

GLOBAL PATIENT LEAFLET

Trelegy 100/62.5/25 micrograms, Ellipta Inhaler

Trelegy 200/62.5/25 micrograms, Ellipta Inhaler

Fluticasone furoate/umeclidinium/vilanterol

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

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1. What Trelegy Ellipta is and what it is used for

Trelegy Ellipta contains three active ingredients; fluticasone furoate, umeclidinium and vilanterol, to treat **asthma** and *chronic obstructive pulmonary disease (COPD)*. To take Trelegy Ellipta, you breathe it into your lungs through your mouth using the Ellipta inhaler.

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 inhaler (such as salbutamol).

Fluticasone furoate belongs to a group of medicines called *corticosteroids*, often simply called *steroids*. Corticosteroids reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

Umeclidinium and vilanterol belong to a group of medicines called *bronchodilators*. They work together to help open the airways and make it easier for air to get in and out of the lungs.

When Trelegy Ellipta is used regularly, it can help to control the breathing difficulties related to your disease, minimise the effects of the disease on your everyday life, and may increase survival.

Asthma is when 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.

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. Before you use Trelegy Ellipta

Don't use Trelegy Ellipta

- if you are **allergic** (*hypersensitive*) to lactose or milk protein.
 - if you are **allergic** (*hypersensitive*) to fluticasone furoate, umeclidinium, vilanterol or any other ingredients of Trelegy Ellipta (*listed in Section 6*).
- ➔ If you think either of these applies to you, **don't use Trelegy Ellipta** until you have checked with your doctor.

Take special care with Trelegy Ellipta

Before you use Trelegy Ellipta your doctor needs to know:

- if you have **asthma**
 - if you have **heart problems** or **high blood pressure**
 - if you have **liver disease**, as you may be more likely to have side effects. If you have moderate or severe liver disease, your doctor will limit your dose to Trelegy Ellipta 100/62.5/25 micrograms once daily.
 - 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**.
- ➔ **Check with your doctor** before you use Trelegy Ellipta if you think any of these apply to you.

While you're using Trelegy Ellipta

Trelegy Ellipta helps to control your asthma and COPD when used regularly. If your asthma symptoms (shortness of breath, wheezing, chest tightness, cough) or 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 Ellipta 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 section 4 '*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.

Blurred vision or other visual disturbances

➔ **Contact your doctor** if you experience these

Other medicines and Trelegy Ellipta

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

Some medicines may affect how Trelegy Ellipta works, or make it more likely that you'll 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 breast-feeding

If you are **pregnant**, or **think you could be**, or if you are **planning to have a baby**, **don't take Trelegy Ellipta** without checking with your doctor. **Your doctor** will consider the benefit to you and the risk to your baby of taking Trelegy Ellipta while you are pregnant.

It is not known whether the ingredients of Trelegy Ellipta can pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you take Trelegy Ellipta.

3. How to use Trelegy Ellipta

How much to use

Always use Trelegy Ellipta exactly as your doctor has told you to. Check with your doctor, nurse or pharmacist if you are not sure.

The dose of Trelegy Ellipta for COPD is one inhalation of fluticasone furoate/umeclidinium/vilanterol 100/62.5/25 micrograms once daily at the same time each day.

The usual dose of Trelegy Ellipta for asthma is one inhalation of fluticasone furoate/umeclidinium/vilanterol 100/62.5/25 micrograms once daily at the same time each day. However, if you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol 200/62.5/25 micrograms). This dose is used once daily at the same time each day.

Use Trelegy Ellipta regularly

It is very important that you use Trelegy Ellipta every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

How to use the inhaler

See '*Step-by-step instructions*' after section 6 of this leaflet for full information.

Trelegy Ellipta is ready for use when you take the inhaler out of the sealed tray.

If you forget to use Trelegy Ellipta

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.

If you use too much Trelegy Ellipta

If you accidentally take more Trelegy Ellipta than you should, and have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness, **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 Ellipta may reduce the amount of steroid hormones produced naturally by your body.

Don't stop Trelegy Ellipta without advice

Use Trelegy Ellipta 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

Like all medicines, Trelegy Ellipta can cause side effects, although not everybody gets them. Your doctor will consider the risk of side effects when deciding which strength of Trelegy Ellipta you should use.

Allergic Reactions

Allergic reactions to Trelegy Ellipta are rare (they affect less than 1 person in 1000).

If you have any of the following symptoms after taking Trelegy Ellipta, stop taking 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)

Immediate breathing difficulties

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

➔ **Stop using it immediately, and tell your doctor** as soon as possible.

Infection of the lungs

Infection of the lungs (pneumonia) after using Trelegy Ellipta is common (it may affect up to 1 in 10 people).

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

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

Very common side effects

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

- common cold

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 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*) (See earlier in **Section 4**)
- flu (*influenza*)
- headache
- cough
- hoarseness
- painful and frequent urination (may be signs 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
- faster heart beat
- dry mouth
- weakening of the bones, leading to fractures
- 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 earlier in **Section 4**)

- difficulties passing urine (urinary retention)
- pain or discomfort passing urine (*dysuria*)
- awareness of heart beat (palpitations)
- anxiety
- tremor
- muscle spasms
- increase in blood sugar (*hyperglycaemia*)

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5. How to store Trelegy Ellipta

Keep this medicine out of the sight and reach of children.

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

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 this medicine after the expiry date shown on the pack.

The storage conditions are indicated on the packaging.

If you store in a refrigerator **allow the inhaler to return to room temperature for at least one hour** before use.

- Once the tray is opened, the inhaler can be used for up to 1 month, starting from the date you first open the tray.

Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. Further information

What Trelegy Ellipta contains

The active substances are fluticasone furoate, umeclidinium and vilanterol.

Each dose from the Ellipta inhaler contains either:

100 micrograms of fluticasone furoate, 74.2 micrograms of umeclidinium bromide (equivalent to 62.5 micrograms of umeclidinium) and 25 micrograms of vilanterol (as trifenate).

OR

200 micrograms of fluticasone furoate, 74.2 micrograms of umeclidinium bromide (equivalent to 62.5 micrograms of umeclidinium) and 25 micrograms of vilanterol (as trifenate).

Trelegy Ellipta also contains lactose monohydrate (which contains milk proteins) and magnesium stearate.

What Trelegy Ellipta looks like and contents of the pack

Trelegy Ellipta is inhaled through the mouth using the Ellipta inhaler. The active substances are present in a powder form in separate blister strips inside the inhaler. Trelegy Ellipta contains either 14 or 30 doses. The 14-dose inhaler has 14 blisters on each strip, and the 30-dose inhaler has 30 blisters on each strip. Not all presentations are available locally.

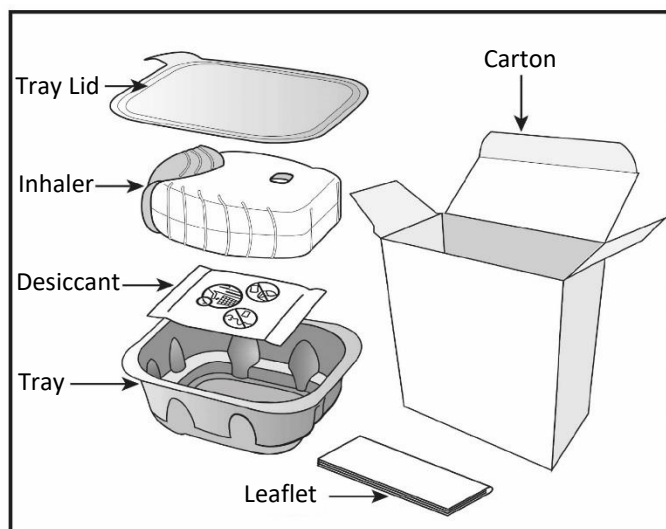
The Ellipta inhaler itself consists of a light grey body, a beige mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant sachet, to reduce moisture in the packaging. Once you have opened the lid of the tray, throw the desiccant sachet away — do not open, eat or inhale it.

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.

7. Step-by-step instructions

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 1 month from the date you first open the tray. **After this date, the inhaler should no longer be used.**

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.

Dose counter

This shows how many doses of medicine are left in the inhaler.

Before the inhaler has been used, it shows exactly 30 doses.

It counts down by **1** each time you open the cover.

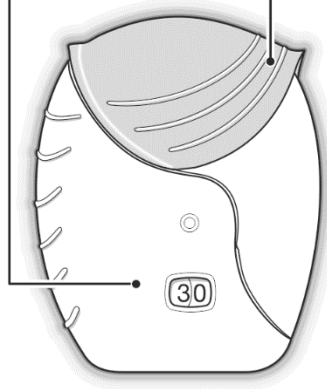
When fewer than 10 doses are left, half of the dose counter shows red.

After you have used the last dose, **half of the dose counter shows red and the number 0 is displayed.** Your inhaler is now empty.

If you open the cover after this, the dose counter will change from half red to completely red.

Cover

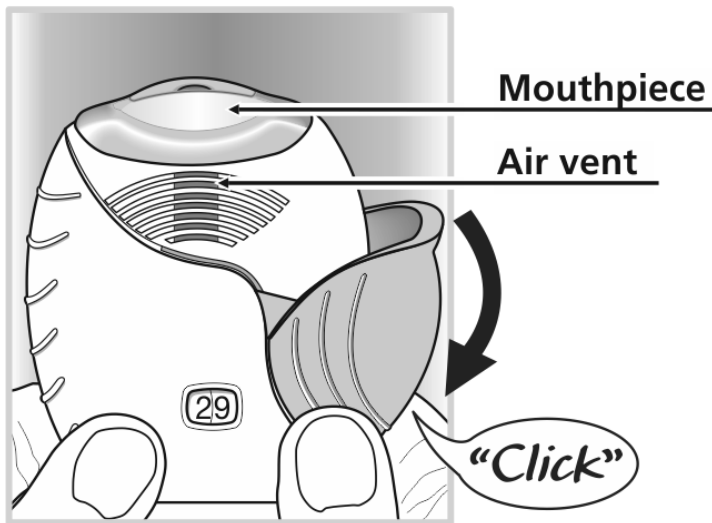
Each time you open this, you prepare one dose of medicine.



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.

- **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.**

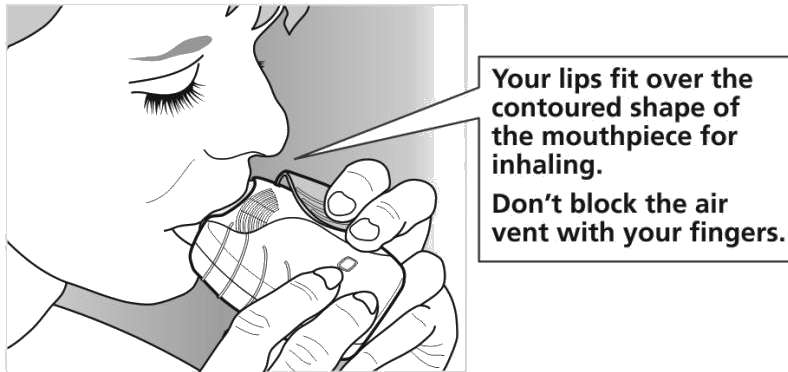
Inhale your medication

- 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.



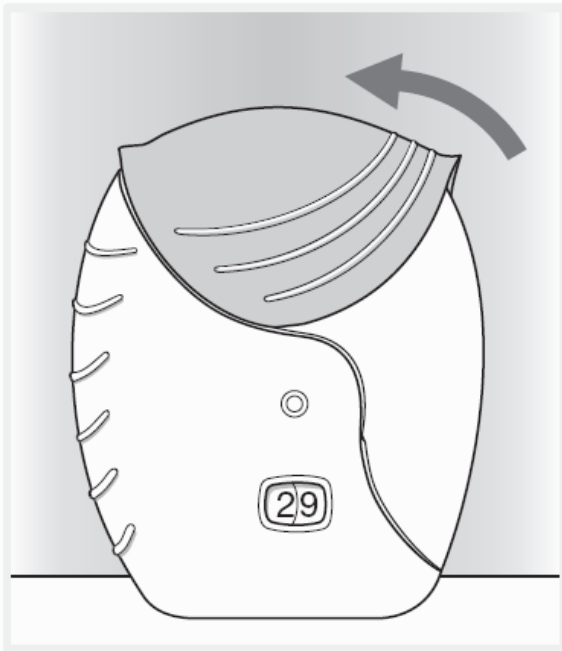
- Take one long, steady, deep breath in. Hold this breath for as long as possible (at least 3-4 seconds).
- Remove the inhaler from your mouth.
- Breathe out slowly and gently.

! 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.

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.

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