

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
- beta blocker medicines
- diuretics
- digoxin
- monoamine oxidase inhibitors
- 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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This Patient Information has been approved by the U.S. Food and Drug Administration.

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