COPD AND TRELEGY ELLIPTA



fluticasone furoate/umeclidinium/vilanterol

TRELEGY ELLIPTA fluticasone furoate/umeclidinium/vilanterol

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You can take an active role in treating your COPD. Explore this booklet to learn more about TRELEGY ELLIPTA and how it can treat your COPD.

About Chronic Obstructive Pulmonary Disease (COPD)

COPD is a lung disease that includes chronic bronchitis and emphysema. In COPD, the lungs become blocked, which leads to breathing difficulties.

- In chronic bronchitis, the airways are swollen and may be congested with mucus
- In emphysema, the air sacs in the lungs are damaged

COPD flare-ups (exacerbations)

If your COPD symptoms get worse, or new symptoms develop, this is called a *flare-up*, or an exacerbation.

If you think you are experiencing a flare-up, <u>tell your healthcare professional immediately</u>.

What is TRELEGY ELLIPTA?

Your healthcare professional has chosen TRELEGY ELLIPTA to treat your COPD. TRELEGY ELLIPTA is used in adults for the long-term treatment of COPD. It is used in patients who are not adequately treated by other combination medications (ICS/LABA or LAMA/LABA).

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

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

TRELEGY ELLIPTA should not be used to treat sudden severe symptoms of COPD, such as sudden shortness of breath or wheezing. **TRELEGY ELLIPTA should not be used to give fast relief from COPD as it is not a rescue inhaler.** Keep a rescue inhaler with you at all times and use it during a sudden COPD flare-up.

It's important that you continue to take TRELEGY ELLIPTA as prescribed even if you feel fine and do not have any symptoms.

How does TRELEGY ELLIPTA work?

TRELEGY ELLIPTA contains three active ingredients:

- Fluticasone furoate: an inhaled corticosteroid (ICS)
- **Umeclidinium:** a long-acting muscarinic antagonist (LAMA)
- **Vilanterol:** a long-acting beta₂-adrenergic agonist (LABA)

Fluticasone furoate (ICS)

TRELEGY ELLIPTA contains an ICS. An ICS reduces inflammation in the airways of your lungs, which can ease breathing problems and help prevent flare-ups.

Umeclidinium (LAMA) and vilanterol (LABA)

TRELEGY ELLIPTA also contains umeclidinium and vilanterol. These two medicines work together to help open the airways and make it easier for air to get in and out of the lungs.

THE INHALED
CORTICOSTEROIDS
USED FOR MANAGING
COPD ARE NOT THE
SAME AS PERFORMANCEENHANCING (ANABOLIC)
STEROIDS.

(For more information, see Question 6 on page 8 of this brochure.)

TRELEGY ELLIPTA should not be used to treat sudden severe symptoms of COPD such as shortness of breath or wheezing, or to treat asthma, or if you are allergic to fluticasone furoate, umeclidinium, vilanterol, or any of the non-medicinal ingredients contained in the product. TRELEGY ELLIPTA should also not be used if you have a lactose or severe milk protein allergy, or if you are under 18 years of age.



Before taking TRELEGY ELLIPTA

When you first receive TRELEGY ELLIPTA, the ELLIPTA inhaler will be in the "closed" position. It is ready to use and you do not need to prime it before using it for the first time.

Do not shake the ELLIPTA inhaler.

Only open the ELLIPTA inhaler when you are ready to take a dose. If you open and close the cover without inhaling the medicine, you will lose the dose.

Mouthpiece

Air vent

Cover

Dose counter

Dose counter

30 Doses

How do I use TRELEGY ELLIPTA?



1. OPEN

- Activate the ELLIPTA inhaler by sliding the cover to the side and down until you hear a "click" to prepare a dose.
- Hold the ELLIPTA inhaler away from you and exhale a complete breath. Don't breathe out into the inhaler.



2. INHALE

- Put the mouthpiece between your lips and close your lips firmly around it.
- Do not block the air vent with your fingers.
- Take one long, steady, deep breath and hold for as long as possible (at least 3-4 seconds).



3. CLOSE

- Remove the inhaler from your mouth. Exhale slowly and gently.
- Clean the mouthpiece of the inhaler with a clean, dry tissue.
- Slide the cover upwards as far as it will go.

About your TRELEGY ELLIPTA inhaler

TRELEGY ELLIPTA is packaged in a tray with a peelable foil lid. Don't open the foil lid until you are ready to use the inhaler. In the tray is a sachet that contains a drying agent to help prevent moisture from forming inside the packaging. Once opened, throw the sachet away in the household trash.



Rinse your mouth with water after use. Do not swallow the water.

For complete instructions, see the Patient Information leaflet that comes with your TRELEGY ELLIPTA.

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Questions and answers about TRELEGY ELLIPTA

The more you know about COPD and TRELEGY ELLIPTA, the better you can understand your symptoms and how to use TRELEGY ELLIPTA.

Your doctor knows your medical history best. Talk to your doctor if you have questions about your condition. Ask for personalized advice that can help you treat your COPD.

1. Should I save taking TRELEGY ELLIPTA for when my COPD symptoms get really serious?

No, do not save TRELEGY ELLIPTA for when your COPD symptoms get really serious. TRELEGY ELLIPTA is prescribed for adults for the long-term treatment of COPD. There is no cure for COPD, but TRELEGY ELLIPTA helps to control it. It is therefore important to keep taking your TRELEGY ELLIPTA once daily every day. Do not stop taking TRELEGY ELLIPTA without speaking to your healthcare professional. If your COPD becomes out of control, talk to your healthcare professional.

2. Can I use my TRELEGY ELLIPTA to provide quick relief when I feel breathless?

TRELEGY ELLIPTA should not be used to treat sudden severe symptoms of COPD, such as sudden shortness of breath or wheezing. TRELEGY ELLIPTA should not be used to give fast relief from COPD as it is not a rescue inhaler. Keep a rescue inhaler with you at all times and use it during a sudden COPD flare-up.

3. Does TRELEGY ELLIPTA treat other respiratory infections, such as chest infections?

No. TRELEGY ELLIPTA is used in adults for the long-term treatment of COPD. TRELEGY ELLIPTA is not an antibiotic and it does not treat chest infections.

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. If you think you have a chest infection, you should tell your healthcare professional immediately. It is very important that even mild chest infections are treated right away.

You should also avoid close contact with people who have colds or the flu. Talk to your healthcare professional about getting the flu vaccine. Proper hand washing can help prevent you from getting sick, and it also reduces the risk of infecting others.

4. Can I stop taking TRELEGY ELLIPTA if I'm feeling better?

No, it is important that you continue to take TRELEGY ELLIPTA regularly even if you feel fine and do not have any symptoms.

COPD affects different people in different ways. Your symptoms may vary over time. Talk to your healthcare professional if your COPD worsens.

5. Can I become addicted to TRELEGY ELLIPTA?

No, you cannot become addicted to TRELEGY ELLIPTA.

It's a myth that the longer you take your medications, the more medication you'll eventually need.

COPD is a chronic lung disease. People with COPD have blocked lungs, which leads to breathing difficulties. COPD can't be cured, but it can be treated.

If your COPD gets worse, talk to your healthcare professional.

6. Is the steroid used in TRELEGY ELLIPTA the same as a performance-enhancing (anabolic) steroid?

Absolutely not.

The ICSs used for controlling COPD are not the same as performance-enhancing (anabolic) steroids.

ICSs are inhaled directly into your lungs and help reduce inflammation in the airways of your lungs.

Helpful COPD resources

COPD education, support, and resources are widely available to help you when you need them.

The Lung Association www.lung.ca

Living Well with COPD www.livingwellwithcopd.com

COPD Canada www.copdcanada.info

Side effects

Medications affect different people in different ways. If you experience any side effects that bother you, please contact your healthcare professional. Side effects may include:

- Infection of the nose, sinuses, or throat; inflammation of the sinuses or of the lungs (bronchitis); headache; back pain; joint pain
- Infection of the upper airways; itchy, runny, or blocked nose; influenza; cough; the common cold
- Painful and frequent urination (may be signs of a urinary tract infection); constipation
- Pain in the mouth, throat, or tongue after taking this medication; dry mouth; hoarseness
- A yeast infection of the mouth or throat called candidiasis (thrush). Rinsing your mouth and gargling with water immediately after taking each dose may help. Do not swallow the water after rinsing and gargling. Talk to your healthcare professional in all cases.
- A fast or irregular heartbeat, broken bones, or weakening of the bones. These side effects are uncommon, but if you experience any of them, talk to your healthcare professional.

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.

This is not a complete list of side effects. Please refer to the Consumer Information leaflet provided with your medication for complete TRELEGY ELLIPTA Safety Information.



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 likely to experience "flare-ups" during which their symptoms become worse. If you have a history of flare-ups, TRELEGY ELLIPTA can help reduce the symptoms you feel when this happens.

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. Do not use TRELEGY ELLIPTA: 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.

Before you use TRELEGY ELLIPTA, talk to your healthcare professional 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).

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) and weak bones (osteoporosis and 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 such as 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, this may lead to permanent vision loss), and 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.

If you notice any of the following symptoms, <u>tell your healthcare professional immediately</u>. 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

Drugs that may interact with TRELEGY ELLIPTA include other medications that contain a LABA (e.g., salmeterol, formoterol fumarate, indacaterol, olodaterol), or a LAMA (e.g., tiotropium, glycopyrronium, aclidinium, umeclidinium). Ask your healthcare professional if any of your other medicines are LABA- or LAMA-containing medicines. The following may also interact with TRELEGY ELLIPTA: 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), also known as "water pills", which are used to lower blood pressure; medicines used in the treatment of depression (i.e., antidepressants, monoamine oxidase inhibitors).

Make sure that your healthcare professional knows what other medicines you are taking, including those you can buy without a prescription as well as herbal and alternative medicines.

Some people find that their mouth, throat, or tongue becomes sore after taking TRELEGY ELLIPTA. In some people, a yeast infection of the mouth or throat called *candidiasis* (thrush) may occur.

If you experience the following serious side effects, talk to your healthcare professional: fast or irregular heartbeat; broken bones or weakening of the bones (osteoporosis).

If you experience the following serious side effect, stop taking TRELEGY ELLIPTA and seek immediate emergency medical attention: sudden breathing difficulties (tightness of the chest, coughing, wheezing, or breathlessness) immediately after using TRELEGY ELLIPTA.

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