

YOUR GUIDE TO USING

TRELEGY[▽] ELLIPTA

fluticasone furoate/umeclidinium/vilanterol

This guide is for people who have been prescribed
TRELEGY Ellipta as a treatment for COPD¹

This guide should always be read together with the printed
TRELEGY Ellipta Patient Information Leaflet (PIL). It is not meant to replace it.

If you have questions about your treatment/medicines,
always speak with your doctor, nurse or pharmacist.



[▽] This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Adverse events should be reported to the Health Products Regulatory Authority (HPRA) using an Adverse Reaction Report Form obtained either from the HPRA or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 6764971. Adverse events should also be reported to GlaxoSmith-Kline on 1800 244 255. Information about this product, including adverse reactions, precautions, contra-indications and method of use can be found at www.medicines.ie

TRELEGY Ellipta was developed in collaboration with INNOVIVA



What is TRELEGY Ellipta used for?

You have been prescribed TRELEGY Ellipta for chronic obstructive pulmonary disease, also known as COPD.

COPD is a long-term condition that occurs when the airways of the lungs become inflamed, damaged and narrowed making breathing more difficult. Symptoms of COPD can be different for each person, but common symptoms are:

- **SHORTNESS OF BREATH**
- **FREQUENT COUGHING** (with or without mucus)
- **WHEEZING**
- **EXACERBATIONS** where the symptoms of COPD suddenly worsen or flare up

Though COPD is a progressive disease, with the right diagnosis and treatment, there are many things you can do to manage your condition in order to breathe better. Changes to your lifestyle and routine can be effective in helping you manage your COPD, such as stopping smoking, undertaking daily physical activity and regularly taking your medication as prescribed to you by your doctor.

When used as prescribed, TRELEGY Ellipta helps relax the breathing muscles lining the airways of the lungs, and reduces swelling and irritation in the small air passages. This makes it easier for air to get in and out of the lungs.

What is TRELEGY Ellipta?

TRELEGY Ellipta is a combination of three different COPD medicines that are delivered together in the Ellipta inhaler:

1. FLUTICASONE FUROATE

Fluticasone furoate is an inhaled corticosteroid that helps to decrease inflammation in the small airways of the lungs by reducing swelling and irritation. This makes it easier for air to get into and out of the lungs.

2. UMECLIDINIUM

Umeclidinium is a bronchodilator. Bronchodilators help the muscles around the airways in your lungs stay relaxed to reduce symptoms such as wheezing, coughing and shortness of breath. These symptoms can happen when the muscles around the airways tighten, making it harder to breathe.

3. VILANTEROL

Like umeclidinium, vilanterol is also a bronchodilator and relaxes the muscles of the small air passages in the lungs. As with umeclidinium, this helps to open the airways, and makes it easier for air to get into and out of the lungs.

Taking TRELEGY Ellipta as prescribed may help to control your breathing difficulties.

DO'S

- DO read the Patient Information Leaflet, which is in the box with your TRELEGY Ellipta, as it has important information about your medicine
- DO use your TRELEGY Ellipta as prescribed and not only when you have breathing problems. This may help to control your symptoms day and night
- DO tell your doctor if your symptoms do not improve, or get worse, despite using TRELEGY Ellipta as prescribed
- DO contact your doctor or pharmacist for advice immediately if you use too much TRELEGY Ellipta, as you may need medical attention

DO'S

- **DO NOT** use more TRELEGY Ellipta than your doctor tells you to use
- **DO NOT** use TRELEGY Ellipta to treat 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)
- **DO NOT** use TRELEGY Ellipta if you are allergic to fluticasone furoate, umeclidinium, vilanterol, lactose monohydrate or magnesium stearate
- **DO NOT** cover the air vents. Make sure your fingers are clear of the vents when taking your medicine
- **DO NOT** store above 30°C



THE RECOMMENDED DOSE IS
ONE INHALATION ONCE A DAY

SAME TIME EVERY DAY

If you forget to take a dose one day, don't worry,
just take your next dose at the usual time
– do not take two doses.

When should I TRELEGY Ellipta?

Always use this medicine exactly
as your doctor has told you.

Check with your doctor, nurse or
pharmacist if you are not sure.

If you use more TRELEGY Ellipta than
you should, **contact your doctor or
pharmacist for advice immediately** as
you may need medical attention.

Are there any side effects?

Like all medicines, TRELEGY Ellipta may cause side effects. If your breathing or wheezing gets worse straight after using TRELEGY Ellipta, stop using it and get medical help immediately.

Some patients who take this medicine for COPD can develop an infection of the lungs called pneumonia. Tell your doctor as soon as possible if you have fever or chills; increased mucus production or change in mucus colour; or increased cough or increased breathing difficulties. These could be symptoms of pneumonia.

Other common side effects of TRELEGY Ellipta include 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 (bronchitis), flu (influenza), common cold, headache, cough, painful and frequent urination (may be signs of a urinary tract infection), joint pain, back pain, constipation.

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 prevent this side effect. These may affect up to 1 in 10 people.

A full list of side effects is included in the printed Patient Information Leaflet (PIL), which is in the box with your TRELEGY Ellipta.

If you get any side effects – including any that are not already mentioned here – you should tell your doctor, nurse or pharmacist.

Also, you can help to make sure that medicines remain as safe as possible by reporting any side effects via the internet at www.hpra.ie or via email at medsafety@hpra.ie.

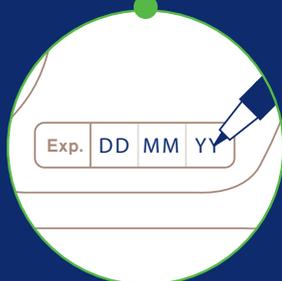
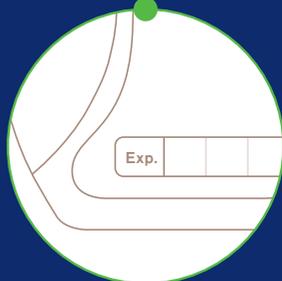
Alternatively you can call the HPRA on (01) 6764971. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

Getting ready to use your TRELEGY Ellipta inhaler

Keep the inhaler inside the sealed tray to protect from moisture and only remove immediately before first use. The inhaler will be in the 'closed' position.

When the tray is opened, write the "Discard by" date on the inhaler label in the space provided, which is 6 weeks from the date you opened the tray, after which the inhaler should no longer be used.

Your TRELEGY Ellipta comes pre-filled and is ready to use straight away.

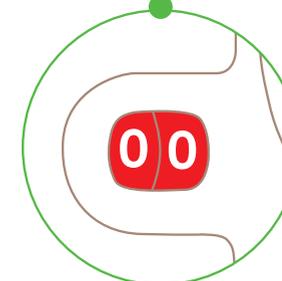
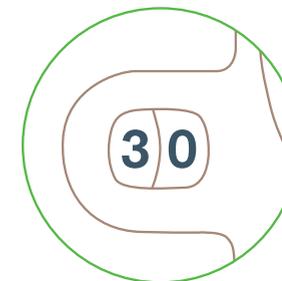


The dose counter on the front tells you how many doses are left in the inhaler

Each inhaler contains 30 doses. It counts down by one each time you open the cover.

When you have fewer than 10 doses left, half the dose counter will show red. If this is the last inhaler of your prescription, get in touch with your doctor about another prescription before you run out of medicine.

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.



How to take a dose

It is important to use this medicine exactly as your doctor told you. If you are not sure, please check with your doctor or pharmacist.

Do not shake your Ellipta inhaler. It doesn't need to be shaken before a dose. **Do not** breathe into the inhaler. When breathing out before inhaling your medicine, do so away from the mouthpiece.

For full instructions, you can also view the short instruction 'How to use Ellipta' video at <https://public.gsk.ie/products/Ellipta/I-am-a-Patient.html>

Your TRELEGY Ellipta inhaler is ready to use straight away – there is no need to check it before you start.

step: one

OPEN

Slide the cover down until you hear a 'click'.

1. The dose counter will go down by one.
2. It is now ready for use.

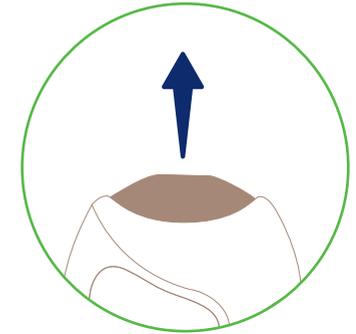


step: two

INHALE

Hold the inhaler away from your mouth and breathe out as far as you comfortably can.

1. Put the mouthpiece between your lips and close your lips firmly around it. Be sure not to block the air vent with your fingers.
2. Take one long, steady, deep breath in and hold it for as long as possible, at least 3–4 seconds.
3. Remove the inhaler from your mouth and breathe out slowly and gently.
4. You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.



step: three

CLOSE

To close, slide the cover upwards as far as it will go to cover the mouthpiece.

1. You can wipe the mouthpiece with a dry tissue before closing the cover if you like. Store it safely ready for the next day's dose.
2. 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.





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References: 1. TRELEGY Ellipta Package Leaflet. Available at: <https://www.medicines.ie/medicines/trelegy-ellipta-34025/>
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