

Package leaflet: Information for the user

ANORO 55 micrograms/22 micrograms inhalation powder, pre-dispensed umeclidinium/vilanterol

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ANORO is and what it is used for
 2. What you need to know before you use ANORO
 3. How to use ANORO
 4. Possible side effects
 5. How to store ANORO
 6. Contents of the pack and other information
- Step-by-step instructions

1. What ANORO is and what it is used for

What ANORO is

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

What ANORO is used for

ANORO is used to treat *chronic obstructive pulmonary disease (COPD)* in adults. 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 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).

2. What you need to know before you use ANORO

Do not use ANORO :

- if you are **allergic** to umeclidinium, vilanterol or any of the other ingredients of this medicine (*listed in section 6*).

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

Warnings and precautions

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.

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 association 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.

Children and adolescents

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

Other medicines and ANORO

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, to treat **bacterial infections**
- 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.

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-feeding, you must check with your doctor** before you use ANORO. Don't use this medicine if you are breast-feeding unless your doctor tells you that you can.

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.

3. How to use ANORO

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.

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.

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).

How to use the inhaler

See '*Step-by-step instructions*' in this leaflet for full information.

To use ANORO, you breathe it into your lungs through your 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 your quick-acting inhaler more often:

contact your doctor as soon as possible.

If you use more ANORO than you should

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.

If you forget to use ANORO

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 stop using ANORO

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.

4. Possible side effects

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

Allergic reactions to ANORO are uncommon (they affect less than 1 person in 100).

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

- skin rash (hives) or redness
- 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)

Immediate breathing difficulties

Immediate breathing difficulties after using ANORO are rare (they affect less than 1 person in 1000). 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 **up to 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)
- 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 heart beat (*palpitations*)
- rash
- 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 due to high pressure (possible signs of glaucoma).
- difficulty and pain when passing urine – these may be signs of a bladder obstruction or urinary retention.

Reporting of side effects

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 can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store ANORO

Keep this medicine out of the 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 as soon as the inhaler has been removed from the tray.

Do not store above 30°C.

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

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.

6. Contents of the pack and other information

What ANORO contains

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 (as trifenate).

The other ingredients are lactose monohydrate and magnesium stearate.

What ANORO looks like and contents of the pack

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 desiccant packet, 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. Multipacks containing 90 (3 inhalers of 30) doses are also available. Not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Manufacturer:

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Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations)

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Other sources of information

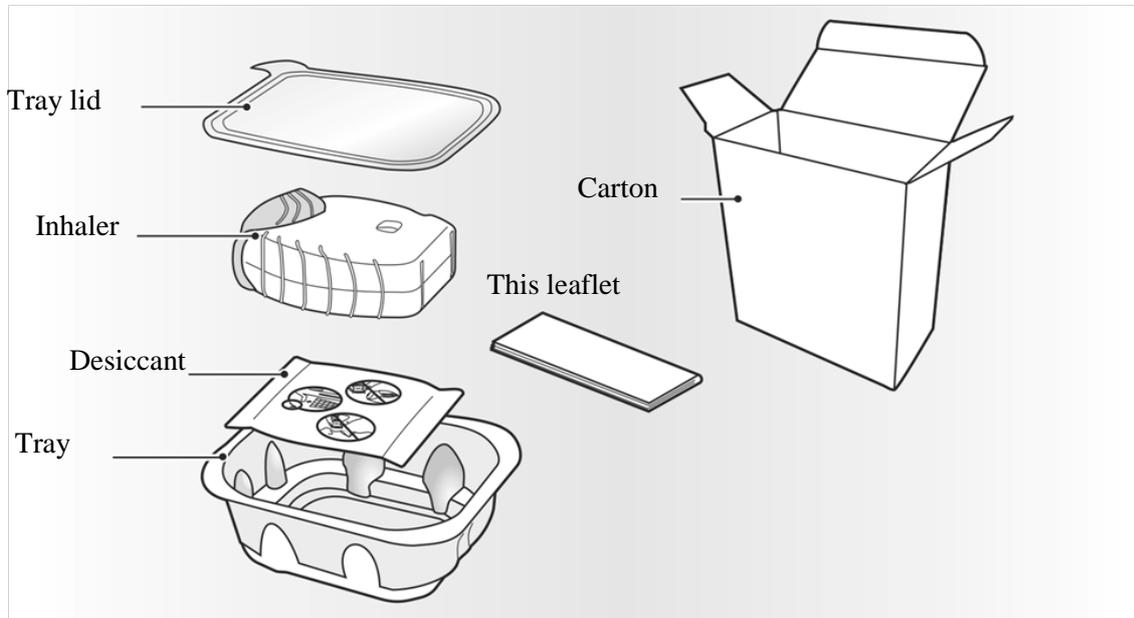
Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

Step-by-step instructions

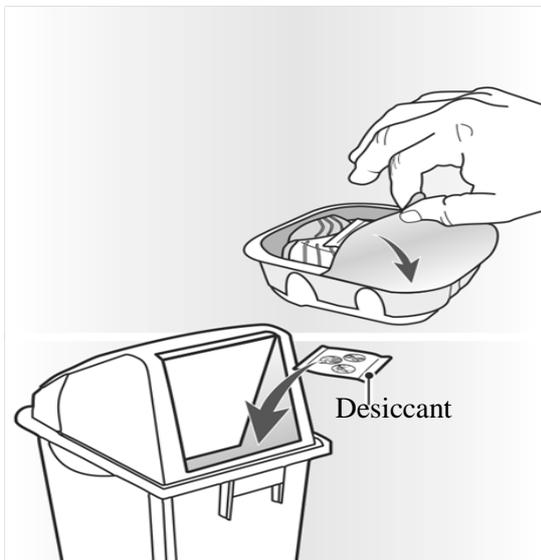
What is the inhaler?

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.

Your ANORO inhaler carton contains



The inhaler is packaged in a tray. **Don't 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.

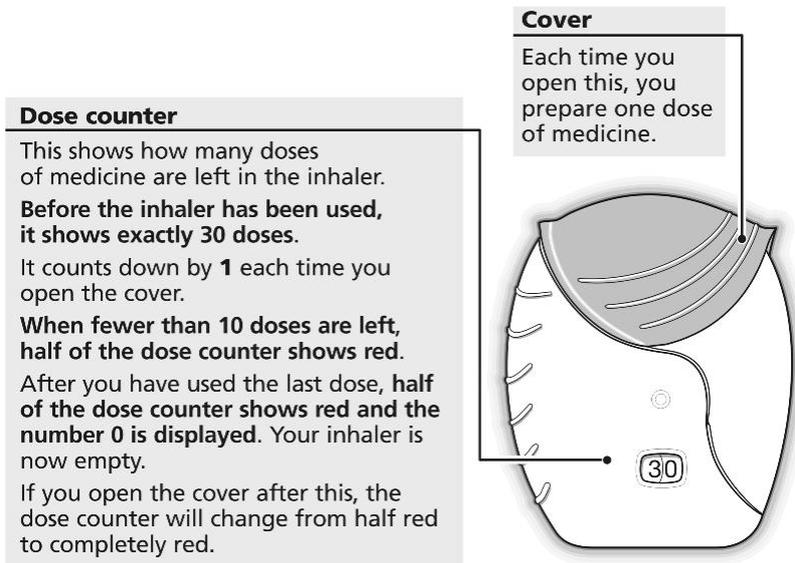


When you take the inhaler out of its tray, it will be in the 'closed' position. **Don't open the inhaler until you are ready to inhale a dose of medicine.** When the tray is opened, write the "Discard by" date on the inhaler label in the space provided. The "Discard by" date is 6 weeks from the date 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 inhaler (30 day supply) or the 7-dose inhaler (7 day supply).

Read this before you start

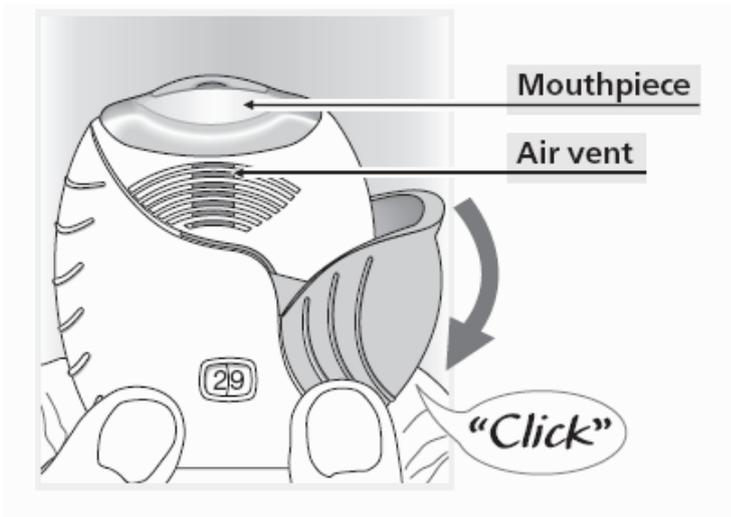
If you open and close the cover without inhaling the medicine, you will lose the dose. The lost dose will be securely held inside the inhaler, but it will no longer be available. It is not possible to accidentally take extra medicine or a double dose in one inhalation.



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 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.**



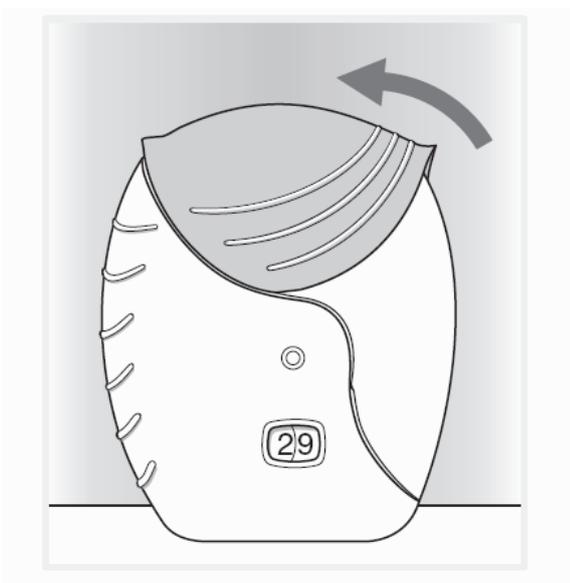
Your lips fit over the contoured shape of the mouthpiece for inhaling.
Don't block the air vent with your fingers.

- 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.

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

3) Close the inhaler



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