

MEDICATION GUIDE

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

What is the most important information I should know about TRELEGY ELLIPTA?

TRELEGY ELLIPTA is approved only for use in chronic obstructive pulmonary disease (COPD).

TRELEGY ELLIPTA is not approved for the treatment of asthma.

TRELEGY ELLIPTA can cause serious side effects, including:

- **People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as vilanterol (one of the medicines in TRELEGY ELLIPTA), have an increased risk of death from asthma problems.** It is not known whether fluticasone furoate, one of the medicines in TRELEGY ELLIPTA, reduces the risk of death from asthma problems seen with LABA medicines.
- **It is not known if LABA medicines, such as vilanterol, increase the risk of death in people with COPD.**
- **Call your healthcare provider if breathing problems worsen over time while using TRELEGY ELLIPTA. You may need different treatment.**
- **Get emergency medical care if:**
 - your breathing problems worsen quickly.
 - you use your rescue inhaler, but it does not relieve your breathing problems.

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 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 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 Medication Guide 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 or cataracts. 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, acridinium)
- 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 Medication Guide.

- **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:

- **See “What is the most important information I should know about TRELEGY ELLIPTA?”**
- **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
- **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
 - chest pain

- a fast or irregular heartbeat, awareness of heartbeat
- **effects on nervous system.**
 - tremor
 - nervousness
- **bone thinning or weakness (osteoporosis).**
- **new or worsening eye problems including glaucoma, narrow angle glaucoma, and cataracts.** 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
 - seeing halos or bright colors around lights
 - nausea or vomiting
 - red eyes
 - blurred vision

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
 - urinating frequently
 - painful urination
 - 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:

- headache
- nausea, vomiting, and diarrhea
- back pain
- cough
- taste disturbance
- mouth and/or throat pain

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 Medication Guide. 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.
Trademarks are owned by or licensed to the GSK group of companies.
TRELEGY ELLIPTA was developed in collaboration with Innoviva.

INNOVIVA

GlaxoSmithKline, Research Triangle Park, NC 27709
©2017 GSK group of companies or its licensor.
TRL:1MG

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: September 2017