

PATIENT INFORMATION

BREO ELLIPTA [BRE-oh e-LIP-ta] (fluticasone furoate and vilanterol inhalation powder) for oral inhalation

What is BREO ELLIPTA?

- BREO ELLIPTA combines an inhaled corticosteroid (ICS) medicine, fluticasone furoate, and a long-acting beta₂-adrenergic agonist (LABA) medicine, vilanterol.
 - ICS medicines such as fluticasone furoate help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.
 - LABA medicines such as vilanterol help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- **BREO ELLIPTA is not used to relieve sudden breathing problems** and will not replace a rescue inhaler.
- BREO ELLIPTA should not be used in children and adolescents. It is not known if BREO ELLIPTA is safe and effective in children and adolescents younger than 18 years of age.
- BREO ELLIPTA is used for COPD and asthma and as follows:

COPD:

BREO ELLIPTA 100/25 is a prescription medicine used to treat COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. BREO ELLIPTA 100/25 is used long term as 1 inhalation 1 time each day to improve symptoms of COPD for better breathing and to reduce the number of flare-ups (the worsening of your COPD symptoms for several days).

Asthma:

- BREO ELLIPTA is a prescription medicine used as 1 inhalation 1 time each day to prevent and control symptoms of asthma for better breathing and to prevent symptoms such as wheezing.
- BREO ELLIPTA contains vilanterol. LABA medicines such as vilanterol when used alone increase the risk of hospitalizations and death from asthma problems. BREO ELLIPTA contains an ICS and a LABA. When an ICS and LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.
- BREO ELLIPTA is not for people with asthma who are well controlled with an asthma control medicine, such as a low to medium dose of an ICS medicine. BREO ELLIPTA is for adults with asthma who need both an ICS and LABA medicine.

Do not use BREO ELLIPTA:

- to treat sudden, severe symptoms of asthma or COPD.
- if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- if you are allergic to fluticasone furoate, vilanterol, or any of the ingredients in BREO ELLIPTA. See the end of this Patient Information for a complete list of ingredients in BREO ELLIPTA.

Before using BREO ELLIPTA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have high blood pressure.
- have seizures.

- have thyroid problems.
- have diabetes.
- have liver problems.
- have weak bones (osteoporosis).
- have an immune system problem.
- have eye problems such as glaucoma or cataracts.
- are allergic to milk proteins.
- have any type of viral, bacterial, fungal, or parasitic infection.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if BREO ELLIPTA may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in BREO ELLIPTA pass into your breast milk and if they can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BREO ELLIPTA and certain other medicines may interact with each other. This may cause serious side effects. Especially tell your healthcare provider if you take antifungal or anti-HIV medicines. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use BREO ELLIPTA?

Read the step-by-step instructions for using BREO ELLIPTA at the end of this Patient Information.

- **Do not** use BREO ELLIPTA unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- BREO ELLIPTA comes in 2 different strengths. Your healthcare provider prescribed the strength that is best for you.
- Use BREO ELLIPTA exactly as your healthcare provider tells you to use it. **Do not** use BREO ELLIPTA more often than prescribed.
- Use 1 inhalation of BREO ELLIPTA 1 time each day. Use BREO ELLIPTA at the same time each day.
- If you miss a dose of BREO ELLIPTA, take it as soon as you remember. Do not take more than 1 inhalation per day. Take your next dose at your usual time. Do not take 2 doses at 1 time.
- If you take too much BREO ELLIPTA, call your healthcare provider or go to the nearest hospital emergency room right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.
- **Do not use other medicines that contain a LABA for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.
- Do not stop using BREO ELLIPTA unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- **BREO ELLIPTA does not relieve sudden symptoms of asthma or COPD and you should not take extra doses of BREO ELLIPTA to relieve these sudden symptoms.** Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.
- Call your healthcare provider or get medical care right away if:
 - your breathing problems get worse.
 - you need to use your rescue inhaler more often than usual.

- your rescue inhaler does not work as well to relieve your symptoms.
- your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.

What are the possible side effects of BREO ELLIPTA?

BREO ELLIPTA can cause serious side effects, including:

- **fungal infection in your mouth or throat (thrush).** Rinse your mouth with water without swallowing after using BREO ELLIPTA to help reduce your chance of getting thrush.
- **pneumonia.** People with COPD have a higher chance of getting pneumonia. BREO ELLIPTA may increase the chance of getting pneumonia. Call your healthcare provider if you notice any of the following symptoms:
 - increase in mucus (sputum) production
 - change in mucus color
 - fever
 - chills
 - increased cough
 - increased breathing problems
- **weakened immune system and increased chance of getting infections (immunosuppression).**
- **reduced adrenal function (adrenal insufficiency).** Adrenal insufficiency is a condition where the adrenal glands do not make enough steroid hormones. This can happen when you stop taking oral corticosteroid medicines (such as prednisone) and start taking a medicine containing an ICS (such as BREO ELLIPTA). During this transition period, when your body is under stress from fever, trauma (such as a car accident), infection, surgery, or worse COPD symptoms, adrenal insufficiency can get worse and may cause death.

Symptoms of adrenal insufficiency include:

 - feeling tired
 - lack of energy
 - weakness
 - nausea and vomiting
 - low blood pressure (hypotension)
- **sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop taking BREO ELLIPTA and call your healthcare provider right away.
- **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following symptoms of a serious allergic reaction:
 - rash
 - hives
 - swelling of your face, mouth, and tongue
 - breathing problems
- **effects on heart.**
 - increased blood pressure
 - a fast or irregular heartbeat, awareness of heartbeat
 - chest pain
- **effects on nervous system.**
 - tremor
 - nervousness
- **bone thinning or weakness (osteoporosis).**
- **eye problems including glaucoma and cataracts.** You should have regular eye exams while using BREO ELLIPTA.
- **changes in laboratory blood levels,** including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia).
- **slowed growth in children.**

Common side effects of BREO ELLIPTA include:

COPD:

- runny nose and sore throat
- upper respiratory tract infection
- headache
- thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this.
- back pain
- pneumonia
- bronchitis
- inflammation of the sinuses
- cough
- mouth and throat pain
- joint pain
- increased blood pressure
- flu
- fever

Asthma:

- runny nose and sore throat
- thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this.
- headache
- flu
- respiratory tract infection
- bronchitis
- inflammation of the sinuses
- mouth and throat pain
- hoarseness and voice changes
- cough

These are not all the possible side effects of BREO ELLIPTA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BREO ELLIPTA?

- Store BREO ELLIPTA at room temperature between 68°F and 77°F (20°C and 25°C). Keep in a dry place away from heat and sunlight.
- Store BREO ELLIPTA in the unopened foil tray and only open when ready for use.
- Safely throw away BREO ELLIPTA in the trash 6 weeks after you open the foil tray or when the counter reads “0”, whichever comes first. Write the date you open the tray on the label on the inhaler.

Keep BREO ELLIPTA and all medicines out of the reach of children.

General information about the safe and effective use of BREO ELLIPTA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BREO ELLIPTA for a condition for which it was not prescribed. Do not give BREO ELLIPTA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about BREO ELLIPTA that is written for health professionals.

What are the ingredients in BREO ELLIPTA?

Active ingredients: fluticasone furoate, vilanterol trifenate

Inactive ingredients: lactose monohydrate (contains milk proteins), magnesium stearate



For more information about BREO ELLIPTA, call 1-888-825-5249 or visit our website at www.myBREO.com.

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BREO ELLIPTA was developed in collaboration with INNOVIVA.

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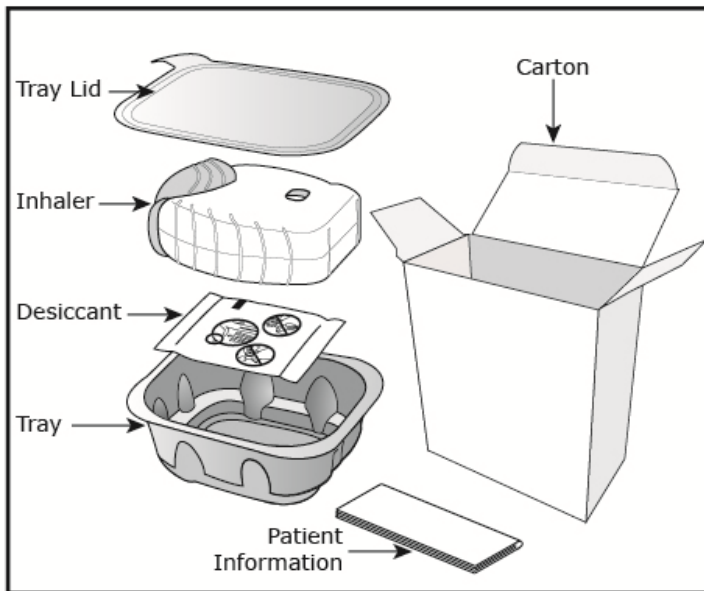
INSTRUCTIONS FOR USE

BREO ELLIPTA [BRE-oh e-LIP-ta] (fluticasone furoate and vilanterol inhalation powder) for oral inhalation

Read this before you start:

- If you open and close the cover without inhaling the medicine, you will lose the dose.
- The lost dose will be securely held inside the inhaler, but it will no longer be available to be inhaled.
- It is not possible to accidentally take a double dose or an extra dose in 1 inhalation.

Your BREO ELLIPTA inhaler



How to use your inhaler

- BREO ELLIPTA comes in a foil tray.
- Peel back the lid to open the tray. See **Figure A**.
- The tray contains a desiccant to reduce moisture. Do not eat or inhale. Throw it away in the household trash out of reach of children and pets. See **Figure B**.

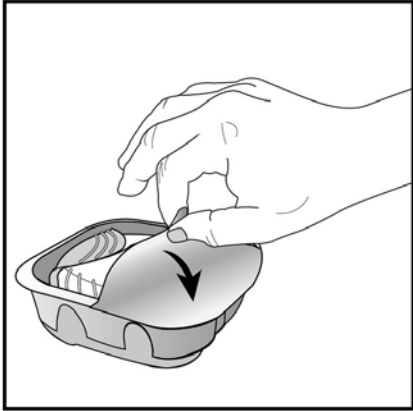


Figure A

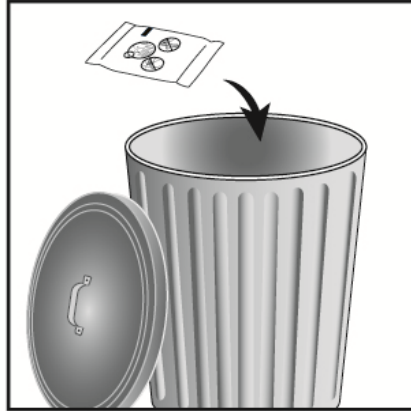


Figure B

Important Notes:

- Your inhaler contains 30 doses (14 doses if you have a sample or institutional pack).
- Each time you fully open the cover of the inhaler (you will hear a clicking sound), a dose is ready to be inhaled. This is shown by a decrease in the number on the counter.
- If you open and close the cover without inhaling the medicine, you will lose the dose. The lost dose will be held in the inhaler, but it will no longer be available to be inhaled. It is not possible to accidentally take a double dose or an extra dose in 1 inhalation.
- **Do not** open the cover of the inhaler until you are ready to use it. To avoid wasting doses after the inhaler is ready, **do not** close the cover until after you have inhaled the medicine.
- Write the “Tray opened” and “Discard” dates on the inhaler label. The “Discard” date is 6 weeks from the date you open the tray.

Check the counter. See Figure C.

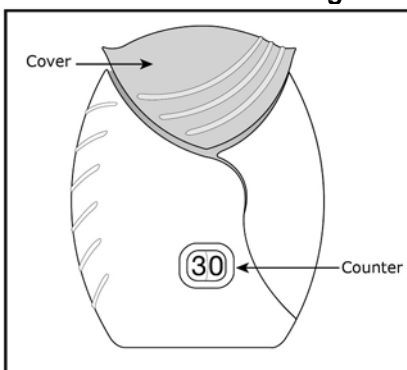


Figure C

- Before the inhaler is used for the first time, the counter should show the number 30 (14 if you have a sample or institutional pack). This is the number of doses in the inhaler.
- Each time you open the cover, you prepare 1 dose of medicine.
- The counter counts down by 1 each time you open the cover.

Prepare your dose:

Wait to open the cover until you are ready to take your dose.

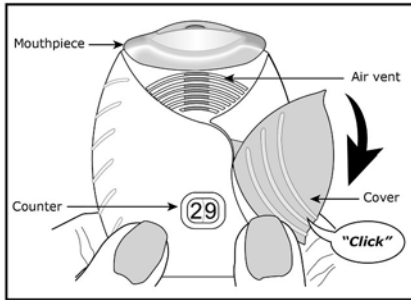


Figure D

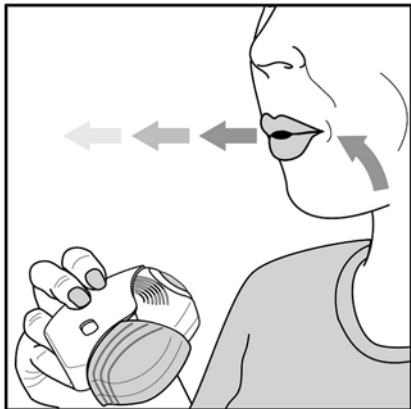


Figure E

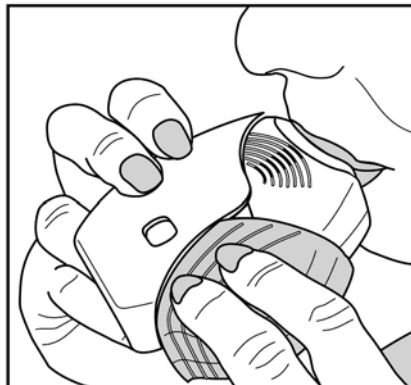


Figure F

Do not block the air vent with your fingers.



Figure G

Step 1. Open the cover of the inhaler. See Figure D.

- Slide the cover down to expose the mouthpiece. You should hear a “click.” The counter will count down by 1 number. You do not need to shake this kind of inhaler.

Your inhaler is now ready to use.

- If the counter does not count down as you hear the click, the inhaler will not deliver the medicine. Call your healthcare provider or pharmacist if this happens.

Step 2. Breathe out. See Figure E.

- While holding the inhaler away from your mouth, breathe out (exhale) fully. Do not breathe out into the mouthpiece.

Step 3. Inhale your medicine. See Figure F.

- Put the mouthpiece between your lips, and close your lips firmly around it. Your lips should fit over the curved shape of the mouthpiece.
- Take one long, steady, deep breath in through your mouth. **Do not** breathe in through your nose.

- Do not block the air vent with your fingers. **See Figure G.**

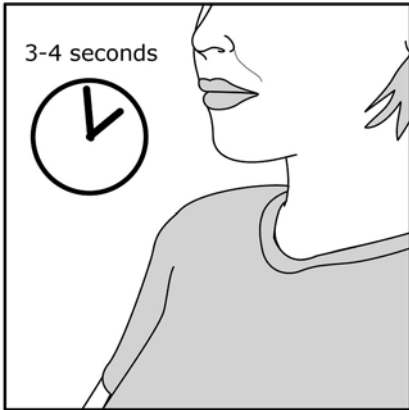


Figure H

- Remove the inhaler from your mouth and hold your breath for about 3 to 4 seconds (or as long as comfortable for you). See Figure H.

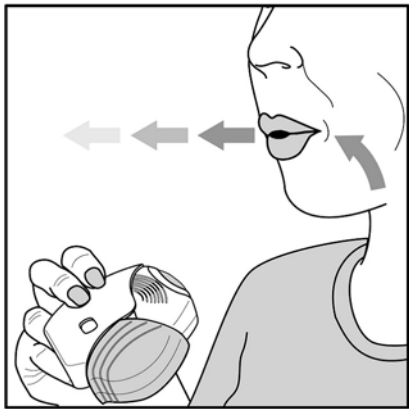


Figure I

Step 4. Breathe out slowly and gently. See Figure I.

- You may not taste or feel the medicine, even when you are using the inhaler correctly.
- **Do not** take another dose from the inhaler even if you do not feel or taste the medicine.

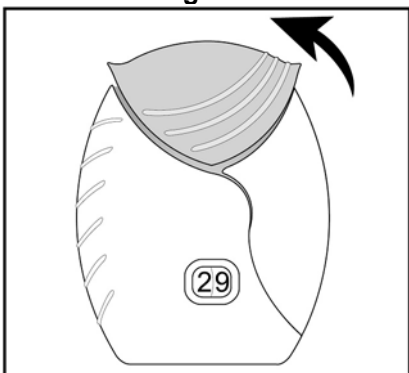


Figure J

Step 5. Close the inhaler. See Figure J.

- You can clean the mouthpiece if needed, using a dry tissue, before you close the cover. Routine cleaning is not required.
- Slide the cover up and over the mouthpiece as far as it will go.



Figure K

Step 6. Rinse your mouth. See Figure K.

- Rinse your mouth with water after you have used the inhaler and spit the water out. **Do not** swallow the water.

Important Note: When should you get a refill?

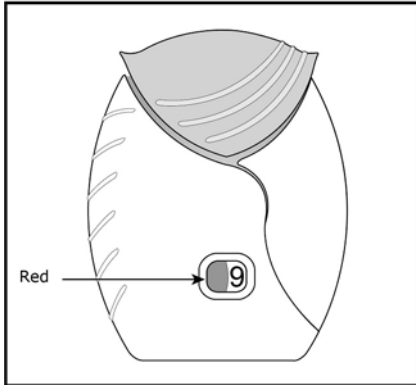


Figure L

- **When you have fewer than 10 doses remaining** in your inhaler, the left half of the counter shows red as a reminder to get a refill. **See Figure L.**
- After you have inhaled the last dose, the counter will show “0” and will be empty.
- Throw the empty inhaler away in your household trash out of reach of children and pets.



For more information about BREO ELLIPTA or how to use your inhaler, call 1-888-825-5249 or visit our website at www.myBREO.com.

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

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