

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

TRELEGY ELLIPTA

Fluticasone furoate/umeclidinium/vilanterol dry powder for oral inhalation

Read this leaflet carefully before you start taking TRELEGY ELLIPTA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about TRELEGY ELLIPTA.

What is TRELEGY ELLIPTA used for?

TRELEGY ELLIPTA is used in adults for the long-term treatment of a lung disease called Chronic Obstructive Pulmonary Disease or COPD. This includes chronic bronchitis and emphysema. TRELEGY ELLIPTA is used in patients who are not adequately treated by other combination medications (ICS/LABA or LAMA/LABA).

People with COPD are also likely to experience “flare-ups” during which their symptoms become worse. If you have a history of experiencing “flare-ups” TRELEGY ELLIPTA can help reduce the symptoms you feel when this happens.

If you are a smoker, it is important to quit smoking. This will help decrease the symptoms of COPD and potentially increase your lifespan.

How does TRELEGY ELLIPTA work?

TRELEGY ELLIPTA contains three active ingredients, fluticasone furoate, umeclidinium and vilanterol.

- Fluticasone furoate is an inhaled corticosteroid (ICS). It reduces inflammation in the airways of the lungs, which can ease breathing problems, and helps prevent “flare-ups” in COPD.
- Umeclidinium is a long-acting muscarinic antagonist (LAMA) and vilanterol is a long-acting beta₂-agonist (LABA). These two medicines work together to help open the airways and make it easier for air to get in and out of the lungs.

There is no cure for COPD, but TRELEGY ELLIPTA helps to control it. It is therefore important that you continue to take TRELEGY ELLIPTA regularly, even if you feel fine.

What are the ingredients in TRELEGY ELLIPTA?

Medicinal ingredients: fluticasone furoate, umeclidinium (as bromide), and vilanterol (as trifenate).

Non-medicinal ingredients: lactose monohydrate (which contains milk proteins) and magnesium stearate.

TRELEGY ELLIPTA comes in the following dosage forms:

Dry powder for oral inhalation delivered by the ELLIPTA inhaler. Each dose contains 100 mcg fluticasone furoate, 62.5 mcg umeclidinium, and 25 mcg vilanterol.

Each inhaler contains 14 doses (one inhalation per day for 14 days) or 30 doses (one inhalation per day for 30 days).

Do not use TRELEGY ELLIPTA:

- To treat sudden severe symptoms of COPD such as sudden shortness of breath or wheezing. **TRELEGY ELLIPTA is not a rescue inhaler and should not be used to give you fast relief from your COPD.** You must use a rescue inhaler during sudden COPD flare-ups. Keep this rescue medication with you at all times.
- To treat asthma.
- If you are allergic to fluticasone furoate, umeclidinium, vilanterol or any of the non-medicinal ingredients contained in the product.
- If you have a lactose or severe milk protein allergy.
- If you are younger than 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRELEGY ELLIPTA. Talk about any health conditions or problems you may have, including if you:

- Have liver disease, as you may be more likely to experience side effects;
- Have heart problems, such as rapid or irregular heart beat or an abnormal electrical signal called “prolongation of the QT interval”;
- Have high blood pressure;
- Have eye problems such as increased pressure in the eye, glaucoma, cataracts, blurry vision or other changes in vision;
- Have prostate or bladder problems, or problems passing urine;
- Have ever had thrush or a yeast infection in your mouth;
- Have ever had seizures;
- Have thyroid gland problems or disease;
- Have diabetes;
- Have ever had to stop taking another medication for your breathing problems because you were allergic to it or it caused problems;
- Have been taking other corticosteroids by mouth or by inhalation;
- Have an immune system problem;
- Have any allergies to food or drugs;
- Have low levels of potassium in your blood;
- Have ever had herpes simplex of the eye, a history of tuberculosis infections, or any type of viral, bacterial, fungal (yeast), or parasitic infection.
- Are pregnant, think you could be pregnant, or if you are planning to become pregnant. Your healthcare professional will consider the benefit to you and the risk to your unborn baby.
- Are breastfeeding. It is not known whether TRELEGY ELLIPTA can pass into breast milk.

Other warnings you should know about:

TRELEGY ELLIPTA is not approved for the treatment of asthma. When LABA medicines are used alone without an ICS, they increase the risk of hospitalization and death from asthma problems. TRELEGY ELLIPTA contains both an ICS and LABA. Studies showed that when an ICS and LABA are used together, there is not a significantly increased risk in hospitalizations and death from asthma problems.

TRELEGY ELLIPTA does not relieve sudden symptoms. Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare professional to have one prescribed for you.

If you no longer take an oral corticosteroid you should carry a warning card indicating that you may need supplementary corticosteroid treatment during periods of stress or a COPD flare-up.

When using medicines like TRELEGY ELLIPTA for long-term treatment, you may be at risk of:

- Breaking a bone (bone fractures);
- Weak bones (osteoporosis; increased risk of broken bones).

Take extra care to avoid any injury, especially falls. Your healthcare professional may test your bone mineral density (BMD) before you start taking TRELEGY ELLIPTA and periodically during treatment.

You should avoid coming into contact with people who have measles or chicken pox while taking TRELEGY ELLIPTA. If you are exposed, tell your healthcare professional right away.

Medicines like TRELEGY ELLIPTA can cause eye problems:

- Cataracts: clouding of the lens in the eye, blurry vision, eye pain;
- Glaucoma: an increased pressure in your eyes, eye pain, halos around lights or coloured images, red eyes. Untreated, it may lead to permanent vision loss;
- Central serous chorioretinopathy (CSCR): blurry vision or other changes in vision.

Contact your healthcare professional right away if you experience any eye or vision problems. You should have regular eye exams.

COPD flare-up:

If you notice any of the following symptoms, tell your healthcare professional immediately. They could be warning signs that you are having a COPD flare-up or your condition is worsening.

- Unusual increase in the severity of breathlessness, cough, wheezing, or fatigue.
- Unusual colour, amount or thickness of mucus.
- Tightness in the chest or symptoms of a cold.
- You need to use your rescue medication more often than usual.
- Your rescue medication does not work as well to relieve your symptoms.

Pneumonia:

Patients with COPD have a higher chance of getting pneumonia (a lung infection). Medicines like TRELEGY ELLIPTA may also increase your chance of getting pneumonia. You have an

even higher chance if you smoke, have had pneumonia before or are underweight. Symptoms of pneumonia and COPD flare ups frequently overlap. It is therefore important that you tell your healthcare professional immediately if you think you have an infection as even mild chest infections should be treated immediately. Your healthcare professional may also recommend that you receive a flu shot each year.

Driving and Using Machines:

TRELEGY ELLIPTA can cause headaches and blurred vision which may affect your ability to drive and use machines. Use caution when driving and using machines until you know how TRELEGY ELLIPTA affects you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TRELEGY ELLIPTA:

- Other medications that contain a long-acting beta₂-adrenergic agonist (LABA) (e.g., salmeterol, formoterol fumarate, indacaterol, olodaterol), or a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, glycopyrronium, aclidinium, umeclidinium). Ask your healthcare professional if any of your other medicines are LABA or LAMA containing medicines.
- Ketoconazole, itraconazole and voriconazole used to treat fungal infections;
- Medicines used to treat HIV/AIDS (i.e. ritonavir, indinavir, lopinavir, nelfinavir, saquinavir, atazanavir, cobicistat-containing products);
- Clarithromycin used to treat bacterial infections;
- Beta-blockers used to lower blood pressure (e.g., propranolol) or for other heart or eye problems (e.g., timolol);
- Medicines that decrease the level of potassium in your blood (i.e., diuretics). These are also known as “water pills” and are used to lower blood pressure;
- Medicines used in the treatment of depression (i.e., antidepressants, monoamine oxidase inhibitors).

How to take TRELEGY ELLIPTA:

- Take TRELEGY ELLIPTA exactly as recommended by your healthcare professional.
- TRELEGY ELLIPTA should be taken once a day, at about the same time each day.
- Rinse your mouth with water after taking TRELEGY ELLIPTA. Do not swallow the water after rinsing.
- It is important that you continue to take TRELEGY ELLIPTA regularly even if you feel fine and do not have any symptoms.
- Do not stop taking TRELEGY ELLIPTA without speaking to your healthcare professional.
- Do not take TRELEGY ELLIPTA more than once every 24 hours.

If you have any difficulties or you are unsure about how or when to take TRELEGY ELLIPTA check with your healthcare professional.

Usual adult dose:

One inhalation through the mouth once daily.

Overdose:

If you think you have taken too much TRELEGY ELLIPTA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you accidentally take a larger dose of TRELEGY ELLIPTA (i.e., more drug than recommended by your healthcare professional), you may feel shaky, have a headache, dry mouth, blurred vision, or feel like your heart is beating faster than usual. Talk to your healthcare professional right away if this occurs.

If you have taken larger doses than instructed for a long period of time, talk to your healthcare professional.

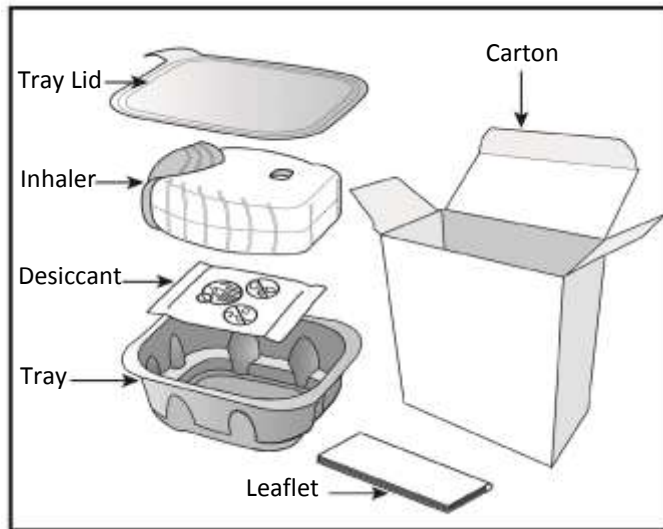
Missed Dose:

If you miss a dose, carry on and take your next dose at the usual time the next day. Do not take an extra dose to make up for the missed one.

About your TRELEGY ELLIPTA Inhaler:

The ELLIPTA inhaler is the device used to deliver your medication.

Your ELLIPTA inhaler carton contains:



The plastic ELLIPTA inhaler is packaged in a tray, with a peelable foil lid. **Do not remove the foil lid until you are ready to use the inhaler.** Peel back the lid to open the tray.

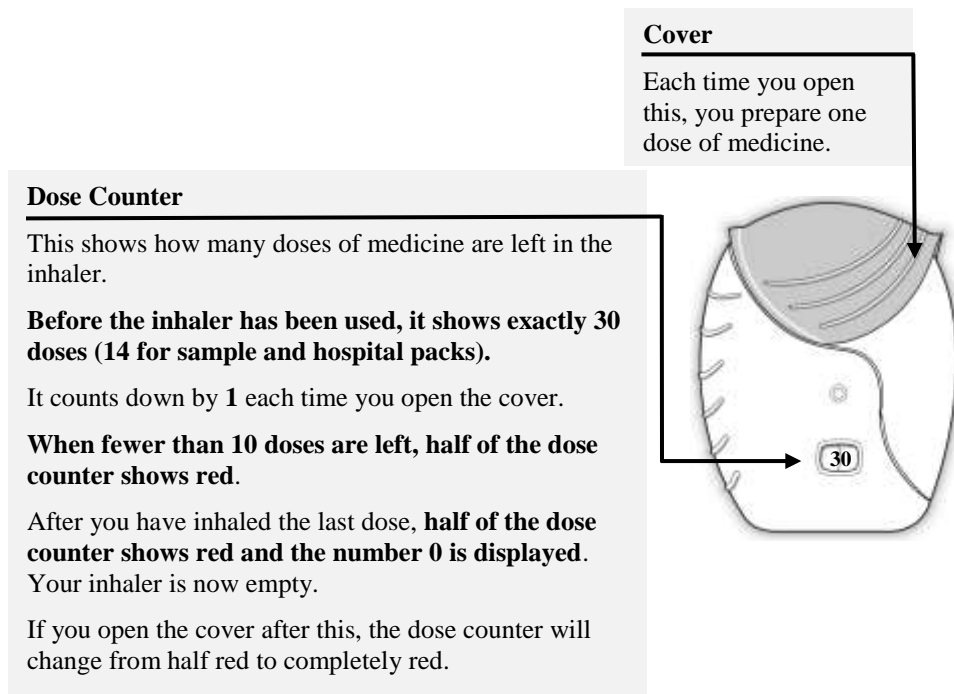


In the tray, you will find a small desiccant sachet containing a drying agent. The desiccant sachet helps to prevent moisture from forming inside the tray. **Keep it away from children and pets.** Do **not** open, eat or inhale the desiccant sachet. **Throw it away in the household trash** once you have opened the lid of the tray. It is dangerous to eat or inhale the contents of the desiccant sachet.



When you take your ELLIPTA inhaler out of its tray it will be in the closed position. Write the “Discard by” date on the inhaler label in the space provided. The “Discard by” date is 6 weeks from the date you open the tray.

The plastic ELLIPTA inhaler has a light grey body, a beige mouthpiece cover, and a dose counter. The mouthpiece and the air vent are hidden by the cover and can only be seen when the cover is opened. The ELLIPTA inhaler is ready-to-use. You will not need to prime it before using it for the first time.



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

Never try to alter the numbers on the counter or detach the counter on the front of the ELLIPTA inhaler. The counter cannot be reset and is permanently attached to the inhaler.

How to use TRELEGY ELLIPTA:

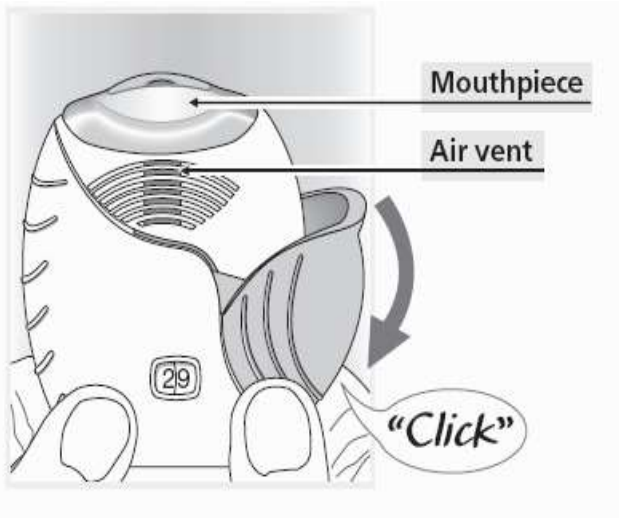
Please follow the instructions ‘**OPEN, INHALE, and CLOSE**’ to use your ELLIPTA inhaler. The instructions shown below apply to the 30-dose and 14-dose ELLIPTA inhaler.

Keep the cover closed until you are ready to inhale a dose. Do not shake the ELLIPTA inhaler at any point during use as this is not necessary.

Sit down or stand in a comfortable position.

OPEN:

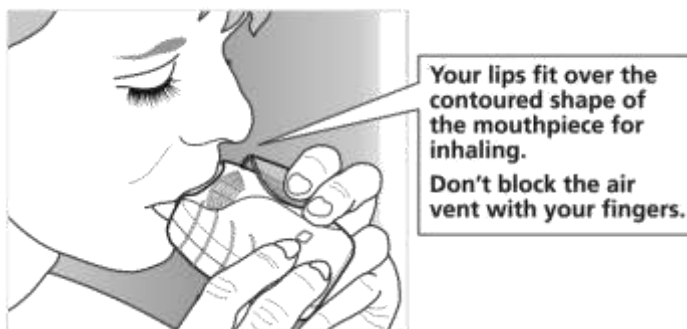
1. When you are ready, activate the inhaler by sliding the beige cover down until you hear a 'click' to prepare a dose.
2. The dose counter will now count down by one number ("1"). *It is unlikely the dose counter will not count down as you hear the 'click'. If this happens, it may mean the inhaler did not load the medicine. Bring it back to your pharmacist for advice.*
3. While holding the inhaler away from your mouth, exhale a complete breath (i.e., breathe out as far as is comfortable). *Don't breathe out into the inhaler.*



You are now ready to inhale a dose.

INHALE:

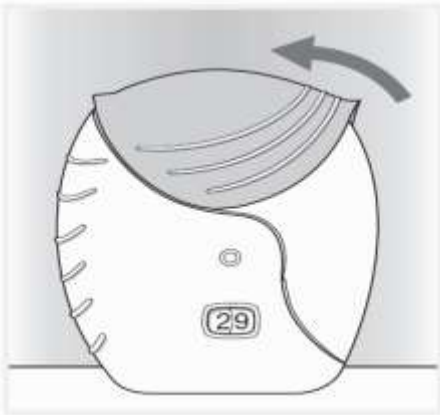
1. Put the mouthpiece between your lips, and close your lips firmly around it. *Don't block the air vent with your fingers.*



2. Take one long, steady, deep breath in. Hold this breath for as long as possible (minimum 3-4 seconds).

CLOSE:

1. Remove the inhaler from your mouth. Exhale slowly and gently. Continue to breathe normally.
2. You can clean the mouthpiece of the inhaler with a clean dry tissue after you have inhaled the medicine.
3. Close the inhaler by sliding the cover upwards as far as it will go to cover the mouthpiece.



You may not be able to taste or feel the medicine (this is normal), even when you are using the inhaler correctly.

4. Rinse your mouth with water. **Do not** swallow.



What are possible side effects from using TRELEGY ELLIPTA?

These are not all the possible side effects you may feel when taking TRELEGY ELLIPTA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- infection of the nose, sinuses or throat
- inflammation of the sinuses
- inflammation of the lungs (bronchitis)
- infection of the upper airways
- itchy, runny or blocked nose
- flu (influenza)
- common cold

- headache
- cough
- painful and frequent urination (may be signs of a urinary tract infection)
- joint pain
- back pain
- sore, raised patches in the mouth or throat caused by a fungal infection (*candidiasis*).
Rinsing your mouth out with water immediately after using TRELEGY ELLIPTA may help stop this side effect developing
- pain in the back of the mouth and throat
- constipation
- dry mouth
- hoarseness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Pneumonia (an infection of the lungs): Fever or chills, increase in mucus production, change in mucus colour, increased cough or an increase in breathing difficulties.		✓	
Thrush (yeast infection): white patches in the mouth and/or tongue, sore throat		✓	
UNCOMMON			
Fast or irregular heartbeat		✓	
Broken bone or weakening of the bones (osteoporosis): In situations where healthy people would not normally break a bone you may have sudden pain in any location and especially in the wrist, spine or hip. This may be a broken bone.		✓	
UNKNOWN			
Sudden breathing difficulties (bronchospasm): Tightness of the chest, coughing, wheezing or breathlessness immediately after using TRELEGY ELLIPTA			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep out of sight and reach of children. Your medicine may harm them.**
- **Keep your inhaler in a cool dry place away from direct heat or sunlight.** Keep it closed when not in use.
- Do not store TRELEGY ELLIPTA above 30°C. If you store in a refrigerator, **allow the inhaler to return to room temperature for at least an hour** before use.
- Store in the original package container in order to protect from moisture and do not open the foil lid until ready for first use.
- Once the tray is opened:
 - **You can use the inhaler for up to 6 weeks, starting from the date you opened the lid of the tray.**
 - Write the date the inhaler should be discarded on the inhaler in the space provided.
- Safely discard TRELEGY ELLIPTA when the dose counter reads “0” or 6 weeks after you open the lid of the tray, whichever comes first.

If you want more information about TRELEGY ELLIPTA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the latest available Patient Medication Information by visiting the Health Canada website www.canada.ca/en/health-canada.html; the manufacturer’s website www.gsk.ca or by calling 1-800-387-7374.

This leaflet was prepared by GlaxoSmithKline Inc.

Last Revised March 19, 2019

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TRELEGY ELLIPTA was developed in collaboration with Innoviva Inc.