (5.1)*].

Concomitant Drug Use

Inform patients that, while they are taking ProAir Digihaler, they should take other inhaled drugs and asthma medications only as directed by a physician [see *Drug Interactions (7)*].

Common Adverse Events

Common adverse effects of treatment with inhaled albuterol include palpitations, chest pain, rapid heart rate, tremor, and nervousness.

Pregnancy

Inform patients who are pregnant or nursing that they should contact their physician about the use of ProAir Digihaler [see *Use in Specific Populations (8.1)*].

General Information on Use

Effective and safe use of ProAir Digihaler includes an understanding of the way that it should be administered. Do not use a spacer or volume holding chamber with ProAir Digihaler. Patients should be instructed on the proper use of the inhaler. See the FDA-approved Patient Information and Patient Instructions for Use. Discard ProAir Digihaler 13 months after opening the foil pouch, when the dose counter displays 0 or after the expiration date on the product, whichever comes first.

In general, the technique for administering ProAir Digihaler to children is similar to that for adults. Children should use ProAir Digihaler under adult supervision, as instructed by the patient's physician.

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United States Patent Nos. 6701917, 6718972, 6748947, 6871646, 7540282, 8006690, 8651103, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131



PRORDH-002

Rev. 09/2020

PATIENT INFORMATION
ProAir® Digihaler® (prō´ār di´ji haye´´ ler)
(albuterol sulfate)
inhalation powder

What is ProAir Digihaler?

ProAir Digihaler is a prescription medicine used in people 4 years of age and older to:

- treat or prevent bronchospasm in people who have reversible obstructive airway disease
- prevent exercise-induced bronchospasm

ProAir Digihaler contains a built-in electronic module that records and stores information about inhaler events. The ProAir Digihaler may be used with, and transmits information to, an App through Bluetooth® wireless technology.

ProAir Digihaler does not need to be connected to the App in order for you to take your medicine. The electronic module does not control or interfere with delivery of the medicine through the inhaler.

It is not known if ProAir Digihaler is safe and effective in children under 4 years of age.

Do not use ProAir Digihaler if you are allergic to albuterol sulfate, lactose, milk proteins, or any of the ingredients in ProAir Digihaler. See the end of this leaflet for a complete list of ingredients in ProAir Digihaler.

Before using ProAir Digihaler, tell your doctor about all of your medical conditions, including if you:

- have heart problems
- have high blood pressure (hypertension)
- have convulsions (seizures)
- have thyroid problems
- have diabetes
- have low potassium levels in your blood
- are pregnant or plan to become pregnant. It is not known if ProAir Digihaler will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if ProAir Digihaler passes into your breast milk. Talk to your doctor about the best way to feed your baby if you are using ProAir Digihaler.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ProAir Digihaler and other medicines may affect each other and cause side effects. ProAir Digihaler may affect the way other medicines work, and other medicines may affect the way ProAir Digihaler works.

Especially tell your doctor if you take:

- | | |
|---|--------------------------------|
| • other inhaled medicines or asthma medicines | • digoxin |
| • beta blocker medicines | • monoamine oxidase inhibitors |
| • diuretics | • tricyclic antidepressants |

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use ProAir Digihaler?

- For detailed instructions on how to use the inhaler, see “**Instructions for Use**” at the end of this Patient Information.
- For detailed instructions on how to set up the App, go to www.ProAirDigihaler.com or call Teva at 1-888-603-0788.
- Connection to the App, having your Bluetooth turned on, or being near your smartphone is not required for your ProAir Digihaler to work and for you to get your medicine.
- The electronic module does not control or interfere with delivery of the medicine through the inhaler.
- Use ProAir Digihaler exactly as your doctor tells you to use it.
- If your child needs to use ProAir Digihaler, watch your child closely to make sure your child uses the inhaler correctly. Your doctor will show you how your child should use ProAir Digihaler.
- Each dose of ProAir Digihaler should last up to 4 hours to 6 hours.
- **Do not** increase your dose or take extra doses of ProAir Digihaler without first talking to your doctor.
- Do not use a spacer or volume holding chamber with ProAir Digihaler.
- ProAir Digihaler does not need priming.
- Get medical help right away if ProAir Digihaler no longer helps your symptoms.
- Get medical help right away if your symptoms get worse or if you need to use your inhaler more often.
- While you are using ProAir Digihaler, **do not** use other inhaled rescue medicines and asthma medicines unless your doctor tells you to do so.

Call your doctor if your asthma symptoms, like wheezing and trouble breathing, become worse over a few hours or days. Your doctor may need to give you another medicine (for example, corticosteroids) to treat your symptoms.

What are the possible side effects of ProAir Digihaler?

ProAir Digihaler may cause serious side effects, including:

- **worsening trouble breathing, coughing and wheezing (paradoxical bronchospasm).** If this happens stop using ProAir Digihaler and call your doctor or get emergency help right away.
- **heart problems, including faster heart rate and higher blood pressure**
- **possible death in people with asthma who use too much ProAir Digihaler**
- **allergic reactions.** Call your doctor right away if you have the following symptoms of an allergic reaction:
 - itchy skin
 - swelling beneath your skin or in your throat
 - rash
 - worsening trouble breathing
- **worsening of other medical problems in people who also use ProAir Digihaler including increases in blood sugar**
- **low potassium levels in your blood**

The most common side effects of ProAir Digihaler include:

- | | |
|---|-------------------|
| • back pain | • fast heart rate |
| • pain | • shakiness |
| • upset stomach | • nervousness |
| • sinus headache | • headache |
| • urinary tract infection | • dizziness |
| • your heart feels like it is pounding or racing (palpitations) | • sore throat |
| • chest pain | • runny nose |
| | • vomiting |

These are not all of the possible side effects of ProAir Digihaler.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ProAir Digihaler?

- Store ProAir Digihaler at room temperature between 59°F and 77°F (15°C and 25°C).
- Avoid exposure to extreme heat, cold, or humidity.
- Keep the cap on the inhaler closed during storage.
- Keep your ProAir Digihaler inhaler dry and clean at all times.
- **Do not wash or put any part of your ProAir Digihaler inhaler in water.** Replace your inhaler if washed or placed in water.

Keep ProAir Digihaler and all medicines out of the reach of children.

General information about the safe and effective use of ProAir Digihaler.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ProAir Digihaler for a condition for which it was not prescribed. Do not give ProAir Digihaler to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or doctor for information about ProAir Digihaler that was written for health professionals.

What are the ingredients in ProAir Digihaler?

Active ingredient: albuterol sulfate

Inactive ingredients: lactose (may contain milk proteins)

For more information about ProAir Digihaler, call 1-888-603-0788, or go to www.ProAirDigihaler.com

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Parsippany, NJ 07054

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PRODHPL-002

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 09/2020

Instructions for Use
ProAir® Digihaler® (prō´ār di`ji haye´´ler)
(albuterol sulfate)
inhalation powder

Your ProAir Digihaler Inhaler

When you are ready to use ProAir Digihaler for the first time, remove the ProAir Digihaler inhaler from the foil pouch.

There are 3 main parts of your ProAir Digihaler inhaler including:

- the white inhaler with the mouthpiece. **See Figure A.**
- the red cap that covers the mouthpiece and vent of the inhaler. **See Figure A.**
- the electronic module. **See Figure A.**

There is an electronic module built into the top of the inhaler that records and stores information about inhaler events. The electronic module sends information through Bluetooth® wireless technology to a mobile application (App). The electronic module does not control or interfere with delivery of the medicine through the inhaler.

There is a dose counter in the back of the inhaler with a viewing window that shows you how many doses of medicine you have left. **See Figure A.**

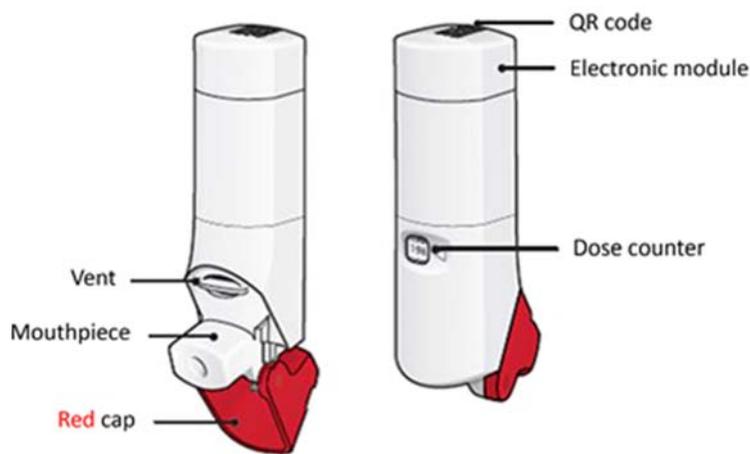


Figure A

- Your ProAir Digihaler inhaler contains 200 doses (inhalations). **See Figure B.**
- The dose counter shows the number of doses left in your inhaler.
- When there are 20 doses left, the dose counter will change to red and you should refill your prescription or ask your doctor for another prescription.
- When the dose counter displays '0' your inhaler is empty and you should stop using the inhaler and throw it away. **See Figure B.**

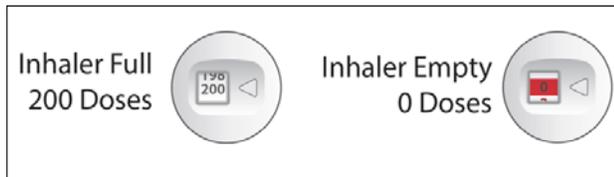


Figure B

IMPORTANT:

- **Always close the cap after each inhalation so your inhaler will be ready for you to take your next dose.** Do not open the cap unless you are ready for your next dose.
- You will hear a “click” sound when the cap is opened fully. If you do not hear the “click” sound the inhaler may not be activated to give you a dose of medicine.
- **ProAir Digihaler does not have an activation button or medicine canister.** When you open the cap, a dose of ProAir Digihaler will be activated for delivery of the medicine.
- **ProAir Digihaler does not need to be wirelessly connected to the mobile application (App) in order for it to work and for you to take your medicine.**
- In general, the technique for administering ProAir Digihaler to children is similar to that for adults. Children should use ProAir Digihaler under adult supervision, as instructed by the patient’s physician.
- Do not use a spacer or volume holding chamber with ProAir Digihaler. ProAir Digihaler does not need priming.

Using your ProAir Digihaler inhaler:

Important: Make sure the red cap is closed before you start using your inhaler.

Step 1. Open

- Hold the inhaler upright and open the red cap fully until you feel and hear a “click”. **See Figure C.**
- Each time you open the red cap and it “clicks”, a dose of ProAir Digihaler is ready to be inhaled.

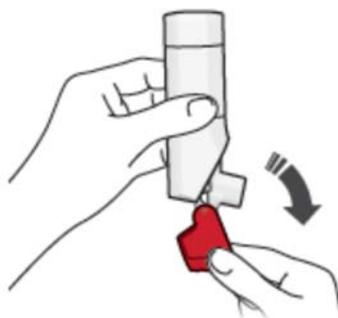


Figure C

Remember:

- For the correct use of ProAir Digihaler, **hold the inhaler upright** as you open the red cap. **See Figure D.**
- **Do not** hold the inhaler in any other way as you open the red cap.
- **Do not** open the red cap until you are ready to take a dose of ProAir Digihaler.

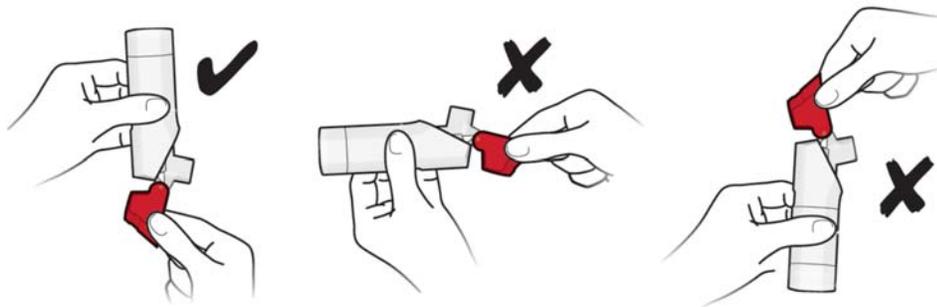
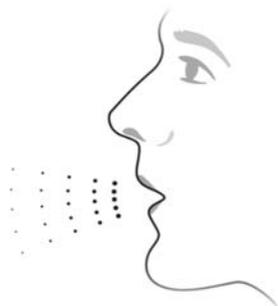


Figure D

Step 2. Inhale



- Before you inhale, breathe out (exhale) through your mouth and push as much air from your lungs as you can. **See Figure E.**
- **Do not** exhale into the inhaler mouthpiece.

Figure E



- Put the mouthpiece in your mouth and close your lips tightly around it. **See Figure F.**

Figure F

- **Do not** block the vent above the mouthpiece with your lips or fingers. **See Figure G.**

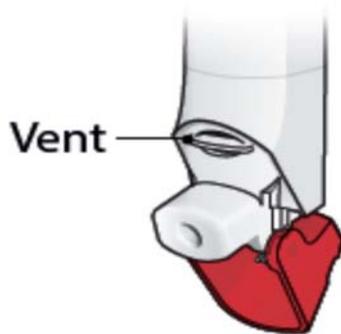


Figure G

- **Breathe in quickly and deeply through your mouth, to deliver the dose of medicine to your lungs.**
- Remove the inhaler from your mouth.
- Hold your breath for about 10 seconds or for as long as you comfortably can.
- Your ProAir Digihaler Inhaler delivers your dose of medicine as a very fine powder that you may or may not taste or feel. **Do not** take an extra dose from the inhaler even if you do not taste or feel the medicine.

Step 3. Close

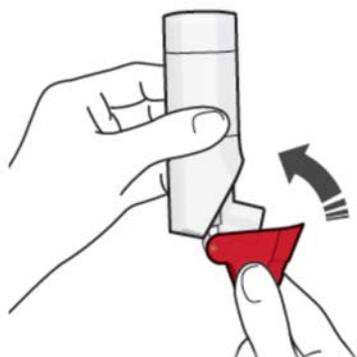


Figure H

- Close the red cap firmly over the mouthpiece. **See Figure H.**
- Make sure you close the red cap after each inhalation so that the inhaler will be ready for your next dose.
- **If you need another dose,** close the red cap and then repeat steps 1-3.



Storing your ProAir Digihaler inhaler

- Store ProAir Digihaler at room temperature between 59°F and 77°F (15°C and 25°C).
- Avoid exposure to extreme heat, cold, or humidity.
- Keep the red cap on the inhaler closed during storage.
- Keep your ProAir Digihaler inhaler dry and clean at all times.
- **Do not wash or put any part of your ProAir Digihaler inhaler in water.** Replace your inhaler if washed or placed in water.
- **Keep your ProAir Digihaler inhaler and all medicines out of the reach of children.**

Cleaning your ProAir Digihaler inhaler

- **Do not wash or put any part of your ProAir Digihaler inhaler in water.** Replace your inhaler if washed or placed in water.
- ProAir Digihaler contains a powder and must be kept clean and dry at all times.
- If the mouthpiece needs cleaning, gently wipe it with a dry cloth or tissue.

Replacing your ProAir Digihaler inhaler

- The dose counter on the back of your inhaler shows how many doses you have left. **Do not** try to change the numbers for the dose counter.
- When there are 20 doses left, the dose counter color will change to red and you should refill your prescription or ask your doctor for another prescription.
- When the dose counter displays '0' your ProAir Digihaler inhaler is empty and you should stop using the inhaler and throw it away.
- Throw away your ProAir Digihaler inhaler 13 months after removing it from the foil pouch for the first time, when the dose counter displays '0', or after the expiration date on the package, whichever comes first.
- ProAir Digihaler contains a lithium – manganese dioxide battery and should be thrown away (disposed of) in accordance with state and local regulations.

Important information

- Do not open the red cap unless you are taking a dose. Repeatedly opening and closing the cap without inhaling a dose will waste the medicine and may damage your inhaler.
- Your ProAir Digihaler inhaler contains dry powder so it is important that you do not blow or breathe into it.
- **Do not** take the inhaler apart.

Support

- For instructions on setting up the App, go to www.ProAirDigihaler.com or call Teva at 1-888-603-0788.
- If you have any questions about ProAir Digihaler, how to use your inhaler, go to www.ProAirDigihaler.com or call 1-888-603-0788.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Teva could void the user's authority to operate the equipment.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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