

PATIENT INFORMATION

TRELEGY ELLIPTA (TREL-e-gee e-LIP-ta) (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) for oral inhalation use

What is TRELEGY ELLIPTA?

- TRELEGY ELLIPTA combines 3 medicines in one inhaler, an inhaled corticosteroid (ICS) medicine (fluticasone furoate), an anticholinergic medicine (umeclidinium), 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.
 - Anticholinergic medicines such as umeclidinium and 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.
- TRELEGY ELLIPTA is a prescription medicine used to treat COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. TRELEGY ELLIPTA 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).
- TRELEGY ELLIPTA is not approved for the treatment of asthma. TRELEGY ELLIPTA contains vilanterol. LABA medicines such as vilanterol when used alone increase the risk of hospitalizations and death from asthma problems. TRELEGY ELLIPTA contains an ICS, an anticholinergic, 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.
- **TRELEGY ELLIPTA is not used to relieve sudden breathing problems** and will not replace a rescue inhaler. Always have a rescue inhaler (an inhaled, short-acting bronchodilator) with you to treat sudden breathing problems. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.
- TRELEGY ELLIPTA should not be used in children. It is not known if TRELEGY ELLIPTA is safe and effective in children.

Do not use TRELEGY ELLIPTA if you:

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

Before using TRELEGY 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, increased pressure in your eye, cataracts, blurred vision, or other changes in vision. TRELEGY ELLIPTA may make your glaucoma worse.
- are allergic to milk proteins.
- have prostate or bladder problems, or problems passing urine. TRELEGY ELLIPTA may make these problems worse.
- have any type of viral, bacterial, parasitic, or fungal infection.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if TRELEGY ELLIPTA may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in TRELEGY ELLIPTA pass into your 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. TRELEGY ELLIPTA and certain other medicines may interact with each other. This may cause serious side effects.

Especially tell your healthcare provider if you take:

- anticholinergics (including tiotropium, ipratropium, aclidinium)
- atropine
- other LABA (including salmeterol, formoterol, arformoterol, olodaterol, and indacaterol)
- 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 TRELEGY ELLIPTA?

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

- **Do not** use TRELEGY ELLIPTA unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- Use TRELEGY ELLIPTA exactly as your healthcare provider tells you to use it. **Do not** use TRELEGY ELLIPTA more often than prescribed.
- Use 1 inhalation of TRELEGY ELLIPTA 1 time each day. Use TRELEGY ELLIPTA at the same time each day.
- If you miss a dose of TRELEGY 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 TRELEGY 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 or an anticholinergic for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA or anticholinergic medicines.
- **Do not** stop using TRELEGY 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.
- **TRELEGY ELLIPTA does not relieve sudden symptoms of COPD and you should not take extra doses of TRELEGY 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.

What are the possible side effects of TRELEGY ELLIPTA?

TRELEGY ELLIPTA can cause serious side effects, including:

- **fungal infection in your mouth or throat (thrush).** Rinse your mouth with water without swallowing after using TRELEGY ELLIPTA to help reduce your chance of getting thrush.
- **pneumonia.** People with COPD have a higher chance of getting pneumonia. TRELEGY 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 TRELEGY 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 TRELEGY 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, increased pressure in your eye, cataracts, blurred vision, worsening of narrow-angle glaucoma, or other changes in vision. You should have regular eye exams while using TRELEGY ELLIPTA.

Acute narrow-angle glaucoma can cause permanent loss of vision if not treated. Symptoms of acute narrow-angle glaucoma may include:

- eye pain or discomfort
- nausea or vomiting
- blurred vision
- seeing halos or bright colors around lights
- red eyes

If you have these symptoms, call your healthcare provider right away before taking another dose.

- **urinary retention.** People who take TRELEGY ELLIPTA may develop new or worse urinary retention. Symptoms of urinary retention may include:

- difficulty urinating
- painful urination
- urinating frequently
- urination in a weak stream or drips

If you have these symptoms of urinary retention, stop taking TRELEGY ELLIPTA, and call your healthcare provider right away before taking another dose.

- **changes in laboratory blood values,** including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia).

Common side effects of TRELEGY ELLIPTA include:

- upper respiratory tract infection
- pneumonia
- bronchitis
- thrush in your mouth and throat. Rinse your mouth with water without swallowing after use to help prevent this.
- headache
- back pain
- joint pain
- flu
- inflammation of the sinuses
- runny nose and sore throat
- taste disturbance
- constipation
- painful and frequent urination (signs of a urinary tract infection)
- nausea, vomiting, and diarrhea
- mouth and/or throat pain
- cough
- hoarseness

These are not all the possible side effects of TRELEGY 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 TRELEGY ELLIPTA?

- Store TRELEGY 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 TRELEGY ELLIPTA in the unopened tray and only open when ready for use.
- Safely throw away TRELEGY ELLIPTA in the trash 6 weeks after you open the tray or when the counter reads “0”, whichever comes first. Write the date you open the tray on the label on the inhaler.

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

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TRELEGY ELLIPTA for a condition for which it was not prescribed. Do not give TRELEGY 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 TRELEGY ELLIPTA that is written for health professionals.

What are the ingredients in TRELEGY ELLIPTA?

Active ingredients: fluticasone furoate, umeclidinium, vilanterol

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



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

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TRELEGY ELLIPTA was developed in collaboration with Innoviva.

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This Patient Information has been approved by the U.S. Food and Drug Administration

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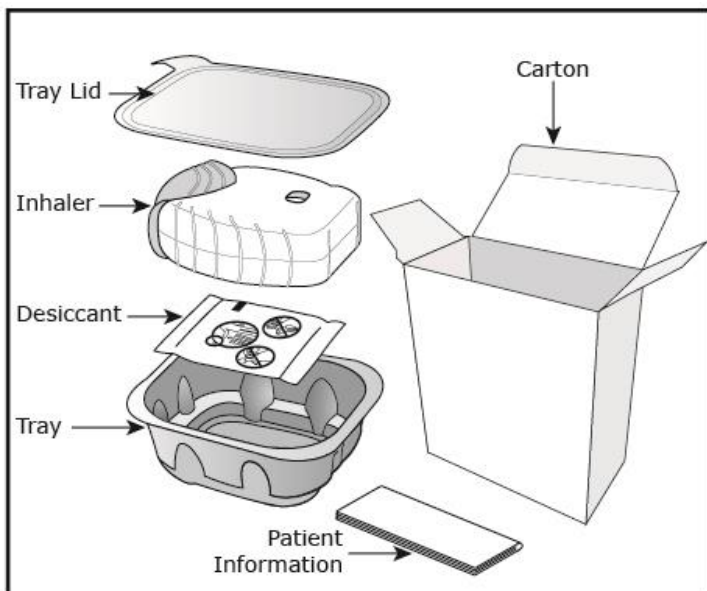
INSTRUCTIONS FOR USE

TRELEGY ELLIPTA (TREL-e-gee e-LIP-ta) (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) for oral inhalation use

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 TRELEGY ELLIPTA inhaler



How to use your inhaler

- TRELEGY ELLIPTA comes in a 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.**

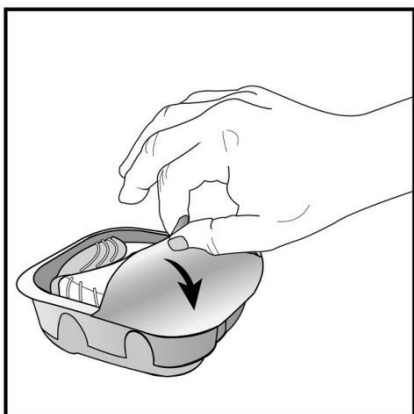


Figure A

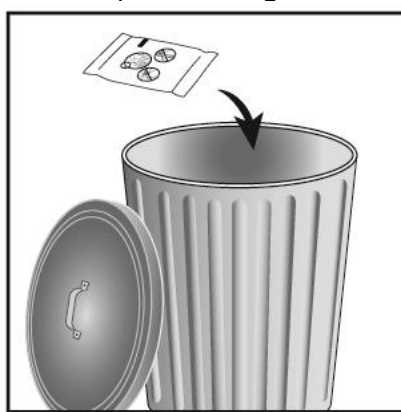


Figure B

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.

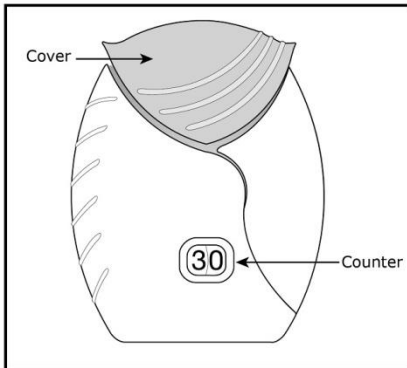


Figure C

- 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.

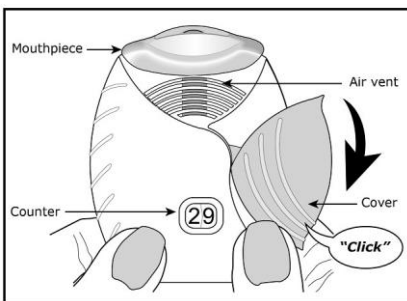


Figure D

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.

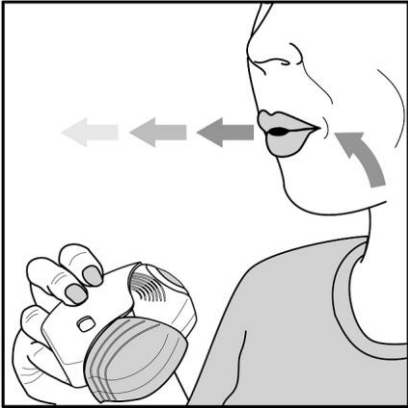


Figure E

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.

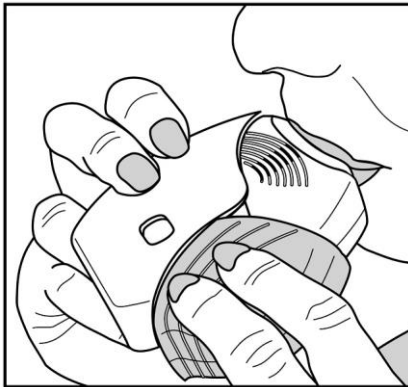


Figure F

Do not block the air vent with your fingers.

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.

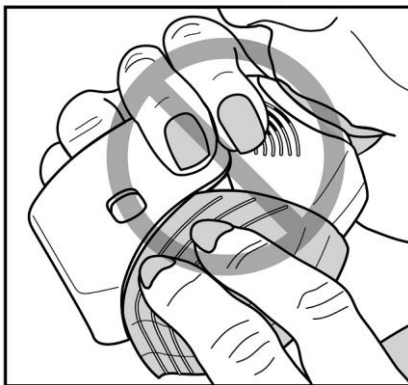


Figure G

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

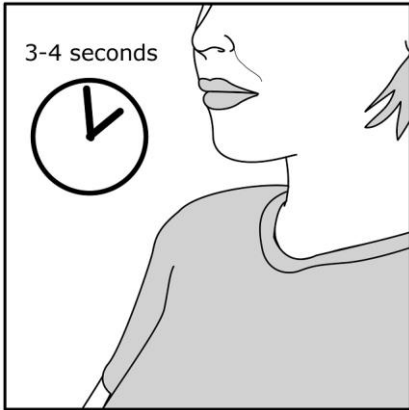


Figure H

- 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.

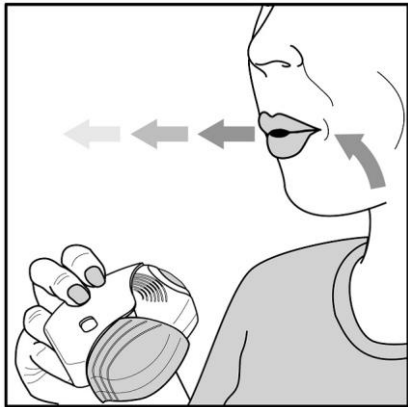


Figure I

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.

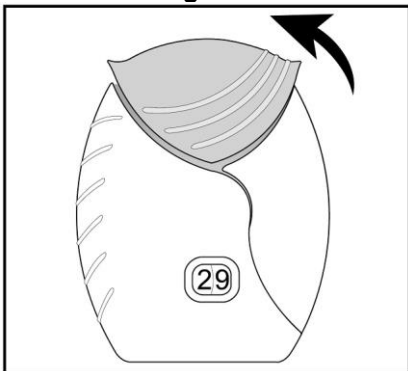


Figure J

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.

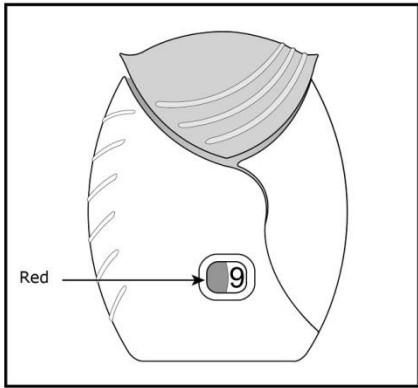


Figure K

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?



- **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.

Figure L



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

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