

## Instructions for Use

**AirDuo Digihaler (ayr'due oh di'ji haye'ler)**  
(fluticasone propionate and salmeterol) inhalation powder 55 mcg/14 mcg

**AirDuo Digihaler (ayr'due oh di'ji haye'ler)**  
(fluticasone propionate and salmeterol) inhalation powder 113 mcg/14 mcg

**AirDuo Digihaler (ayr'due oh di'ji haye'ler)**  
(fluticasone propionate and salmeterol) inhalation powder 232 mcg/14 mcg  
for oral inhalation use

### Your AirDuo Digihaler Inhaler

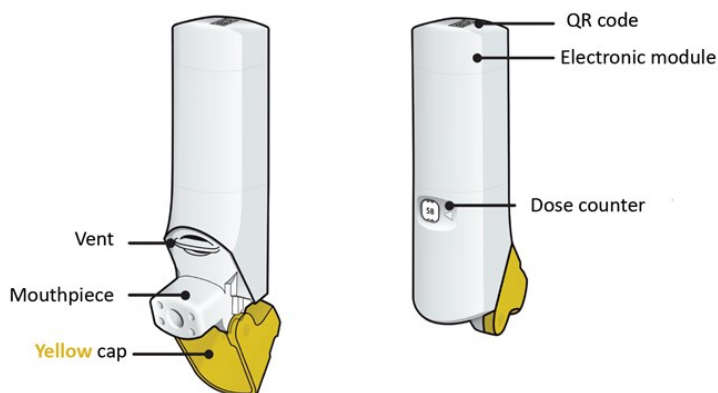
When you are ready to use AirDuo Digihaler for the first time, remove the AirDuo Digihaler inhaler from the foil pouch.

There are 3 main parts of your AirDuo Digihaler inhaler including the:

- white inhaler with the mouthpiece. **See Figure A.**
- yellow cap that covers the mouthpiece of the inhaler. **See Figure A.**
- 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<sup>®</sup> 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 AirDuo Digihaler inhaler contains 60 doses (inhalations). **See Figure B.**
- The dose counter shows the number of doses left in your inhaler.
- When there are 20 doses left, the color of the numbers on the dose counter will change to red and you should refill your prescription or ask your healthcare provider 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**

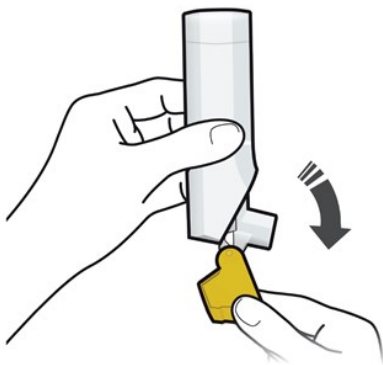
**Important:**

- **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 all the way. If you do not hear the “click” sound the inhaler may not be activated to give you a dose of medicine.
- **AirDuo Digihaler does not have an activation button or medicine canister.** When you open the cap, a dose of AirDuo Digihaler will be activated for delivery of the medicine.
- **AirDuo 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.**
- Do not use a spacer or volume holding chamber with AirDuo Digihaler. AirDuo Digihaler does not need priming.

**Using your AirDuo Digihaler inhaler:**

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

**Step 1. Open**



- Hold the inhaler upright and open the yellow cap all the way until it “clicks”. **See Figure C.**
- Each time you open the yellow cap and it “clicks”, 1 dose of AirDuo Digihaler is ready to be inhaled.

**Figure C**

**Remember:**

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

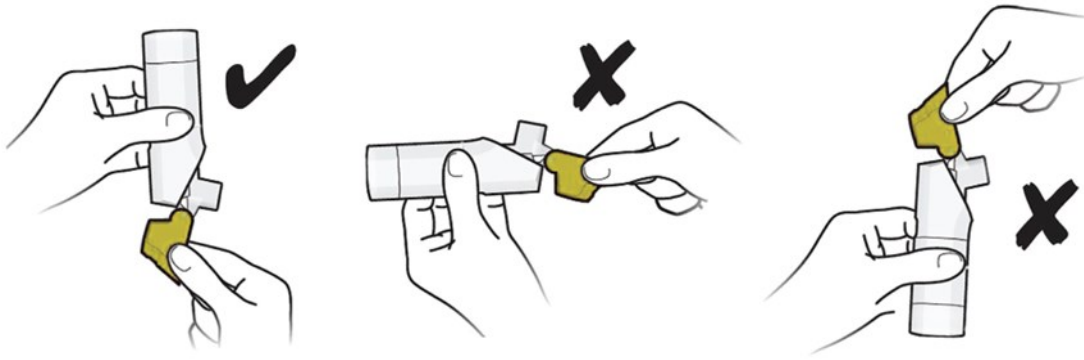


Figure D

## Step 2. Inhale



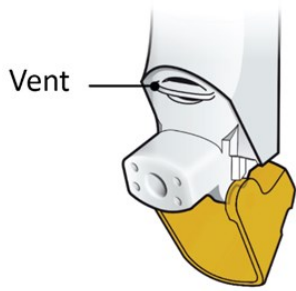
- Before you inhale, breathe out (exhale) through your mouth and push as much air from your lungs as you can. **See Figure E.**
- **Do not** exhale into the inhaler mouthpiece.

Figure E



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

Figure F

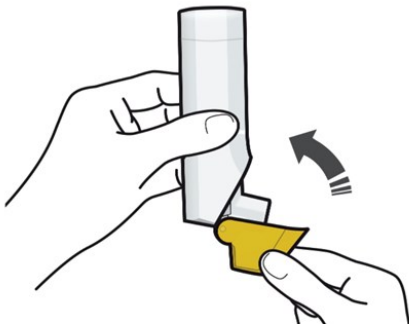


- **Do not** block the vent above the mouthpiece with your lips or fingers. **See Figure G.**

**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 AirDuo 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 yellow cap firmly over the mouthpiece. **See Figure H.**
- Make sure you close the yellow cap after each inhalation so that the inhaler will be ready for your next dose.
- Rinse your mouth with water **without swallowing** after each inhalation.

### How should I store AirDuo Digihaler?

- Store AirDuo Digihaler at room temperature between 59°F and 77°F (15°C and 25°C).
- Avoid exposure to extreme heat, cold, or humidity.
- Store AirDuo Digihaler in the unopened foil pouch and only open when ready for use.
- Keep the yellow cap on the inhaler closed during storage.
- Keep your AirDuo Digihaler inhaler dry and clean at all times.
- **Keep your AirDuo Digihaler inhaler and all medicines out of the reach of children.**

### Cleaning your AirDuo Digihaler inhaler

- **Do not wash or put any part of your AirDuo Digihaler inhaler in water.** Replace your inhaler if washed or placed in water.
- AirDuo Digihaler contains a powder and must be kept clean and dry at all times.
- You can clean the mouthpiece if needed using a dry cloth or tissue. Routine cleaning is not required.

### Replacing your AirDuo Digihaler inhaler

- **Immediately replace your inhaler if the mouthpiece cover is damaged or broken. Never take the inhaler apart.**
- The dose counter on the back of your inhaler shows how many doses you have left.
- When there are 20 doses left, the color of the numbers on the dose counter will change to red and you should refill your prescription or ask your healthcare provider for another prescription.
- When the counter displays '0' your AirDuo Digihaler inhaler is empty and you should stop using the inhaler and throw it away.
- Throw away AirDuo Digihaler 30 days after opening the foil pouch, when the dose counter displays '0', or after the expiration date on the product, whichever comes first.
- AirDuo 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 yellow 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 AirDuo Digihaler inhaler contains dry powder so it is important that you do not blow or breathe into it.

### Support

- For instructions on setting up the App, go to [www.AirDuoDigihaler.com](http://www.AirDuoDigihaler.com) or call Teva at 1-888-603-0788.
- If you have any questions about AirDuo Digihaler or how to use your inhaler, go to [www.AirDuoDigihaler.com](http://www.AirDuoDigihaler.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.

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

The *Bluetooth*<sup>®</sup> word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Teva Respiratory, LLC is under license.

Marketed by: Teva Respiratory, LLC, Frazer, PA 19355; Copyright ©2019, Teva Respiratory, LLC; All rights reserved.

The logo for Teva, consisting of the word "teva" in a bold, lowercase, sans-serif font.

AIRDDHIFU-001

Rev. July 2019