

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

The medicine is dispensed according to a physician's prescription only

Anoro Ellipta 55/22 mcg, Inhalation powder

Each dose released from the Anoro Ellipta inhaler contains:

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

For the list of the inactive and allergenic ingredients in the preparation, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the 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?

Anoro Ellipta is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Anoro Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

Therapeutic group:

Anoro Ellipta contains two active substances: umeclidinium bromide and vilanterol trifenate belonging to a group of medicines called bronchodilators:

- umeclidinium bromide: anti cholinergic.
- vilanterol trifenate: beta-2 receptor agonist.

Chronic obstructive pulmonary disease (COPD) is a long-term condition characterised by breathing difficulties that slowly get worse

In COPD the muscles around the airways tighten. This medicine blocks the tightening of these muscles in the lungs, making it easier for air to get in and out of the lungs. When used regularly, it can help to control your breathing difficulties and reduce the effects of COPD on your everyday life.

Anoro 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). 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 umeclidinium, vilanterol or to any of the additional ingredients contained in the medicine (listed in section 6).
- If you think this applies to you, **do not use** this medicine until you have checked with the physician.

Special warnings regarding the use of the medicine

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

- you have **asthma** (do not use Anoro Ellipta to treat asthma)
 - you have **heart problems** or **high blood pressure**
 - you have an eye problem called **narrow-angle glaucoma**
 - you have an **enlarged prostate, difficulty passing urine** or a **blockage in your bladder**
 - you suffer from **epilepsy**
 - you have **thyroid gland problems**
 - you have a **low potassium level** in the blood
 - you have **diabetes**
 - you have **severe liver problems**
- **Check with the physician** if you think any of these may apply to you.

Breathing difficulties immediately after use of Anoro Ellipta

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

If you get eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes during treatment with Anoro Ellipta:

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

Children and adolescents

Do not give this medicine to **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 the 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:

- medicines called beta blockers (such as propranolol), to treat **high blood pressure** or other **heart problems**
- ketoconazole or itraconazole, to treat **fungal infections**

- clarithromycin or telithromycin, to treat **bacterial infections**
 - ritonavir, to treat **HIV infection**
 - medicines that lower the amount of potassium in your blood, such as some diuretics or some medicines used to treat asthma (e.g. methylxanthine or steroids)
 - other long-acting medicines similar to this medicine that are used to treat breathing problems, e.g. tiotropium, indacaterol. Do not use Anoro Ellipta if you already use these medicines.
- **Tell the physician or pharmacist** if you are taking any of these.
Your doctor may wish to monitor you carefully if you are taking any of these medicines as they may increase the side effects of Anoro 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 tells you that you can.

It is not known whether the ingredients of Anoro Ellipta can pass into breast milk. **If you are breast-feeding, you must check with the physician** before you use Anoro Ellipta. Do not use this medicine if you are breast-feeding unless the physician tells you that you can.

Driving and using machines

It is unlikely that Anoro Ellipta will affect your ability to drive or use machines.

Important information about some of the ingredients of the medicine

Anoro Ellipta contains lactose

If you have been told by the physician that you have an intolerance to some sugars, talk to 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 the pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.

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

The usual dosage is generally one inhalation every day at the same time of day. You only need to inhale once a day because the effect of this medicine lasts for 24 hours.

Do not exceed the recommended dose.

Use Anoro Ellipta regularly

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

Anoro 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 Ellipta inhaler

See 'Step by step instructions for use' after section 6 in this leaflet for full information.

Anoro Ellipta is intended for inhalation use. To use Anoro Ellipta, inhale it into your lungs through the mouth, using the Ellipta inhaler.

If your symptoms do not improve

If your COPD 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 have taken a higher dosage

You should contact the physician or pharmacist for advice immediately as you may need medical attention. 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 took an overdose or if a child has accidentally taken the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, **do not inhale a double dose to make up for a forgotten dose.** Inhale the next dose at the usual time.

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

Adhere to the treatment as recommended by the physician.

If you stop using the medicine

Use this medicine for as long as the physician recommends. It will only be effective as long as you are using it. Do not stop unless the physician advises you to, even if you feel better, as your symptoms may get worse.

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

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

4. SIDE EFFECTS

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

Allergic reactions

If you have any of the following symptoms after taking Anoro Ellipta **stop using this medicine and tell your doctor immediately.**

Uncommon side effects

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

- skin rash (hives) or redness

Rare side effects

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

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

Breathing difficulties that occur immediately after using Anoro Ellipta

Immediate breathing difficulties after using Anoro Ellipta are rare. If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using this medicine:

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

Other side effects

Common side effects

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

- painful and frequent urination (may be a sign of a urinary tract infection)
- combination of sore throat and runny nose
- sore throat
- feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis)
- headache
- cough
- pain and irritation in the back of the mouth and throat
- constipation
- dry mouth
- infection of the upper airways.

Uncommon side effects

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

- irregular heart beat
- faster heart beat
- awareness of heartbeat (*palpitations*)
- muscle spasms
- tremor
- taste disturbance
- hoarseness.

Rare side effects

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

- blurred vision
- increase of the measured eye pressure
- decrease in vision or pain in your eyes (possible signs of glaucoma)
- difficulty and pain when passing urine - these may be signs of a bladder

obstruction or urinary retention.

Side effect of unknown frequency

Frequency cannot be estimated from the available data:

- dizziness.

If a side effect occurred, 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.il) that directs you to the online form for reporting side effects, or by entering the link:

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

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) stated on the carton box, tray and inhaler. 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 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, starting from the date of opening the tray and 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 stored in a refrigerator, allow the inhaler to return to room temperature for at least an hour before use.
- Do not discard medicines in the wastewater or household waste. Consult the pharmacist as to how to dispose of medicines no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active substances the medicine also contains:

Lactose monohydrate, magnesium stearate

(Also see section 2 - “Important information about some of the ingredients of the medicine”).

What the medicine looks like and the contents of the package:

Anoro Ellipta is an inhalation powder.

The Ellipta inhaler consists of a light grey plastic body, a red mouthpiece cover and a dose counter. It is packaged in a tray with a removable aluminium

cover. The tray contains a *desiccant packet*, to reduce moisture in the packaging.

The active substances are present as a white powder in separate blisters inside the inhaler.

Anoro Ellipta is available in packs of 1 inhaler containing either 7 or 30 doses. Not all pack sizes may be marketed.

License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

Manufacturer: Glaxo Operations UK Ltd. (Glaxo Wellcome Operations), Ware, UK.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 153-37-34077.

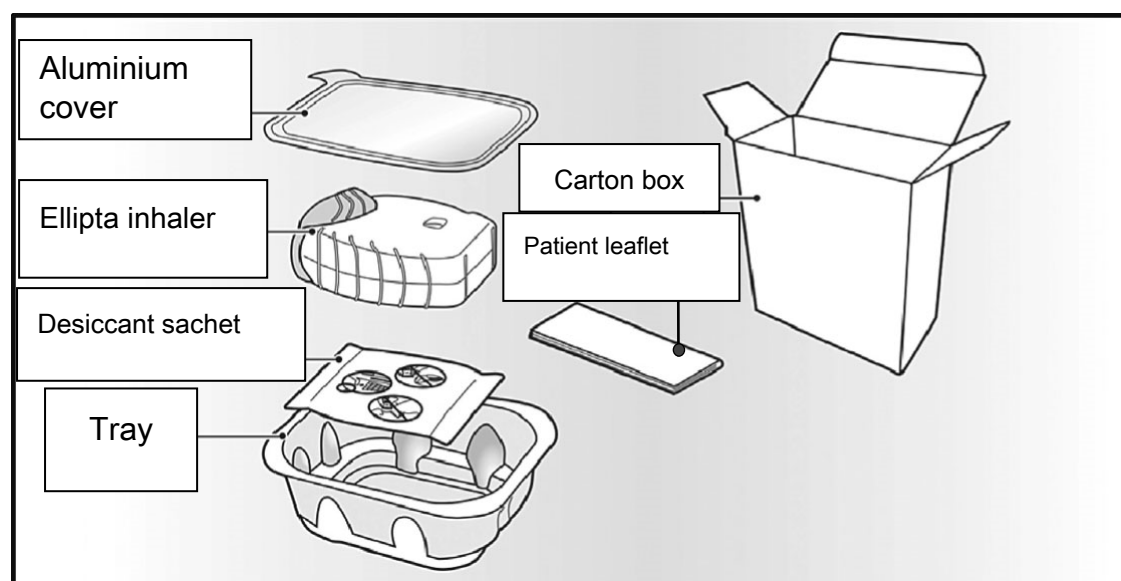
Revised in December 2023.

Step by step instructions for use

What is the Ellipta inhaler?

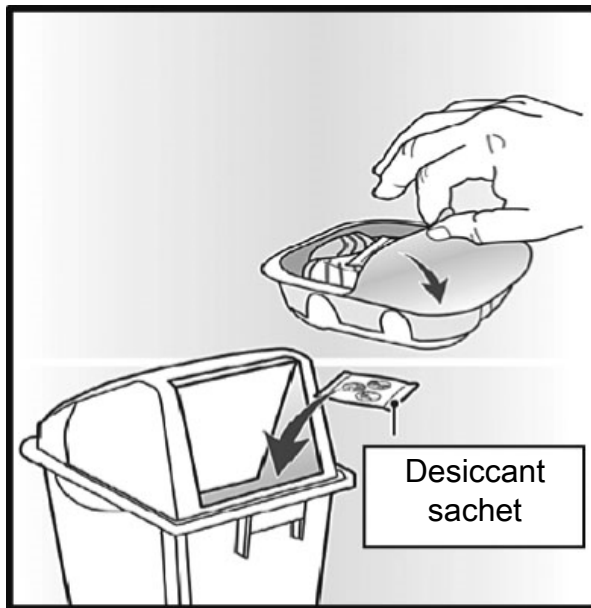
The first time you use Anoro Ellipta you do not need to check that the inhaler is working properly; it contains previously measured doses and is ready to use straight away.

The carton box of your Anoro Ellipta inhaler contains:



The inhaler is packaged in a tray. **Do not open the tray until you are ready to start using your new inhaler.** When you are ready to use the inhaler, peel back the aluminium cover to open the tray.

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



When you take the inhaler out of the tray, it will be in the 'closed' position. **Do not open it until you are ready to inhale a dose of medicine.** When opening the tray, write the "Discard by" date on the inhaler back label and the carton box in the space provided. The "Discard by" date is 6 weeks from the date you opened 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 step-by-step instructions for use of the inhaler provided below can be used for either the 30 dose inhaler (sufficient for 30 days of treatment) or the 7 dose inhaler (sufficient for 7 days of treatment).

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.

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.

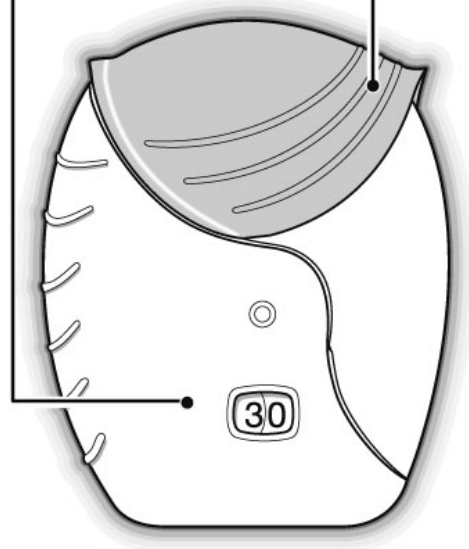
When fewer than 10 doses are left, half of the dose counter shows red.

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

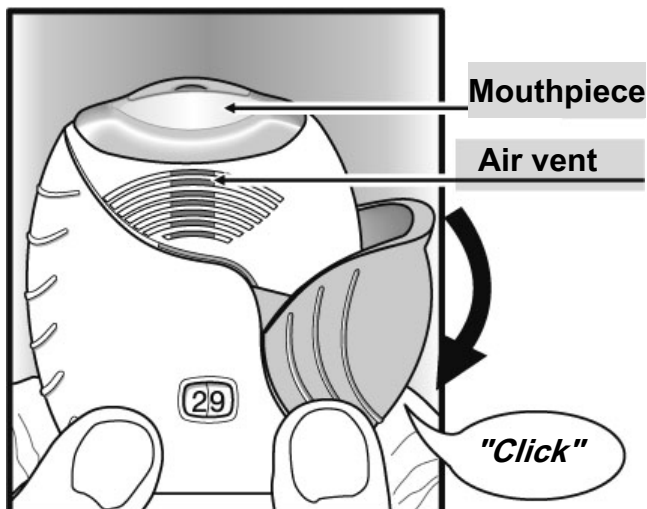
Each time you open this, you prepare one dose of medicine.



2) Prepare a dose

Wait to open the cover until you are ready to inhale 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 the pharmacist for advice.

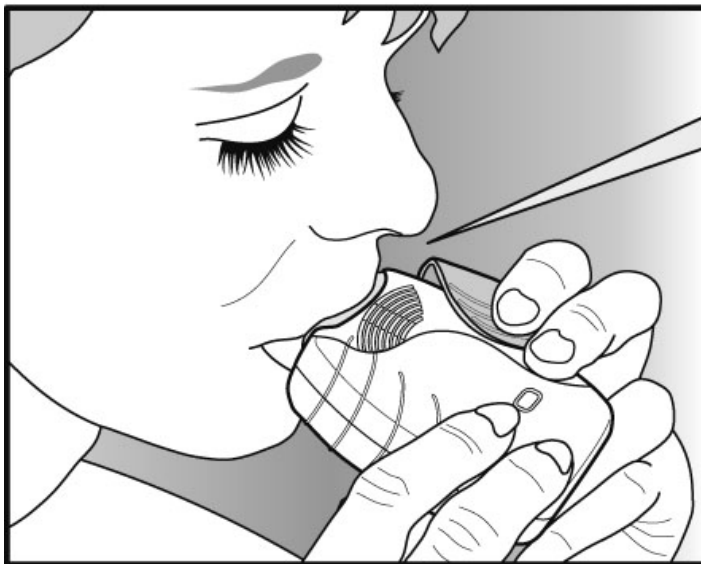
3) Inhale your medicine

- ▶ **While holding the inhaler away from your mouth, breathe out as far as is comfortable.**

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.

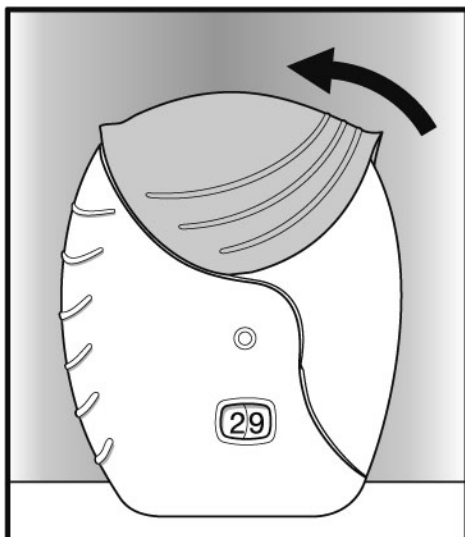


Your lips fit over the contoured shape of the mouthpiece for inhaling.

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



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

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