

ANORO ELLIPTA INHALATION POWDER, PRE-DISPENSED

Umeclidinium/vilanterol (62.5 micrograms/25 micrograms)

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What ANORO is used for

ANORO is used to treat chronic obstructive pulmonary disease (COPD) in adults. COPD is a long-term condition characterized by breathing difficulties that slowly get worse.

ANORO contains two active substances called umeclidinium and vilanterol. These belong to a group of medicines called bronchodilators. 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.

Before you use ANORO

- When you must not use it

ANORO 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).

Do not use ANORO:

- If you are allergic to umeclidinium, vilanterol or any of the other ingredients of this medicine (listed under Ingredients)

If you think this applies to you, don't use this medicine until you have checked with your doctor.

Children and adolescents

This medicine should not be given to children or adolescents below the age of 18 years.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Don't use this medicine if you are pregnant unless your doctor tells you that you can.

It is not known whether the ingredients of ANORO can pass into breast milk. If you are breast-doctor before you use ANORO. Don't use this medicine if you are breast-feeding unless your doctor tells you that you can.

- Before you start to use it

Talk to your doctor before using this medicine:

- If you have asthma (Don't use ANORO to treat asthma)
- If you have heart problems or high blood pressure
- 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 suffer from epilepsy
- If you have thyroid gland problems
- If you have diabetes
- If you have severe liver problems

Check with your doctor if you think any of these may apply to you.

Driving and using machines

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

ANORO contains lactose

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

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how this medicine works, or make it more likely that you'll 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,
 - Ritonavir, to treat HIV infection
 - Medicines that lower the amount of potassium in your blood, such as some diuretics (water tablets)
 - Other long-acting medicines similar to this medicine that are used to treat breathing problems, e.g. tiotropium, indacaterol.
- Don't use ANORO if you already use these medicines.

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

How to use ANORO

- How much to use

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 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. Don't use more than your doctor tells you to use.

How to use the inhaler

To use ANORO, you breathe it into your lungs through your mouth using the ELLIPTA inhaler.

Step-by-step instructions

What is the inhaler?

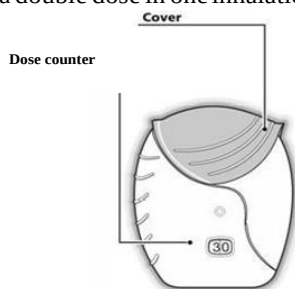
The first time you use ANORO you do not need to check that the inhaler is working properly; it contains previously measured doses and is ready to use straight away. The inhaler is packaged in a tray. When you are ready to use the inhaler, peel back the lid to open the tray containing a desiccant sachet, to reduce moisture. Throw this sachet away – don't eat or inhale it.

When you take the inhaler out of its box (sealed tray), it will be in the 'closed' position. Don't open it until you are ready to inhale a dose of medicine. When the tray is opened, 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 tray can be discarded after first opening.

The instructions for use of the inhaler provided below can be used for either the 30-dose (30 day supply) or the 7-dose (7 day supply) inhaler.

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.



Cover

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

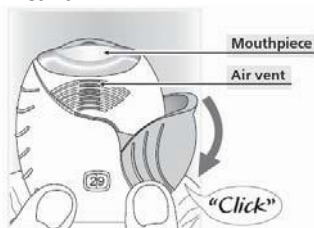
Dose counter

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.

1) 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 the medicine. Take it back to your pharmacist for advice.

2) Inhale your medicine

- 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.



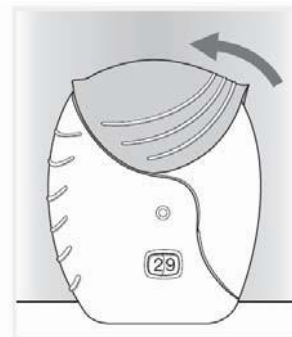
Your lips fit over the contoured shape of the mouthpiece for inhaling. Don't block the air vent with your fingers.

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.

3) Close the inhaler

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



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

- When to use it

Use ANORO regularly.

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

- How long to use it

Use this medicine for as long as your doctor recommends. It will only be effective as long as you are using it. 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.

- If you forget to use it

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 (overdose)

If you accidentally use too much of this medicine, contact your doctor 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, have a dry mouth, or have a headache.

While you are using it

- Things you must do

If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse, or if you are using your quick-acting inhaler more often: contact your doctor as soon as possible.

- Things you must not do

ANORO 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).

- Things to be careful of

Immediate breathing difficulties
If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your ANORO 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

If you get eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in associated with red eyes during treatment with ANORO: Stop using this medicine and seek

medical help immediately, these may be signs of an acute attack of narrow-angle glaucoma.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Immediate breathing difficulties

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.

Common side effects

These may affect between 1 in 100 and 1 in 10 people:

- Painful and frequent urination (may be signs 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)
- 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 between 1 in 1000 and 1 in 100 people:

- Irregular heart beat
- Faster heart beat
- Rash
- Tremor
- Altered taste
- Irregular heart beat

Rare side effects

These may affect between 1 in 10,000 and 1 in 1000 people:

- Severe and life-threatening allergic reaction
- Swelling under the skin
- Hives
- Vision blurred

- Glaucoma
- Increased intraocular pressure
- Eye pain
- Paradoxical bronchospasm
- Urinary retention
- Dysuria (painful or difficult urination)
- Dysphonia (difficulty in speaking)
- Headache

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ANORO

- Storage

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, tray and inhaler after 'EXP'. The expiry date refers to the last day of that month.

Store in the sealed tray in order to protect from moisture and do not open the foil lid until ready for first use. Once the tray is opened, the inhaler can be used for up to 6 weeks, starting from the date of opening the tray. Write the date the inhaler should be discarded on the label in the space provided. The date should be added

Do not store above 30°C.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like

The inhaler itself consists of a light grey plastic body, a red mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a dessicant sachet, to reduce moisture in the packaging.

The active substances are present as a white powder in separate blisters inside the inhaler. Each inhaler contains either 7 or 30 doses.

- Ingredients

Active ingredient(s)

The active substances are umeclidinium bromide and vilanterol. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide) and 22 micrograms of vilanterol (astrifenatate).

Inactive ingredient(s)

Lactose monohydrate and magnesium stearate

MAL number

MAL15095033ARZ

Manufacturer

GlaxoSmithKline LLC
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Product Registration Holder

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28/06/2023

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