

Instructions for Use
ARMONAIR® DIGIHALER™ (ar´ moe nayr di´ji haye´´ ler)
(fluticasone propionate) inhalation powder 55 mcg
ARMONAIR DIGIHALER (ar´ moe nayr di´ji haye´´ ler)
(fluticasone propionate) inhalation powder 113 mcg
ARMONAIR DIGIHALER (ar´ moe nayr di´ji haye´´ ler)
(fluticasone propionate) inhalation powder 232 mcg
for oral inhalation use

Your ARMONAIR DIGIHALER Inhaler

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

There are 3 main parts of your ARMONAIR DIGIHALER inhaler including the:

- white inhaler with the mouthpiece. **See Figure A.**
- green 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® 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.**

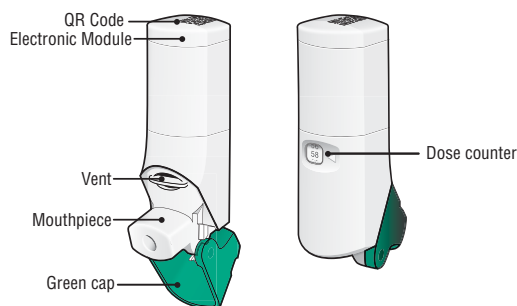


Figure A

- Your ARMONAIR DIGIHALER inhaler contains 60 doses (inhalations). **See Figure B.**
- The dose counter shows the number of doses you have 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 fully. If you do not hear the "click" sound the inhaler may not be activated to give you a dose of medicine.
- **ARMONAIR DIGIHALER does not have an activation button or medicine canister.** When you open the cap, a dose of ARMONAIR DIGIHALER will be activated for delivery of the medicine.
- **ARMONAIR 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 ARMONAIR DIGIHALER. ARMONAIR DIGIHALER does not need priming.

Using your ARMONAIR DIGIHALER inhaler

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

Step 1. Open

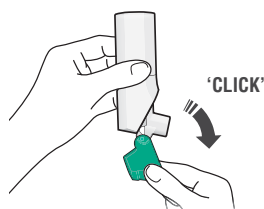


Figure C

- Hold the inhaler upright and open the green cap all the way back until it "clicks". **See Figure C.**
- Each time you open the green cap and it clicks, **a dose of ARMONAIR DIGIHALER is ready to be inhaled.**
- **Do not** open the green cap until you are ready to take a dose of ARMONAIR DIGIHALER.

Remember:

- For correct use of ARMONAIR DIGIHALER, hold the inhaler upright as you open the green cap. See Figure D.
- Do not hold the inhaler in any other way as you open the green cap.

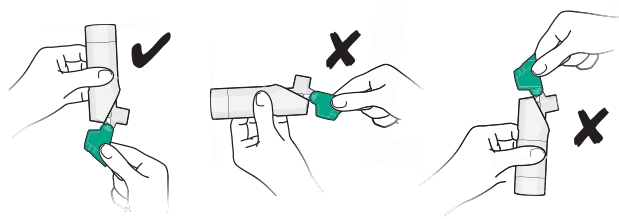


Figure D

Step 2. Inhale

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



Figure E

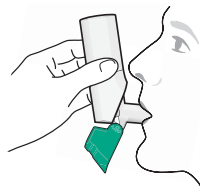


Figure F

- Put the mouthpiece in your mouth and close your lips tightly around it. See Figure F.
- Breathe in quickly and deeply through your mouth, to deliver the dose of medicine to your lungs.
- Do not block the vent above the mouthpiece with your lips or fingers. See Figure G.

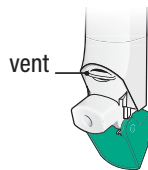


Figure G

- Remove the inhaler from your mouth.
- Hold your breath for about 10 seconds or for as long as you comfortably can.
- Your ARMONAIR 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

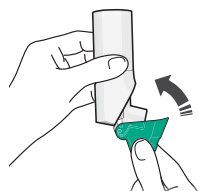


Figure H

- Close the green cap after each inhalation so that the inhaler will be ready for your next dose. See Figure H.
- Rinse your mouth with water without swallowing after each inhalation.

How should I store ARMONAIR DIGIHALER?

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

Cleaning your ARMONAIR DIGIHALER inhaler

- **Do not wash or put any part of your ARMONAIR DIGIHALER inhaler in water.** Replace your inhaler if washed or placed in water.
- ARMONAIR 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.
- **Do not** take the ARMONAIR DIGIHALER inhaler apart.

Replacing your ARMONAIR DIGIHALER inhaler

- **Immediately replace your inhaler if the mouthpiece cover is damaged or broken. Never take the inhaler apart.**
- The 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 ARMONAIR DIGIHALER inhaler is empty and you should stop using it.
- Throw away ARMONAIR DIGIHALER 30 days 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.
- ARMONAIR 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 green 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 ARMONAIR 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.ArmonAir.com or call Teva at 1-888-603-0788.
- If you have any questions about ARMONAIR DIGIHALER or how to use your inhaler, go to www.ArmonAirDigihaler.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.

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