

## Instructions for Use

### **TUDORZA® PRESSAIR®** (TU-door-za PRESS-air) (acclidinium bromide inhalation powder)

#### **For oral inhalation only**

This Instructions for Use contains information on how to use your TUDORZA PRESSAIR inhaler. It is important that you read this information as the TUDORZA PRESSAIR inhaler may work differently from inhalers you have used before.

**Read this Instructions for Use before you start using TUDORZA PRESSAIR and each time you get a refill.** There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

If you have any questions about how to use your inhaler, ask your doctor, pharmacist, or nurse for help.

The Instructions for Use is divided into the following sections:

- Getting started
- Before use
- Step 1: Prepare your dose
- Step 2: Inhale your medicine
- Additional information
- Questions and Answers about your TUDORZA PRESSAIR Inhaler

#### **Getting Started**

Become familiar with the parts of TUDORZA PRESSAIR inhaler (Figure A).

##### **Control window**

Green means inhaler is ready to use

##### **Dose indicator**

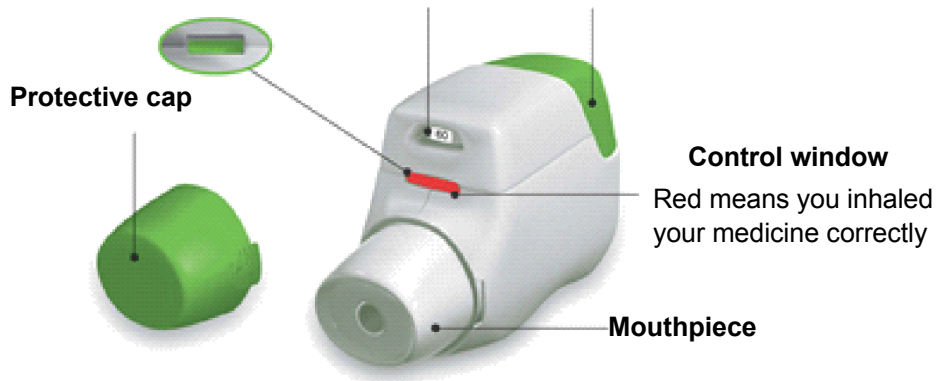
##### **Green button**

##### **Protective cap**

##### **Control window**

Red means you inhaled your medicine correctly

##### **Mouthpiece**

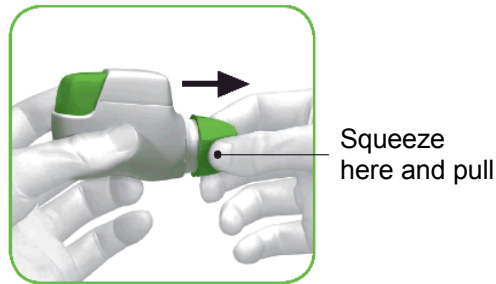


**Figure A**

#### **Before use:**

- a) Right before first use, open the sealed bag at the arrow marking and remove the inhaler. Throw away the bag.

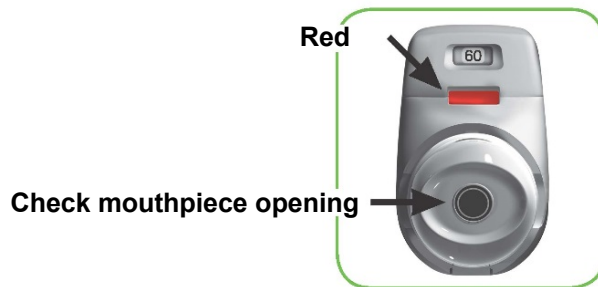
- b) Write the date that you open the sealed bag on the label of the inhaler.
- c) **Do not** press the green button until you are ready to take a dose.
- d) Remove the protective cap by lightly squeezing the arrows marked on each side of the protective cap and pulling straight off (Figure B).



**Figure B**

**Step 1: Prepare your dose**

- 1.1 Look in the opening of the mouthpiece and make sure nothing is blocking it (Figure C).
- 1.2 Look at the control window. The control window should be red (Figure C).



**Figure C**

- 1.3 Hold the inhaler horizontally with the mouthpiece facing you and the green button on top (Figure D).



**Figure D**

- 1.4 Press the green button all the way down to load your dose (Figure E).

When you press the green button all the way down, the control window changes from red to green.

Make sure the green button is on top. **Do not tilt the inhaler.**



Figure E

1.5 Release the green button (Figure F).

Make sure you release the green button, so the inhaler can work correctly.



Figure F

**Stop and Check:**

1.6 Make sure the control window is now green (Figure G).

This means your medicine is ready to be inhaled.

Go to “Step 2: Inhale your medicine”.



Figure G

**What to do if the control window is still red after pressing the button (Figure H).**



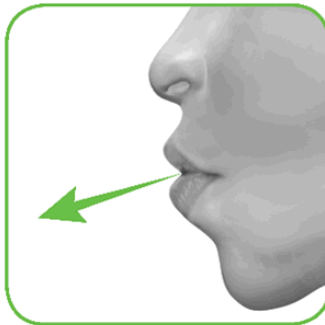
**Figure H**

The dose is not prepared. **Go back to “Step 1: Prepare your dose” and repeat steps 1.1 to 1.6.**

## **Step 2: Inhale your medicine**

Read steps 2.1 to 2.7 fully before use. Do not tilt the inhaler.

2.1 Hold the inhaler away from your mouth, and **breathe out completely**. Never breathe out into the inhaler (Figure I).



**Figure I**

2.2 Hold your head upright, put the mouthpiece between your lips, and close your lips tightly around the mouthpiece (Figure J).

### **Do not hold the green button down while inhaling**



**Figure J**

2.3 Take a **strong, deep breath** through your mouth. Keep breathing in for as long as possible.

A “click” will let you know that you are inhaling correctly. Keep breathing in as long as possible after you hear the “click”. Some people may not hear the “click”. Use the control window to make sure you have inhaled

correctly.

2.4 Take the inhaler out of your mouth.

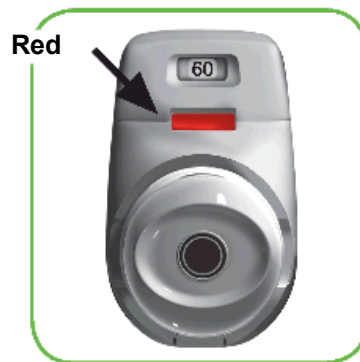
2.5 Hold your breath for as long as possible.

2.6 Slowly breathe out, away from the inhaler.

Some people may have a grainy sensation in their mouth, or a slightly sweet or bitter taste. **Do not** take an extra dose if you do not taste or feel anything after inhaling.

#### **Stop and Check:**

2.7 Make sure the control window is now red (Figure K). This means you have inhaled your medicine correctly.



**Figure K**

#### **What to do if the control window is still green after inhalation (Figure L).**



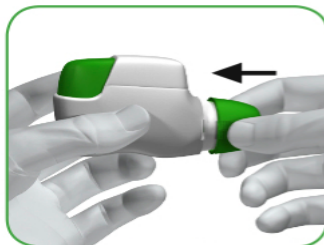
**Figure L**

This means you have not inhaled your medicine correctly. **Go back to “Step 2: Inhale your medicine” and repeat steps 2.1 to 2.7.**

If the control window still does not change to red, you may have forgotten to release the green button before inhaling, or you may not have inhaled strongly enough. If this happens, try again. Make sure you have released the green button, and you have breathed out completely. Then take a strong, deep breath through the mouthpiece.

**Contact your doctor if the control window is still green after repeated attempts.**

Push the protective cap back onto the mouthpiece after each use (Figure M) to prevent contamination of the inhaler with dust or other materials. You should throw away (dispose of) your inhaler if you lose the cap.



**Figure M**

For more information about TUDORZA PRESSAIR and a video demonstration on how to use TUDORZA PRESSAIR, go to [www.tudorza.com](http://www.tudorza.com).

### **Additional information**

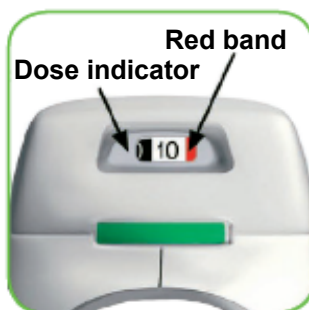
#### **What should I do if I accidentally prepare a dose?**

Store your inhaler with the protective cap in place until it is time to inhale your medicine, then remove the cap and start at Step 1.6.

#### **How does the dose indicator work?**

- The dose indicator shows the total number of doses left in the inhaler (Figure N).
- On first use, every inhaler contains at least 60 doses.
- Each time you load a dose by pressing the green button, the dose indicator moves by a small amount towards the next number (50, 40, 30, 20, 10, or 0).

**Dose indicator moves slowly from 60 to 0: 60, 50, 40, 30, 20, 10, 0.**



**Figure N**

#### **When should I get a new inhaler?**

You should throw away (dispose of) your inhaler if it appears to be damaged or if you lose the protective cap.

When a **red band** appears in the dose indicator, this means you are close to your last dose (Figure N).

You should throw away (dispose of) the inhaler and use a new one:

- when the marking "0" with a red background shows in the middle of the dose indicator (Figure O), or
- if your inhaler is empty and locks out (Figure P), or
- 45 days after the date you opened the sealed bag that the inhaler comes in,

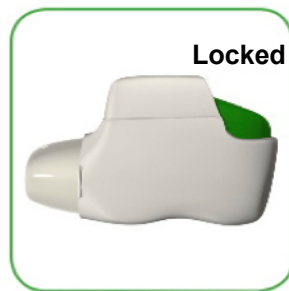
whichever comes first.



**Figure O**

### **How do I know that my inhaler is empty?**

When the green button will not return to its full upper position and is locked in a middle position (Figure P). Even though the green button is locked, your last dose may still be inhaled. After that, the inhaler cannot be used again and you should start using a new inhaler.



**Figure P**

### **How should I clean the inhaler?**

**Never** use water to clean the inhaler, as this may damage your medicine.

If you want to clean your inhaler, wipe the outside of the mouthpiece with a dry tissue or paper towel.

### **How should I store TUDORZA PRESSAIR?**

- Store TUDORZA PRESSAIR at room temperature between 68°F to 77°F (20°C to 25°C) in the sealed bag that it comes in until you are ready to use TUDORZA PRESSAIR. **Do not** open the sealed bag until you are ready to use a dose of TUDORZA PRESSAIR.
- Keep TUDORZA PRESSAIR in a dry place
- **Do not** store the inhaler on a vibrating surface.

**Keep TUDORZA PRESSAIR and all medicines out of the reach of children.**

<b>Questions and Answers about your TUDORZA PRESSAIR Inhaler</b>	
<b>Question</b>	<b>Answer</b>
Do I need to take extra steps to prepare the inhaler before first use?	TUDORZA PRESSAIR comes preloaded with medicine and is ready to use. Remove the inhaler from the sealed bag and follow the step-by-step Instructions for Use.
How do I know if the TUDORZA PRESSAIR inhaler is ready to use before taking each dose?	The TUDORZA PRESSAIR inhaler is ready to use when the control window on the front of the inhaler is green (Figure G) <ul style="list-style-type: none"> <li>If the control window is red (see Step 1.6), press and release the green button completely. This will change the color of the control window from red to green, indicating the medicine is ready to inhale.</li> </ul>
What if the TUDORZA PRESSAIR inhaler window does not change from red to green?	The dose is not prepared. <b>Go back to “Step 1: Prepare your dose” and repeat steps 1.1 to 1.6.</b> <ul style="list-style-type: none"> <li>If the green button is locked, you have used all the medicine in your inhaler and should get a new TUDORZA PRESSAIR inhaler (Figure P).</li> </ul>
How do I know that I used TUDORZA PRESSAIR correctly?	The TUDORZA PRESSAIR inhaler has a helpful feature to let you know that you have inhaled your medicine correctly. <ul style="list-style-type: none"> <li>Look at the control window to see if it has turned to red after you have inhaled fully through the mouthpiece. If the control window is red you have inhaled your full dose of medicine correctly (see Step 2.7).</li> </ul>
What if the TUDORZA PRESSAIR inhaler control window does not change color from green back to red after I inhale?	This means you may not have inhaled the medicine strongly enough. <b>Go back to “Step 2: Inhale your medicine” and repeat steps 2.1 to 2.7.</b> <ul style="list-style-type: none"> <li>Did you breathe out completely before inhaling?</li> <li>Did you let go of the green button before inhaling?</li> <li>Did you form a tight seal with your lips around the mouthpiece?</li> <li>Did you breathe in strongly and deeply?</li> <li>Did you keep breathing in after you heard the “click”?</li> </ul>
What if I do not see the dose indicator move after I inhaled?	Each time you load a dose by pressing the green button, the dose indicator moves by a small amount towards the next number from 60 to 0: 60, 50, 40, 30, 20, 10, 0 (see Figure N). If you see the control window change from green to red, you have successfully inhaled the full dose.
Can the TUDORZA PRESSAIR inhaler release too much medicine or lose doses of medicine from the inhaler?	No. The TUDORZA PRESSAIR inhaler only releases 1 dose of medicine with each inhalation. Pressing and releasing the green button more than one time before inhaling does not increase the dose you will receive or cause any medicine to be lost.

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

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