

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

Trelegy Ellipta 92/55/22 mcg,

powder for inhalation

Each dose released from the Ellipta inhaler contains:

92 mcg fluticasone furoate/55 mcg umeclidinium (equivalent to 65 mcg umeclidinium bromide)/22 mcg vilanterol (as trifenate).

Trelegy Ellipta 184/55/22 mcg,

powder for inhalation

Each dose released from the Ellipta inhaler contains:

184 mcg fluticasone furoate/55 mcg umeclidinium (equivalent to 65 mcg umeclidinium bromide)/22 mcg vilanterol (as trifenate).

For a list of the inactive and allergenic ingredients, see section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Asthma

Trelegy Ellipta 92/55/22 mcg and Trelegy Ellipta 184/55/22 mcg are intended for the maintenance treatment of asthma in patients aged 18 years and older, who are not adequately controlled on maintenance asthma medication, such as a combination treatment with an inhaled corticosteroid and a long-acting beta agonist bronchodilator.

Trelegy Ellipta 92/55/22 mcg and Trelegy Ellipta 184/55/22 mcg are not intended for the relief of acute asthma.

Chronic obstructive pulmonary disease (COPD)

Trelegy Ellipta 92/55/22 mcg is intended for a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD), who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta agonist bronchodilator or combination treatment with a long-acting beta agonist bronchodilator and a long-acting muscarinic antagonist bronchodilator.

Trelegy Ellipta 184/55/22 mcg is not intended for patients with chronic obstructive pulmonary disease (COPD).

Therapeutic group:

Trelegy Ellipta contains three active ingredients: fluticasone furoate, umeclidinium bromide and vilanterol trifenate.

The active ingredient fluticasone furoate is a corticosteroid.

The other active ingredients belong to a group of medicines called bronchodilators:

- Umeclidinium bromide: anticholinergic.
- Vilanterol trifenate: beta-2 receptor agonist.

Asthma is a condition in which the muscles surrounding the smaller airways become tight (bronchoconstriction), swollen and irritated (inflammation). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

COPD is a long-term condition characterised by breathing difficulties that slowly get worse.

In COPD, the muscles around the airways tighten, making breathing difficult. This medicine relaxes these muscles in the lungs, reduces the swelling and irritation in the small air passages and makes it easier for air to get in and out of the lungs. When used regularly, it can help control your breathing difficulties and reduce the effects of COPD on your everyday life.

Trelegy Ellipta should be used every day and not only when you have breathing problems or other symptoms of COPD. It should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you must use a quick-acting inhaler. If you do not have a quick-acting inhaler, contact the physician.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are **sensitive (allergic)** to fluticasone furoate, umeclidinium, vilanterol or to any of the additional ingredients contained in this medicine (as listed in section 6).

Special warnings regarding use of the medicine

Before the treatment with Trelegy Ellipta, tell the physician if:

- You have **heart problems** or **high blood pressure**.
- You have **liver disease**, as you may be more likely to have side effects. If you have moderate or severe liver disease, the physician will limit your dose to the low strength of Trelegy Ellipta (92/55/22 micrograms once daily).
- You have **tuberculosis (TB) of the lung**, or **any long-standing or untreated infections**.
- You have an eye problem called **narrow-angle glaucoma**.
- You have an **enlarged prostate**, **difficulty passing urine** or a **blocking in**

your bladder.

- You suffer from **epilepsy**.
 - You have **thyroid gland problems**.
 - You have **low potassium levels** in your blood.
 - You have a history of **diabetes**.
 - You experience blurred vision or other **visual disturbances**.
- **Check with the physician** if you think any of these apply to you.

Breathing difficulties immediately after using Trelegy Ellipta

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your Trelegy Ellipta inhaler:

- **Stop using this medicine and seek medical help immediately**, as you may have a serious condition called paradoxical bronchospasm.

Eye problems during treatment with Trelegy Ellipta

If you get eye pain or discomfort, temporary blurring of vision, see halos or coloured images as well as red eyes during treatment with Trelegy Ellipta:

- **Stop using this medicine and seek medical help immediately**. These may be signs of an acute attack of narrow-angle glaucoma.

Infection of the lung

If 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 section 4 – “Side effects” for information on symptoms to look out for while you are using this medicine.

- **Tell the physician as soon as possible if you develop any of these symptoms.**

Children and adolescents

This medicine is not intended **for children or adolescents below the age of 18 years**.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. If you are not sure what your medicine contains, talk to the physician or pharmacist.

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

- Beta blockers, such as propranolol, used to treat **high blood pressure** or other **heart problems**.
- Ketoconazole or itraconazole, to treat **fungal infections**.
- Clarithromycin or telithromycin, to treat **bacterial infections**.
- Ritonavir or cobicistat, to treat **HIV infections**.
- Medicines that **lower the level of potassium** in your blood, such as some diuretics or some medicines used to treat chronic obstructive pulmonary

- disease (COPD) and asthma (such as methylxanthine or steroids).
- Other long-acting medicines similar to this medicine that are used to treat **breathing difficulties**, e.g., tiotropium, indacaterol. Do not use Trelegy Ellipta if you already use these medicines.
- **Tell the physician or pharmacist** if you are taking any of these.
- The physician may wish to monitor your condition carefully if you are taking one or more of these medicines as they may increase the side effects of Trelegy Ellipta.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the physician for advice before using this medicine. Do not use this medicine if you are pregnant, unless the physician instructed you to do so.

It is not known whether the ingredients of this medicine can pass into breast milk. If you are breast-feeding, consult with the physician before using Trelegy Ellipta. Do not use this medicine if you are breast-feeding unless the physician instructed you to do so.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or use machines.

Important information about some of the ingredients in the medicine

Trelegy Ellipta contains lactose

If you have been told by the physician that you have an intolerance to some sugars, contact the physician before using this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.

Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Asthma

The recommended dosage for asthma is one inhalation of Trelegy Ellipta 92/55/22 mcg once daily or one inhalation of Trelegy Ellipta 184/55/22 mcg once daily, at the same time each day.

The physician will decide which strength of Trelegy Ellipta is required to treat your asthma.

Chronic obstructive pulmonary disease (COPD)

The recommended dosage for chronic obstructive pulmonary disease (COPD) is one inhalation of Trelegy Ellipta 92/55/22 mcg, once a day, at the same time every day. You only need to inhale the medicine once a day because its effect lasts for 24 hours.

Do not exceed the recommended dose.

Use Trelegy Ellipta regularly

It is very important that you use this medicine every day, as instructed by the physician. This will help to keep you free of symptoms throughout the day and night.

Trelegy Ellipta should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you must use a quick-acting reliever inhaler (such as salbutamol).

How to use the Trelegy Ellipta inhaler

See “Step-by-step instructions” after section 6 in this leaflet for full information.

Trelegy Ellipta is intended for inhalation use.

Once the tray is opened, Trelegy Ellipta is ready for use.

If your symptoms do not improve

If your symptoms (breathlessness, wheezing, cough) do not improve or get worse, or if you are using a quick-acting inhaler more often:

→ **Contact the physician as soon as possible.**

If you accidentally inhaled a higher dosage

If you inhaled an overdose or if a child accidentally inhaled the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If possible, show them the inhaler, the package or this leaflet. You may notice that your heart is beating faster than usual, you feel shaky, you have visual disturbances, a dry mouth, or a headache.

If you forgot to use Trelegy Ellipta

If you forgot to inhale the medicine at the required time, do not inhale a double dose to make up for a forgotten dose. Inhale the next dose at the usual time and consult a physician. If you start suffering from wheezing or breathing difficulties, use your quick-acting inhaler (such as salbutamol), then seek medical advice.

If you stop using Trelegy Ellipta

Adhere to the treatment regimen recommended by the physician. Even if your health condition improves, do not stop treatment with the medicine without consulting the physician, as your symptoms may get worse.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Trelegy Ellipta may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Allergic reactions

Allergic reactions to Trelegy Ellipta are rare (they may affect up to 1 in 1,000 people).

If you have any of the following symptoms after using Trelegy Ellipta, **stop using it and tell the physician** immediately:

- Skin rash or redness, hives (*urticaria – itchy lumps*)
- Swelling, sometimes of the face or the mouth (*angioedema*)
- Wheezing, coughing or having breathing difficulties
- Suddenly feeling weak or dizzy (may lead to collapse or loss of consciousness).

Immediate breathing difficulties after using Trelegy Ellipta

If your breathing or wheezing gets worse straight after using this medicine, **stop using it and get medical help** immediately.

Very common side effects

These may affect **more than 1 in 10** people:

- Common cold

Pneumonia (infection of the lungs) in COPD patients (common side effect)

Tell the physician if you have any of the following while using Trelegy Ellipta – these could be symptoms of a lung infection:

- Fever or chills
- Increased mucus production, change in mucus colour
- Increased cough or increased breathing difficulties.

Other side effects

Common side effects

These may affect **up to 1 in 10** people:

- 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 prevent this side effect.
- Infection of the nose, sinuses or throat
- Infection of the upper airways
- Itchy, runny or blocked nose
- Pain in the back of the mouth and throat
- Inflammation of the sinuses
- Inflammation of the lungs' bronchial tubes (*bronchitis*)
- Flu (*influenza*)
- Headache
- Cough
- Hoarseness
- Painful and frequent urination (may be a sign of a urinary tract infection)
- Joint pain
- Back pain
- Constipation.

Uncommon side effects

These may affect **up to 1 in 100** people:

- Irregular heart beat
- Fast heart beat
- Weakening of the bones, leading to fractures
- Dry mouth
- Taste disturbance
- Blurred vision
- Increased eye pressure
- Eye pain.

Rare side effects

These may affect **up to 1 in 1,000** people:

- Allergic reactions (see beginning of Section 4)
- Difficulties passing urine (urinary retention)
- Pain or discomfort passing urine (dysuria).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.it) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.it/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store the inhaler in the original package in order to protect from moisture and only remove it immediately before first use. Do not open the tray until the start of use. Once the tray is opened, the inhaler can be used for up to 6 weeks, but no later than the expiry date. When taking the inhaler out of the tray, the "Discard by" date should be written on the back label of the inhaler and carton box, in the designated spot.
- If you store the medicine in a refrigerator, allow the inhaler to return to room temperature for at least one hour before use.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These

measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains – Lactose monohydrate, Magnesium stearate.
Also see section 2 in this leaflet – “Important information about some of the ingredients in the medicine”.
- What the medicine looks like and the contents of the package –
Trelegy Ellipta is a powder for inhalation.
The Ellipta inhaler is a light grey plastic inhaler, with a beige-coloured mouthpiece cover and a dose counter. It is packaged in an aluminium tray with a peelable aluminium cover. The tray contains a desiccant sachet, to reduce moisture in the packaging.
The active ingredients are in a white powder form in separate blister strips inside the inhaler.
Each inhaler contains either 14 or 30 doses (14 or 30 day supply).
Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations UK Ltd. (trading as Glaxo Wellcome Operations), Ware, UK.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Trelegy Ellipta 92/55/22 mcg: 160-84-35372
Trelegy Ellipta 184/55/22 mcg: 168-61-36629

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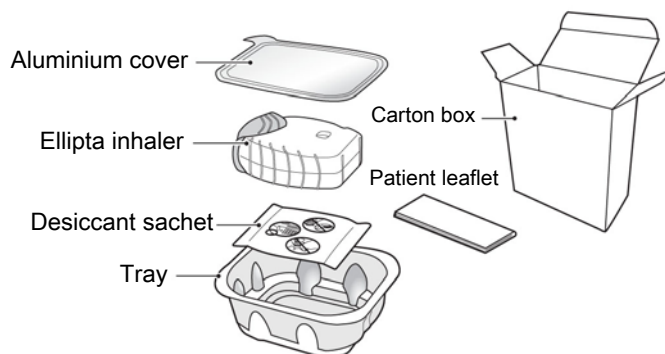
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Step-by-step instructions

What is the Ellipta inhaler?

The first time you use Trelegy Ellipta inhaler, you do not need to check that the inhaler is working properly. It contains previously measured doses and is ready to use straight away.

Your Trelegy 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 medicine.** When you are ready to use the inhaler, peel back the aluminum cover to open the tray.

The tray contains a **desiccant sachet**, to reduce moisture. Throw this sachet away – **do not** open, inhale or eat it.



When you take the inhaler out of the tray, it will be in the ‘closed’ position. **Do not open the inhaler until you are ready to inhale a dose of medicine.** Write the “Discard by” date on the inhaler back label and the carton in the space provided. The “Discard by” date is 6 weeks from the date you first open the tray, but no later than the expiry date. **After this date, the inhaler should no longer be used.** The tray can be discarded after first opening.

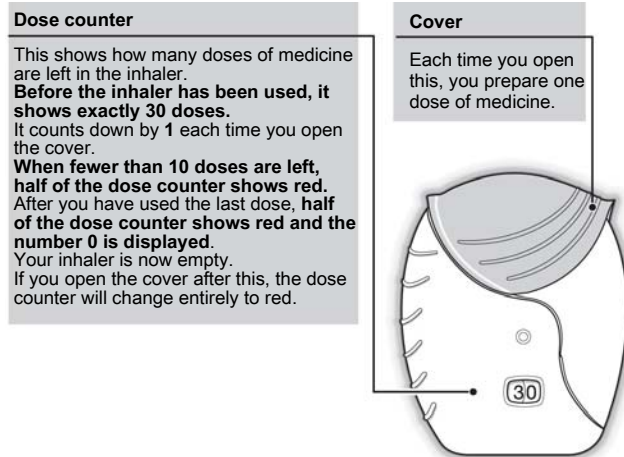
If stored in a refrigerator, allow the inhaler to return to room temperature for at least one hour before use. The instructions for use of the inhaler provided below can be used for either the 30-dose (30 day supply) or the 14-dose (14 day supply) inhaler.

1. Read this information 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.

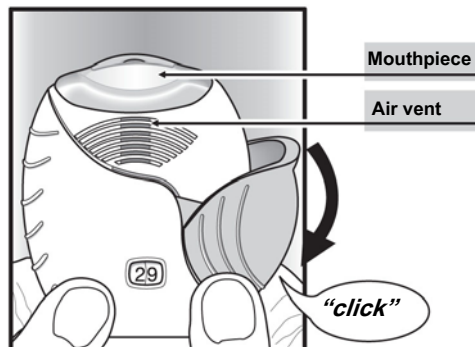


For the 14-dose inhaler, the dose counter will also show half red when there are fewer than 10 doses left, and then will show half red with the number 0 after the last dose is used. If the cover is opened after that, the dose counter will change to completely red.

2. Prepare a dose

Wait to open the cover until you are ready to take your dose. Do not shake the inhaler.

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



Your medicine is now ready to be inhaled.

The dose counter counts down by 1 to confirm that the inhaler is ready for use.

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

3. Inhale your medicine

- ▶ **While holding the inhaler away from your mouth, breathe out as much as you can.**
Do not breathe out into the inhaler.
- ▶ **Put the mouthpiece between your lips, and close your lips firmly around it.**
Do not block the air vent with your fingers.

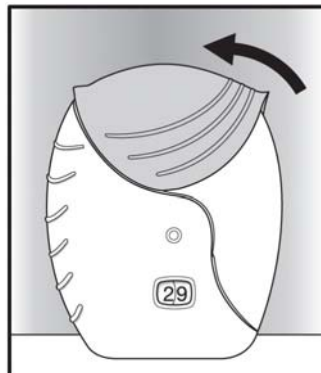


Your lips fit over the contoured shape of the mouthpiece for inhaling. Do not block the air vent with your fingers.

- ▶ **Take one long, steady, deep breath in. Hold this breath in 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.**

4. 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.