Patient Information Leaflet

SCHEDULING STATUS: S4

TRELEGY Ellipta

Powder for Inhalation

Fluticasone furoate 100 µg, umeclidinium 62,5 µg and vilanterol 25 µg

Contains sugar (lactose monohydrate (which contains milk protein) 25 mg/dose).

Read all of this leaflet carefully before you start using TRELEGY.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare professional.
- TRELEGY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What TRELEGY is and what it is used for
2. What you need to know before you use TRELEGY
3. How to use TRELEGY
4. Possible side effects
5. How to store TRELEGY ELLIPTA
6. Contents of the pack and other information.

1. WHAT TRELEGY IS AND WHAT IT IS USED FOR:

TRELEGY Ellipta is used to treat chronic obstructive pulmonary disease (COPD) in adults. To take TRELEGY, you breathe it into your lungs through your mouth, using the Ellipta inhaler.

Chronic obstructive pulmonary disease (COPD) occurs when the airways become inflamed and thickened, often due to smoking. It is a long-term condition that slowly gets worse. Symptoms include shortness of breath, cough, chest discomfort and coughing up mucus.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TRELEGY:

Do not use TRELEGY:

- if you are hypersensitive (allergic) to fluticasone furoate, umeclidinium, vilanterol or to any of the other ingredients of TRELEGY
- if you are allergic (hypersensitive) to lactose or milk protein.

If you think either of these applies to you, **don't use TRELEGY** until you have checked with your doctor.

Warnings and precautions:

Special care should be taken with TRELEGY:

Before you use TRELEGY your doctor needs to know:

- if you have asthma
- if you have heart problems or high blood pressure
- if you have an overactive thyroid
- if you have low blood potassium levels, as treatment with TRELEGY can make this condition worse
- if you have liver disease, as you may be more likely to have side effects
- if you have tuberculosis (TB) of the lung, or any long standing or untreated infections
- if you have an eye problem called narrow-angle glaucoma
- if you have an enlarged prostate, difficulty passing urine or a blockage in your bladder
- if you are diabetic.

Check with your doctor before you use TRELEGY if you think any of these apply to you.

While you are using TRELEGY:

- TRELEGY helps to control your COPD when used regularly. If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse, or if you are using your quick acting inhaler (such as salbutamol) more often, **contact your doctor as soon as possible.**
- **Immediate breathing difficulties**: If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your TRELEGY Ellipta inhaler, **stop using TRELEGY and seek medical help immediately.**
- **Infection of the lung:** Because you are using this medicine for COPD you may be at an increased risk of developing an infection of the lungs known as pneumonia. See POSSIBLE SIDE EFFECTS for information on symptoms to look out for while you are using this medicine. Tell your doctor as soon as possible if you develop any of these symptoms.

Other medicines and TRELEGY:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicine.)

Some medicines may affect how TRELEGY works or make it more likely that you will have side effects. These include:

- medicines called beta-blockers, to treat high blood pressure or other heart problems
- ketoconazole, to treat fungal infections
- ritonavir, to treat HIV
- other long-acting medicines similar to this medicine that are used to treat breathing problems.

Tell your doctor or pharmacist if you are taking any of these medicines.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you start using TRELEGY.

Pregnancy: You should not use TRELEGY when pregnant.

Breastfeeding: You should not use TRELEGY when breastfeeding your baby.

Driving and using machines:

It is unlikely that TRELEGY will affect your ability to drive or use machines. However, do not drive or use machinery if you do not feel well.

TRELEGY contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not use TRELEGY.

3. HOW TO USE TRELEGY:

Do not share medicines prescribed for you with any other person.

Always use TRELEGY exactly as your doctor has told you to. Check with your doctor, nurse or pharmacist if you're not sure.

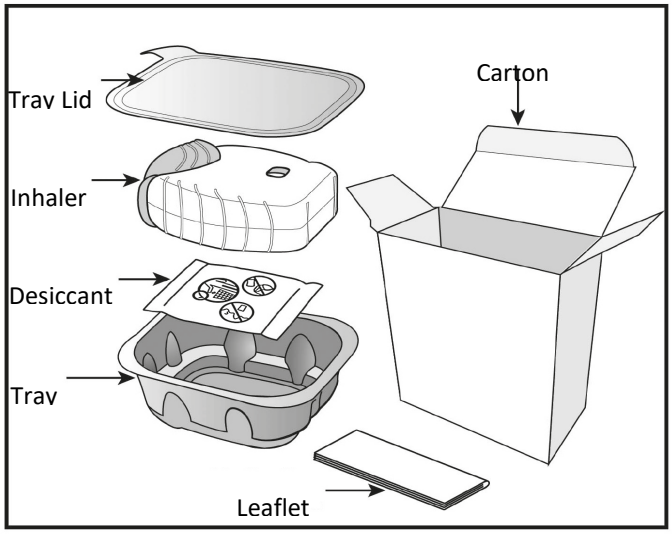
The usual dose of TRELEGY is one inhalation once daily at the same time each day. The dose should not exceed one inhalation per day. **Don't use more than your doctor tells you to use**.

It is very important that you use TRELEGY every day, as instructed by your doctor.

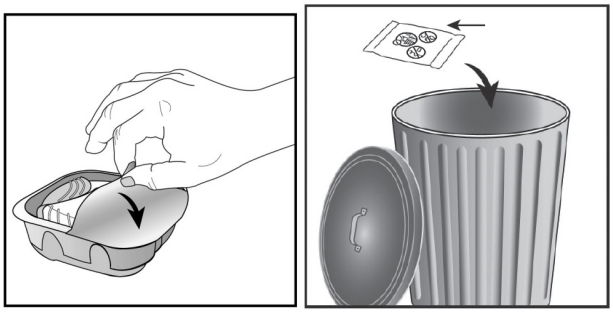
How to use your Inhaler:

When you first use the Ellipta inhaler you do not need to check that it is working properly, and you do not need to prepare it for use in any special way. Just follow the instructions below.

Your Ellipta inhaler carton contains:



The inhaler is packaged in a tray. **Do not open the tray until you are ready to inhale a dose of your medicine.** When you are ready to use your inhaler, peel back the lid to open the tray. The tray contains a desiccant sachet, to reduce moisture. Throw this desiccant sachet away - **don't** open, eat or inhale it.



When you take the inhaler out of the sealed tray, it will be in the 'closed' position. **Don't open the inhaler until you are ready to inhale a dose of medicine.** 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. **After this date, the inhaler should no longer be used.**

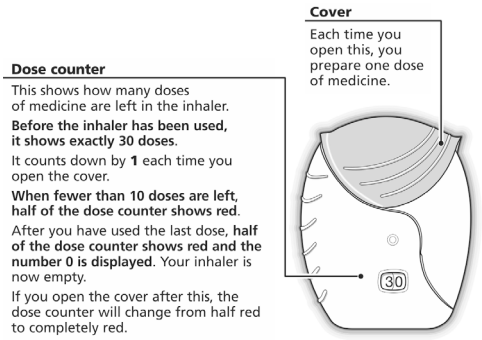
The step-by-step instructions shown below for the 30-dose (30-day supply) Ellipta inhaler also apply to the 14-dose (14-day supply) Ellipta inhaler.

a) 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.

It is not possible to accidentally take extra medicine or a double dose in one inhalation.

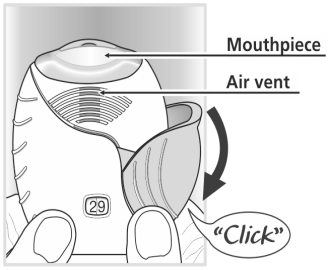


b) Prepare a dose:

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

Do not shake the inhaler.

- Slide the cover fully down until you hear a “click”.



Your medicine is now ready to be inhaled.

The dose counter counts down by 1 to confirm.

- If the dose counter does not count down as you hear the “click”, the inhaler will not deliver medicine. Take it back to your pharmacist for advice.

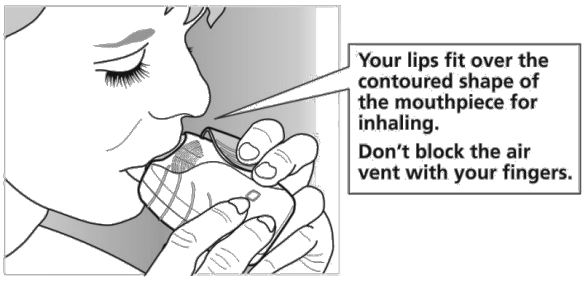
Do not shake the inhaler at any time.

c) Inhale your medication:

While holding the inhaler away from your mouth, breathe out as far as is comfortable. Don’t breathe out into the inhaler.

- Put the mouthpiece between your lips and close your lips firmly around it.

  Don’t block the air vent with your fingers.



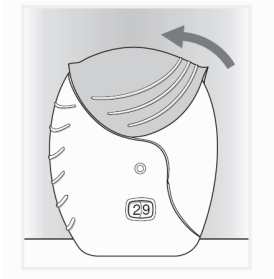
- Take one long, steady, deep breath in. Hold this breath for as long as possible (at least 3-4 seconds).
- Remove the inhaler from your mouth.
- Breathe out slowly and gently.

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

If you want to clean the mouthpiece, use a dry tissue, before you close the cover.

d) Close the inhaler and rinse your mouth:

- Slide the cover upwards as far as it will go, to cover the mouthpiece.



- Rinse your mouth with water after you have used the inhaler, do not swallow.

  This will make it less likely that you will develop a sore mouth or throat as side effects.

If you use more TRELEGY than you should:

If you accidentally take more TRELEGY than you should**, contact your doctor or pharmacist**. If possible, show them the TRELEGY Ellipta inhaler.

If you have used more than instructed for a long period of time, it is particularly important that you ask your doctor or pharmacist for advice. This is because too much TRELEGY may reduce the amount of steroid hormones produced naturally by your body.

If you forget to use TRELEGY:

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you become wheezy or breathless, **use your quick-acting 'reliever' inhaler** (such as salbutamol), then seek medical advice.

Effects when treatment with TRELEGY is stopped:

Use TRELEGY for as long as your doctor recommends. Don't stop unless your doctor advises you to, even if you feel better, as your symptoms may get worse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS:

TRELEGY can have side effects.

Not all side effects reported for TRELEGY are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using TRELEGY, please consult your doctor, pharmacist or other healthcare professional for advice.

Allergic Reactions:

If you have any of the following symptoms after taking TRELEGY Ellipta, stop using this medicine and tell your doctor immediately:

- skin rash or redness, hives (urticaria)

- swelling, sometimes of the face or mouth (angioedema)
- wheezing, coughing or having difficulty in breathing suddenly feeling weak or light-headed (may lead to collapse or loss of consciousness).

These are all very serious side effects. If you have them, you may have had a serious reaction to TRELEGY Ellipta. You may need urgent medical attention or hospitalisation.

Immediate breathing difficulties:

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using TRELEGY, **stop using it immediately,** and **tell your doctor** as soon as possible.

Infection of the lungs:

Infection of the lungs (pneumonia) after using TRELEGY is common.

Tell your doctor if you have any of the following while taking TRELEGY – these could be symptoms of a lung infection:

- fever or chills
- increased sputum production, change in sputum colour
- increased cough or increased breathing difficulties.

Frequent side effects include:

- sore, raised patches in the mouth or throat caused by a fungal infection (*candidiasis*). Rinsing your mouth out with water immediately after using TRELEGY may help stop this side effect developing
- infection of the nose, sinuses or throat
- itchy, runny or blocked nose
- pain in the back of the mouth and throat
- inflammation of the sinuses

- inflammation of the lungs (*bronchitis*)
- infection of the upper airways
- infection of the lungs *(pneumonia)*
- flu (*influenza*)
- common cold
- headache
- cough
- painful and frequent urination (may be signs of a urinary tract infection)
- joint pain
- back pain
- constipation.

Less frequent side effects:

- irregular heartbeat
- faster heartbeat
- dry mouth
- hoarseness
- weakening of the bones, leading to fractures
- taste disturbance
- blurred vision
- increased eye pressure
- eye pain.

Other side effects:

- allergic reactions (see earlier in Section 4)
- difficulties passing urine (urinary retention)

- pain or discomfort passing urine (*dysuria*).

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **'6.04 Adverse Drug Reaction Reporting Form,'** found on-line under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TRELEGY ELLIPTA.

5. HOW TO STORE TRELEGY:

Store at or below 30 °C.

Store in the original package in order to protect from moisture and do not open the foil lid until ready for first use.

Following removal from the tray, the product may be stored for a maximum period of 6 weeks when stored at or below 30 °C. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

Do not use the inhaler after the expiry date shown on the pack.

If stored in the refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TRELEGY contains:

The active substances are fluticasone furoate, umeclidinium and vilanterol.

Each pre-dispensed dose contains 100 µg fluticasone furoate, 62,5 µg umeclidinium (equivalent to 74,2 µg umeclidinium bromide) and 25 µg vilanterol (as trifenatate). Each delivered dose (the dose leaving the mouthpiece of the inhaler) contains 92 µg fluticasone furoate, 55 µg umeclidinium (equivalent to 65 µg umeclidinium bromide) and 22 µg vilanterol (as trifenatate).

Contains sugar (lactose monohydrate 25 mg/dose, which also contains milk protein).

The other ingredient is magnesium stearate.

What TRELEGY looks like and contents of the pack:

The Ellipta inhaler contains two foil blister strips of 14 or 30 regularly distributed blisters, each containing a white powder. The Ellipta device itself is a plastic inhaler with a light grey body, a beige mouthpiece cover and a dose counter.

The plastic Ellipta inhaler consists of a light grey body, a beige mouthpiece cover and a dose counter, packed into a foil laminate tray containing a desiccant sachet. The tray is sealed with a peelable foil lid. Each Ellipta inhaler is packed into a carton. The Ellipta inhaler is available in two pack sizes, delivering either 14 or 30 inhalations.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

This leaflet was last reviewed:

11 April 2024

Registration number:

TRELEGY Ellipta: 52/21.5.1/0177

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