

BREYNA[®] Instructions for Use

How to Use BREYNA

Follow the instructions below for using BREYNA. You will breathe in (inhale) the medicine. If you have any questions, ask your doctor or pharmacist.

Preparing your BREYNA inhaler for use

1. Take your BREYNA out of the moisture-protective foil pouch before you use it for the first time and throw the foil away. Write the date that you open the foil pouch on the box.

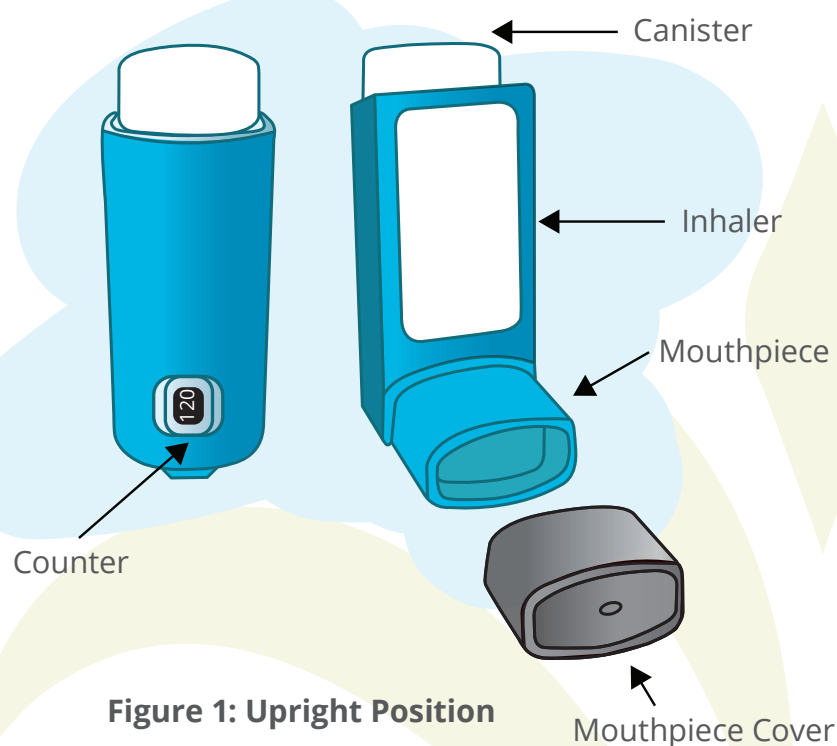


Figure 1: Upright Position

2. The inhaler comes with a counter (see Figure 1). The counter will count down each time you release a puff of BREYNA. The counter will show the number of inhalations (puffs) left in the canister. The counter will stop counting at zero ("0").

3. Use the BREYNA canister only with the blue BREYNA inhaler supplied with the product. Parts of the BREYNA inhaler should not be used with parts from any other inhalation product.
4. Shake your BREYNA inhaler well for 5 seconds right before each use. Remove the mouthpiece cover by squeezing gently at both sides, then pulling out (see Figure 2). Check the mouthpiece for foreign objects before use.

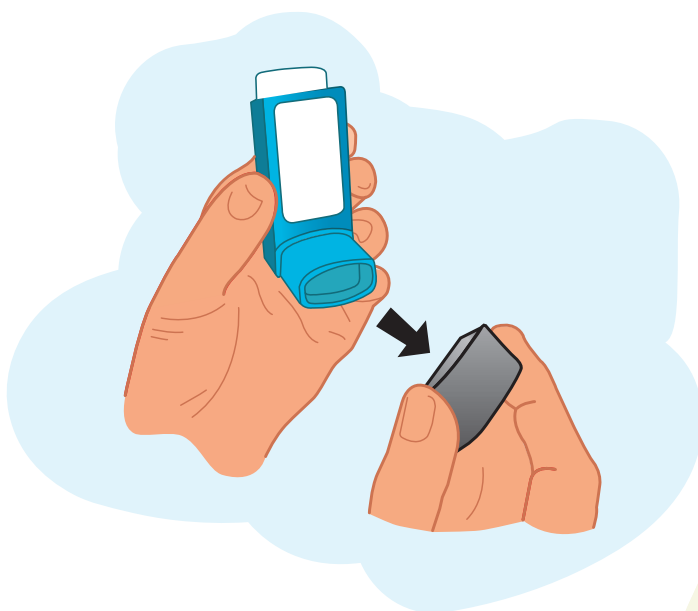


Figure 2

5. Priming your BREYNA inhaler

Before you use BREYNA for the first time, you will need to prime it. To prime BREYNA, hold it in the upright position (see Figure 1). Shake the BREYNA inhaler well for 5 seconds. Hold your BREYNA inhaler facing away from you and press down firmly and fully on the top of the canister to release a test spray. Then shake it again for 5 seconds and release a second test spray. Your BREYNA inhaler is now primed and ready for use. After you have primed the BREYNA inhaler for the first time, the counter will read 120.

If you do not use your BREYNA inhaler for more than 7 days or if you drop it, you will need to prime again.

Using your BREYNA inhaler

6. Shake your BREYNA inhaler well for 5 seconds. Remove the mouthpiece cover. Check the mouthpiece for foreign objects.
7. Breathe out fully (exhale). Hold the BREYNA inhaler up to your mouth. Place the blue mouthpiece fully into your mouth and close your lips around it. Make sure that the BREYNA inhaler is upright and that the opening of the mouthpiece is pointing toward the back of your throat (see Figure 5).
8. Breathe in (inhale) deeply and slowly through your mouth. Press down firmly and fully on the top of the canister to release the medicine (see Figures 3 and 4).
9. Continue to breathe in (inhale) and hold your breath for about 10 seconds or for as long as is comfortable. Before you breathe out (exhale), release your finger from the top of the canister. Keep the BREYNA inhaler upright and remove from your mouth.
10. Shake the BREYNA inhaler again for 5 seconds and repeat steps 7 to 9.

Ways to hold the
BREYNA inhaler
for use.

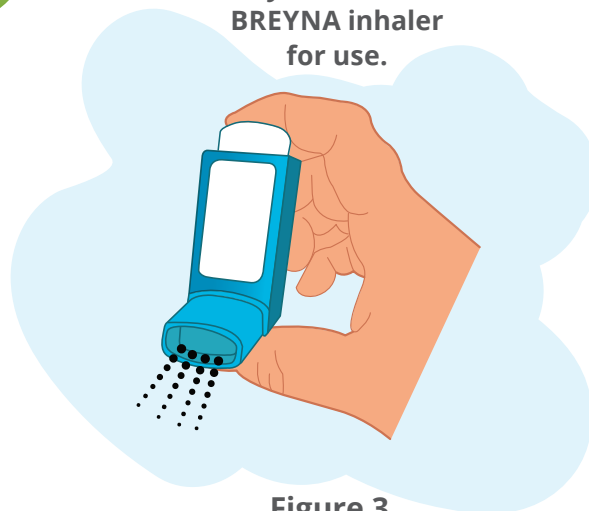


Figure 3
or

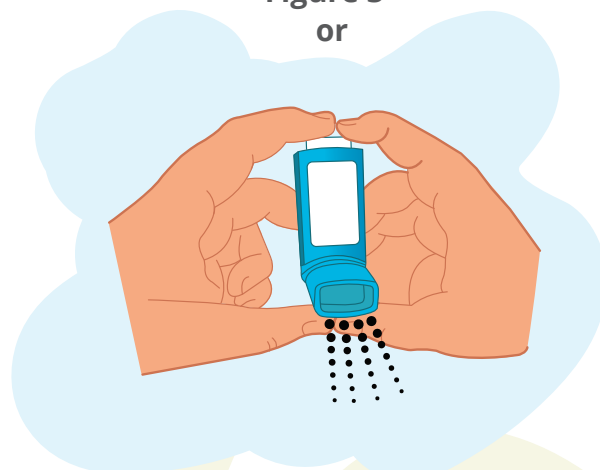


Figure 4

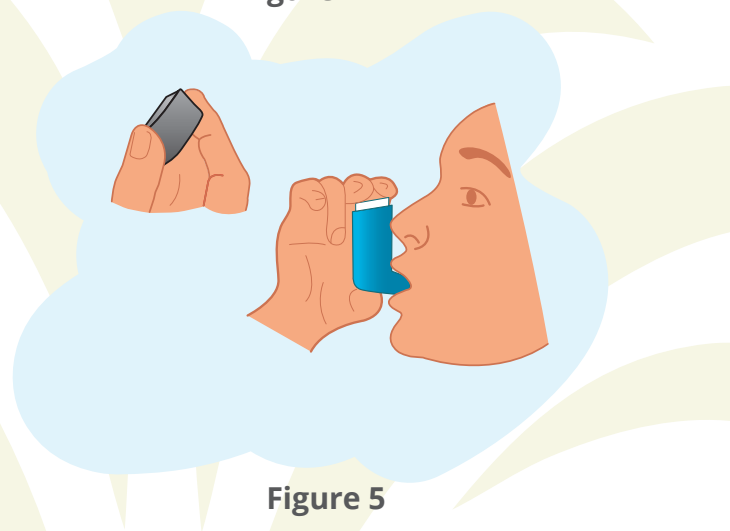
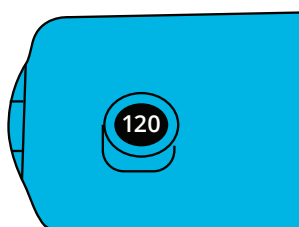


Figure 5

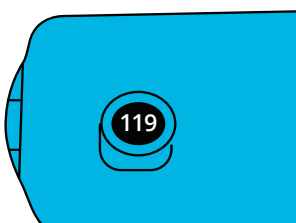
After using your BREYNA inhaler

11. After use, close the mouthpiece cover by pushing until it clicks in place.
12. After you finish taking BREYNA (2 puffs), rinse your mouth with water. Spit out the water. Do not swallow it.

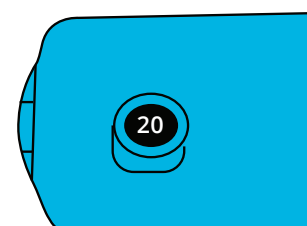
Reading the counter



- The counter shows the number of inhalations (puffs) left in your inhaler.



- The counter will count down each time you release a puff of medicine (either when priming your BREYNA inhaler or when taking the medicine).



- When the counter reads 20, it is time to call your healthcare provider for a refill.
- It is important that you pay attention to the number of inhalations (puffs) left in your BREYNA inhaler by reading the counter. Throw away BREYNA when the counter shows zero ("0") or 3 months after you take your BREYNA inhaler out of its foil pouch, whichever comes first. Your BREYNA inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine if you keep using it. Use a new BREYNA inhaler and follow the instructions for priming (see instruction 5 above).

How to clean your BREYNA inhaler

Clean the blue mouthpiece of your BREYNA inhaler every 7 days.

To clean the mouthpiece:

- Remove the gray mouthpiece cover
- Wipe the inside and outside of the blue mouthpiece opening with a clean, dry cloth
- Replace the mouthpiece cover
- **Do not put the BREYNA inhaler into water**
- Do not try to take apart your **BREYNA** inhaler



Approved Uses and Important Safety Information

APPROVED USES:

Asthma: BREYNA is for the treatment of asthma in adults and children 6 years and older.

BREYNA is not for adults and children with asthma who are well-controlled with an asthma-control medicine such as an inhaled corticosteroid (ICS). BREYNA is for adults and children with asthma who need both an ICS and a long-acting beta₂-adrenergic agonist (LABA).

COPD: COPD is a long-term (chronic) lung disease that includes chronic bronchitis, emphysema, or both. BREYNA 160/4.5 mcg is used long-term in adults to improve symptoms of chronic obstructive pulmonary disease (COPD), for better breathing and to reduce the number of flare-ups (the worsening of your COPD symptoms for several days).

BREYNA is not used to relieve sudden breathing problems and will not replace a rescue inhaler.

IMPORTANT SAFETY INFORMATION

- BREYNA combines an ICS, budesonide and a LABA medicine, formoterol. LABA medicines, such as formoterol, when used alone can increase the risk of hospitalizations and death from asthma problems. When an ICS and LABA are used together, this risk is not significantly increased
- **Do not use BREYNA** for sudden severe symptoms of COPD or asthma or if you are allergic to any of the ingredients in BREYNA
- **Before you use BREYNA, tell your healthcare provider about all of your medical conditions**, including if you have heart conditions or high blood pressure, and all the medicines you may be taking. Some patients taking BREYNA may experience increased blood pressure, heart rate, or change in heart rhythm
- **Do not use BREYNA more often than prescribed.** BREYNA should be taken as 2 puffs 2 times each day
- **While taking BREYNA, do not use another medicine containing a LABA for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines

- **Call your healthcare provider or get medical care right away if:**
 - Your breathing problems worsen
 - You need to use your rescue inhaler more often than usual or your rescue inhaler doesn't work as well at relieving symptoms
- **BREYNA may cause serious side effects, including:**
 - **Using too much of a LABA medicine may cause** chest pain, fast and irregular heartbeat, tremor, increased blood pressure, headache or nervousness
 - **Fungal infection in your mouth or throat (thrush).** Rinse your mouth with water without swallowing after using BREYNA to help reduce your chance of getting thrush
 - **Pneumonia and other lower respiratory tract infections.** People with COPD may have a higher chance of pneumonia and other lung infections. ICS may increase the chance of getting pneumonia. Call your healthcare provider if you notice any of the following symptoms: increase in mucus production or change in color, fever, increased cough, chills, or increased breathing problems
 - **Immune system effects and a higher chance for infections.** Tell your healthcare provider about any signs of infection such as: fever, body aches, feeling tired, vomiting, pain, chills, or nausea
 - **Adrenal insufficiency.** This can happen when you stop taking oral corticosteroid medicines and start inhaled corticosteroid medicine
 - **Increased wheezing right after taking BREYNA.** Always have a rescue inhaler with you to treat sudden wheezing
 - **Serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems.** Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction
 - **Lower bone mineral density** can happen in people who have a high chance for low bone mineral density (osteoporosis)

- **Slowed growth in children.** A child's growth should be checked regularly while using BREYNA
- **Eye problems including glaucoma and cataracts.** You should have regular eye exams while using BREYNA
- **Swelling of blood vessels.** This can happen in people with asthma. Tell your healthcare provider right away if you have: a feeling of pins and needles or numbness of arms or legs, rash, flu like symptoms, or pain and swelling of the sinuses
- **Decreases in blood potassium levels (hypokalemia)**
- **Increases in blood sugar levels (hyperglycemia)**
- **The most common side effects of BREYNA include:**
 - **Asthma:** throat irritation, headache, upper respiratory tract infection, throat pain, sinusitis, flu, back pain, nasal congestion, stomach discomfort, vomiting, and thrush in the mouth and throat
 - **COPD:** throat irritation, thrush in the mouth and throat, bronchitis, sinusitis, and upper respiratory tract infection

This summary does not include all the information about BREYNA and is not meant to take the place of a discussion with your healthcare provider about your treatment.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call [1-800-FDA-1088](tel:1-800-FDA-1088).

Click here for Full [Prescribing Information](#) including [Patient Information](#).

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