

Instructions for Use
BREZTRI AEROSPHERE™ (brez-TREE)
(budesonide, glycopyrrolate, and formoterol fumarate)
inhalation aerosol, for oral inhalation use

Read this Instructions for Use before you start using BREZTRI AEROSPHERE 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 treatment.

Important Information:

- **For oral inhalation use only.**
- Use BREZTRI AEROSPHERE exactly as your healthcare provider tells you to.
- If you have any questions about the use of your inhaler, ask your healthcare provider or pharmacist.
- Clean your inhaler 1 time each week. See Steps 1 to 8, “How to clean your BREZTRI AEROSPHERE inhaler”.

Parts of your BREZTRI AEROSPHERE inhaler (See Figure 1):

- BREZTRI AEROSPHERE comes as a canister that fits into an actuator with a dose indicator.
 - **Do not** use the BREZTRI AEROSPHERE actuator with a canister of medicine from any other inhaler.
 - **Do not** use the BREZTRI AEROSPHERE canister with an actuator from any other inhaler.

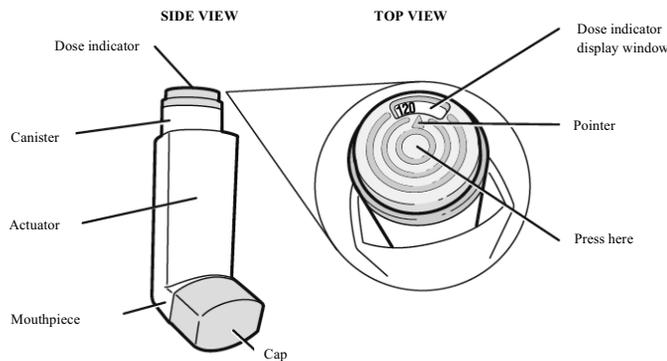


Figure 1

- BREZTRI AEROSPHERE comes with a dose indicator located on the top of the canister (See Figure 1). The dose indicator display window will show you how many puffs of medicine you have left. A puff of medicine is released each time you press the center of the dose indicator.

Before you use BREZTRI AEROSPHERE for the first time make sure that the pointer on the dose indicator should point to the right of the “120” inhalation mark in the dose indicator display window (See Figure 1). If you have a 7-day inhaler (28 inhalation canister), the pointer should point to the right of the “30” inhalation mark.

- The pointer will be pointing to 120 after 10 puffs are delivered from BREZTRI AEROSPHERE. This means that there are 120 puffs of medicine left in the canister (See Figure 2a).
- The pointer will be pointing between 100 and 120 after you take 10 more puffs. This means that there are 110 puffs of medicine left in the canister (See Figure 2b).
- The pointer will be pointing to 100 after you take 10 more puffs. This means that there are 100 puffs of medicine left in the canister (See Figure 2c).

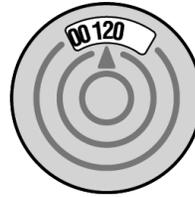


Figure 2a
120 puffs

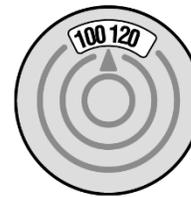


Figure 2b
110 puffs



Figure 2c
100 puffs

- The dose indicator display window will continue to move after every 10 puffs. The number in the dose indicator display window will continue to change after every 20 puffs.

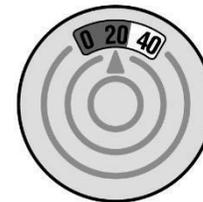


Figure 2d

- The color in the dose indicator display window will change to red, as shown in the shaded area, when there are only 20 puffs of medicine left in your inhaler (See Figure 2d).
- The dose indicator for the 7-day inhaler, 28 inhalation canister, moves after every 10 puffs; with markings for 30, 15 and 0 puffs. The color in the 7-day inhaler, 28 inhalation canister dose indicator display window will change to red when there are only 10 puffs of medicine left in your inhaler.

Preparing your BREZTRI AEROSPHERE inhaler for use:

- Your BREZTRI AEROSPHERE inhaler comes in a foil pouch that contains a drying packet (desiccant).
 - Take the BREZTRI AEROSPHERE inhaler out of the foil pouch.
 - Throw away the pouch and the drying packet. Do not eat or breathe in the contents of the drying packet.
- BREZTRI AEROSPHERE should be at room temperature before you use it.

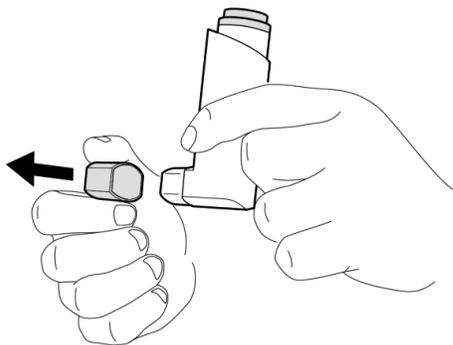


Figure 3

Priming your BREZTRI AEROSPHERE inhaler:

Before you use BREZTRI AEROSPHERE for the first time, you must prime the inhaler.

- Remove the cap from the mouthpiece (See Figure 3). Check inside the mouthpiece for objects before use.
- Hold the inhaler in the upright position away from your face and shake the inhaler well (See Figure 4).

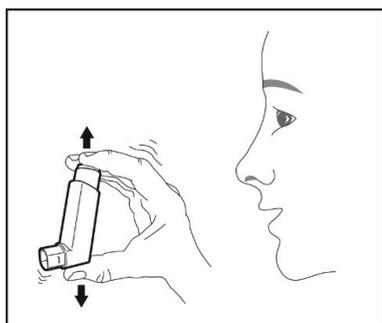


Figure 4

- Press down firmly on the center of the dose indicator until the canister stops moving in the actuator, to release a puff of medicine from the mouthpiece (See Figure 5). You may hear a soft click from the dose indicator as it counts down during use.

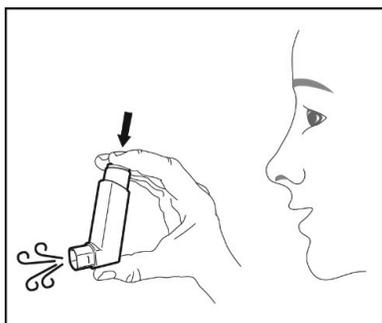


Figure 5

- Repeat the priming steps 3 more times (See Figure 4 and Figure 5). Shake the inhaler well before each priming puff.
- After priming 4 times, the dose indicator should be pointing to the right of “120” (See Figure 1) and your inhaler is now ready to use. If you have a 7-day inhaler (28 inhalation canister), the pointer should point to the right of the “30” inhalation mark.
- Replace the cap until you are ready to use your BREZTRI AEROSPHERE inhaler.

Using your BREZTRI AEROSPHERE inhaler:

Step 1: Remove the cap from the mouthpiece (See Figure 6).

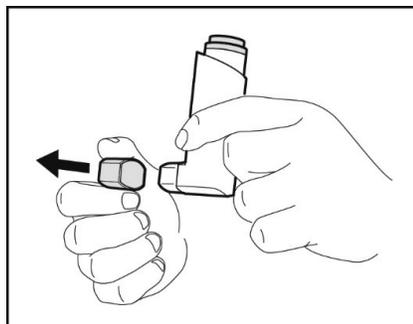


Figure 6

Step 2: Shake the inhaler well before each use (See Figure 7).

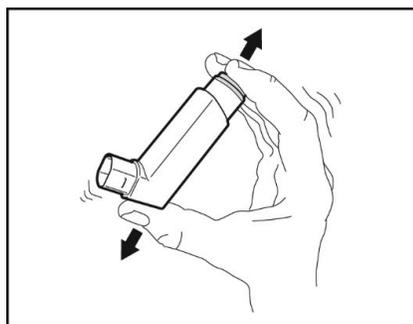


Figure 7

Step 3: Hold the inhaler with the mouthpiece pointing towards you and breathe out as fully as you can through your mouth (See Figure 8).

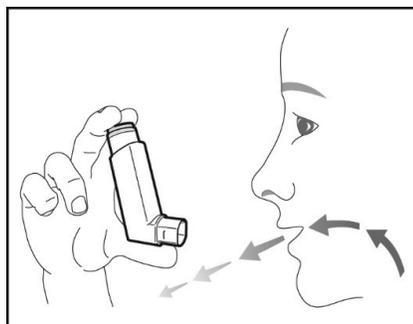


Figure 8

Step 4: Close your lips around the mouthpiece and tilt your head back, keeping your tongue below the mouthpiece (See Figure 9).

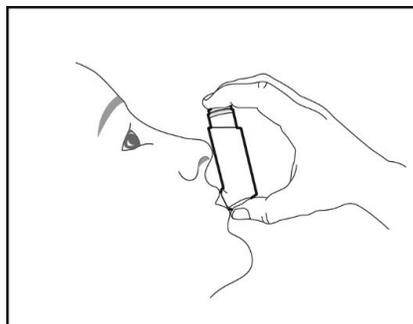


Figure 9

Step 5: While breathing in deeply and slowly, press down on the center of the dose indicator until the canister stops moving in the actuator and a puff of medicine has been released (**See Figure 10**). Then stop pressing the dose indicator.

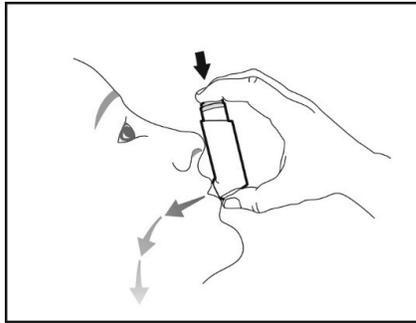


Figure 10

Step 6: When you have finished breathing in, remove the mouthpiece from your mouth. Hold your breath as long as you comfortably can, up to 10 seconds (**See Figure 11**).

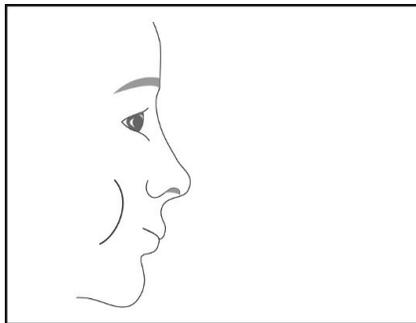


Figure 11

Step 7: Breathe out gently (**See Figure 12**). Repeat Steps 2 through 7 to take your second puff of BREZTRI AEROSPHERE.

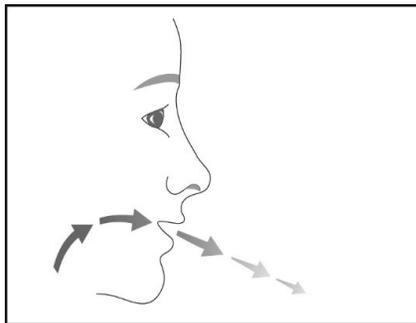


Figure 12

Step 8: Replace the cap over the mouthpiece right away after use (**See Figure 13**).

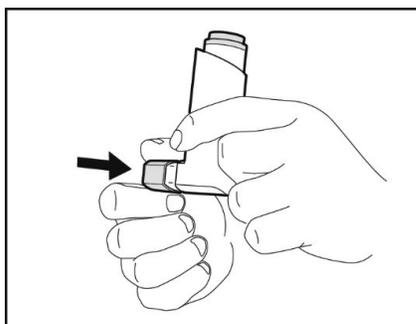


Figure 13

Step 9: Rinse your mouth with water to remove any excess medicine. Do not swallow.

It is important to store BREZTRI AEROSPHERE in a dry place.

How to clean your BREZTRI AEROSPHERE inhaler:

Clean the inhaler once each week. It is very important to keep your inhaler clean so that medicine will not build-up and block the spray through the mouthpiece (**See Figure 14**).

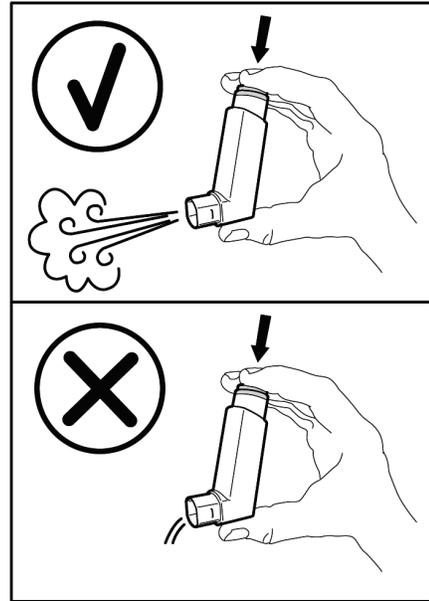


Figure 14

Step 1: Take the canister out of the actuator (**See Figure 15**). Do not clean the canister or let it get wet.

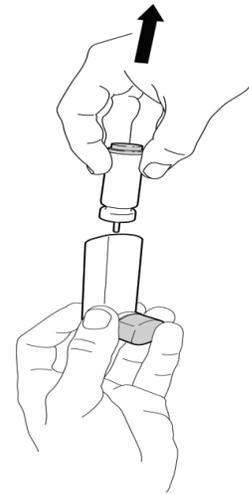


Figure 15

Step 2: Take the cap off the mouthpiece.

Step 3: Hold the actuator under the tap and run warm water through it for about 30 seconds. Turn the actuator upside down and run warm water through it again for about 30 seconds (**See Figure 16**).

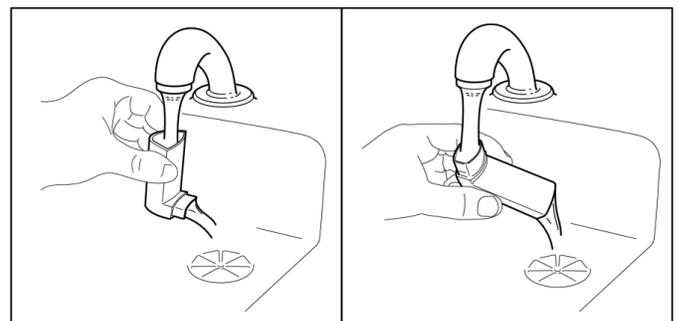


Figure 16

- Step 4:** Shake off as much water from the actuator as you can.
- Step 5:** Look into the actuator and the mouthpiece to make sure any medicine build-up has been completely washed away. If there is any build-up, repeat Steps 3 through 5 in the section “**How to clean your BREZTRI AEROSPHERE inhaler**”.
- Step 6:** Let the actuator air-dry completely, such as overnight (See Figure 17). Do not put the canister back into the actuator if it is still wet.

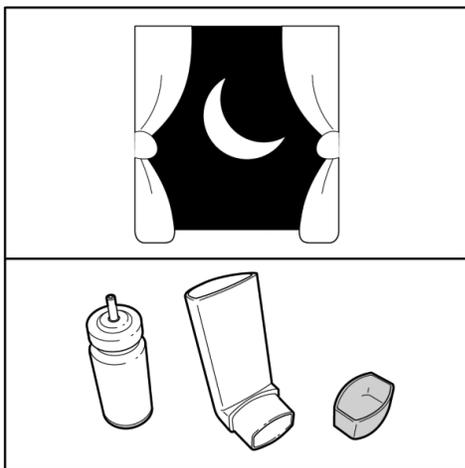


Figure 17

- Step 7:** When the actuator is dry, gently press the canister down in the actuator (See Figure 18). Do not press down too hard on the canister. This could cause a puff of medicine to be released.

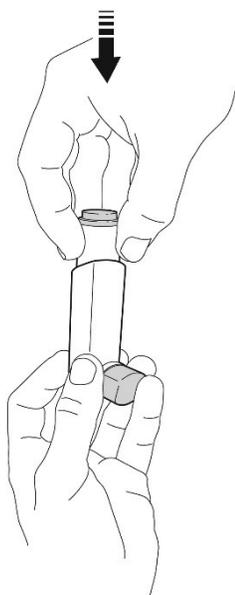


Figure 18

- Step 8:** Re-prime your **BREZTRI AEROSPHERE** inhaler after each cleaning. To re-prime the inhaler, shake the inhaler well and press down on the center of the dose indicator 2 times to release a total of 2 puffs into the air away from your face. Your inhaler is now ready to use.

If BREZTRI AEROSPHERE is not used for more than 7 days, or is dropped, you will need to re-prime it before use.

To re-prime the inhaler, shake the inhaler well and press down on the center of the dose indicator 2 times to release a total of 2 puffs into the air away from your face. Your inhaler is now ready to use again.

This Instructions for Use has been approved by the U.S. Food and Drug Administration (July 2020).

US-38730 7/20