

Package leaflet: Information for the user

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

Read the entire 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.

Do you have any questions? Contact your doctor, pharmacist, or nurse.

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

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

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1. What is ANORO ELLIPTA and what is it used for?

What is ANORO ELLIPTA?

ANORO ELLIPTA contains two active substances, umeclidinium bromide and vilanterol. They belong to a group of medicines called bronchodilators.

What is this medicine used for?

ANORO ELLIPTA is used for the treatment of chronic obstructive pulmonary disease (COPD) in adults. COPD is a long-term condition characterized by breathing difficulties that gradually worsen.

In COPD, the muscles around the airways tighten. This medicine blocks the tightening of these muscles in the lungs, allowing air to flow more easily in and out of the lungs. Regular use will help control your breathing difficulties and reduce the effects of COPD on your daily life.

ANORO ELLIPTA should not be used for the relief of a sudden attack of breathlessness or wheezing.

If you have such an attack, you should use a fast-acting rescue inhaler (such as salbutamol). If you do not have a fast-acting rescue inhaler, contact your doctor.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If you think the above applies to you, do not use this medicine until you have spoken to your doctor.

When should you be extra careful with this medicine?

Contact your doctor before using this medicine:

- if you have asthma (do not use ANORO ELLIPTA for the treatment of asthma)
- if you have heart problems or high blood pressure
- if you have an eye problem called narrow-angle glaucoma is called
- if you have an enlarged prostate, urinary problems, or a blockage in your bladder
- if you have epilepsy has
- if you have thyroid problems has
- if you have low potassium levels in your blood
- if you have diabetes have
- if you severe liver problems have

Talk to your doctor if you think any of the above points may apply to you.

Acute breathing difficulties

If you experience chest tightness immediately after using your ANORO ELLIPTA inhaler, or if you start coughing, wheezing, or become short of breath:

stop using this medicine and seek immediate medical help, as you may have a serious condition called paradoxical bronchospasm.

Eye problems during treatment with ANORO ELLIPTA

If you experience eye pain or discomfort, temporary blurred vision, halos or colored images in association with red eyes during treatment with ANORO ELLIPTA:

stop using this medicine and seek immediate medical help, as these symptoms may indicate an acute attack of narrow-angle glaucoma.

Children and adolescents under 18 years

Do not give this medicine to children or adolescents under 18 years.

Are you using any other medicines?

Are you using any other medicines besides ANORO ELLIPTA, have you recently done so, or is there a possibility that you will use other medicines in the near future? If so, tell your doctor or pharmacist. If you are not sure what your medicine contains, discuss it with your doctor or pharmacist.

Some medicines can affect how this medicine works or increase the chance of side effects.

These include among others::

- medicines the beta-blockers (such as propranolol) are called and are used for the treatment of high blood pressure or other heart problems
- ketoconazole clarithromycin
- or telithromycin , used to treat bacterial infectionsritonavir
- , used to treat HIV infections, used for the treatment of HIV infections
- medicines that lower the amount of potassium in your blood, such as some diuretics (water pills) or some medicines for the treatment of asthma (such as methylxanthine or steroids)

other long-acting medicines similar to this medicine used for the treatment of breathing problems, such as tiotropium and indacaterol. Do not use ANORO ELLIPTA if you are already using these medicines.

Inform your doctor or pharmacist if you are using any of these medicines. Your doctor may want to monitor you closely if you are using any of these medicines, as they can worsen the side effects of ANORO ELLIPTA.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. Do not use this medicine if you are pregnant unless your doctor tells you that you can use it.

It is not known whether the components of ANORO ELLIPTA can pass into breast milk. If you are breastfeeding, you should discuss this with your doctor before using ANORO ELLIPTA. Do not use this medicine if you are breastfeeding unless your doctor tells you that you can use it.

Driving and using machines

It is not likely that ANORO ELLIPTA affects your ability to drive or use machines.

ANORO ELLIPTA contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage 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. Do not use more than your doctor tells you to use.

Use ANORO ELLIPTA regularly

It is very important that you use ANORO ELLIPTA every day as your doctor has told you. This will help keep you symptom-free day and night.

ANORO ELLIPTA should not be used to relieve a sudden attack of breathlessness or wheezing. If you have such an attack, you must use a fast-acting rescue inhaler (such as salbutamol).

How to use the inhaler?

See the 'Step-by-step instructions' at the end of this leaflet for full information.

ANORO ELLIPTA is for inhalation use. To use ANORO ELLIPTA, you inhale it into your lungs through your mouth using the ELLIPTA inhaler.

If your symptoms do not improve

If your COPD symptoms (breathlessness, wheezing, coughing) do not improve or worsen, or if you use your fast-acting medication inhaler more often:

contact your doctor as soon as possible.

Have you used too much of this medicine?

If you accidentally use too much of this medicine, contact your doctor or pharmacist immediately for advice as you may need medical help. If possible, show the inhaler, the packaging, or this leaflet. You may notice that your heart beats faster than normal, you feel shaky, or you experience visual disturbances, a dry mouth, or headache.

Have you forgotten to use this medicine?

Do not inhale a double dose to make up for a forgotten dose. Simply inhale your next dose at the usual time.

If your breathing becomes wheezy or you become short of breath, use your fast-acting rescue inhaler (such as salbutamol) and then consult a doctor.

If you stop using this medicine

Use this medicine as long as your doctor recommends it. It is only effective as long as you use it. Do not stop using this medicine unless advised by your doctor, even if you feel better, as your symptoms may worsen.

Do you have any other questions about using this medicine? Then contact your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects have, although not everyone experiences this.

Allergic reactions

If you experience any of the following symptoms after using ANORO ELLIPTA, stop using this medicine and tell your doctor immediately.

Uncommon side effects (occur in less than 1 in 100 users):

rash (hives) or redness

Rare side effects (occur in less than 1 in 1000 users):

swelling, sometimes of the face or mouth (angioedema)

severe experience wheezing, coughing, or difficulty breathing

feel suddenly weak or lightheaded (this may lead to fainting or loss of consciousness)

Acute breathing difficulties

Acute breathing difficulties after using ANORO ELLIPTA are rare. If you experience chest tightness immediately after using this medicine, or if you start coughing, wheezing, or become short of breath:

stop using this medicine and seek immediate medical help as you may have a serious condition called paradoxical bronchospasm.

Other side effects

Common (occur in less than 1 in 10 users)

pain when urinating or frequent urination (these may be signs of a urinary tract infection)
combination of a sore throat and a runny nose
sore throat
feeling of pressure or pain in the cheeks and forehead (these may be signs of an inflammation of the sinuses called sinusitis)
headache
coughing
pain and irritation at the back of the mouth and in the throat
constipation
dry mouth
infection of the upper airways

Sometimes (occur in less than 1 in 100 users)

irregular heartbeat
faster heartbeat
being aware of the heartbeat (palpitations)
muscle spasms
trembling/shaking
altered taste
hoarseness

Rarely (occur in less than 1 in 1000 users)

blurred vision
increase of the measured intraocular pressure
decrease in vision or pain in your eyes (possible signs of glaucoma)
difficulty urinating and pain during urination – these may be signs of bladder obstruction or urinary retention

Unknown (frequency cannot be determined from the available data)

dizziness

The reporting of side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box, the tray, and the inhaler after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Store the inhaler in the sealed tray to protect against moisture and only remove it just before first use. Once the tray is opened, the inhaler can be used for a maximum of 6 weeks, starting from the day the tray was opened. Write the date the inhaler should be discarded on the label of the inhaler in the designated space. The date must be noted immediately once the inhaler is removed from the tray.

Store below 30°C.

If the inhaler is stored in the refrigerator, allow it to return to room temperature for at least one hour before use.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substances in this medicine are umeclidinium bromide and vilanterol.

Each single inhalation delivers a dose (the dose that leaves the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms umeclidinium bromide) and 22 micrograms vilanterol (as trifenate).

The other ingredients in this medicine are lactose monohydrate (see section 2 under 'ANORO ELLIPTA contains lactose') and magnesium stearate.

What does ANORO ELLIPTA look like and what is in a package?

ANORO ELLIPTA is an inhalation powder, pre-dispensed.

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

The active substances are contained as a white powder in separate blister packs within the inhaler. ANORO ELLIPTA is available in packages with 1 inhaler with either 7 or 30 doses and in multipacks with 90 (3 inhalers of 30) doses. Not all pack sizes may be marketed. Marketing authorization holder

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Other sources of information

More information about this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>.

Transtoyou

Step-by-step instructions

What is the ELLIPTA inhaler?

The first time you use ANORO ELLIPTA, you do not need to check if the inhaler is working properly; it already contains already pre-dosed doses and is immediately ready for use.

The inhaler is packed in a tray. Do not open the tray until you are ready to start using your new inhaler. When you are ready to use your inhaler, peel off the foil from the tray to open it. The tray contains a desiccant sachet to reduce moisture. Discard this desiccant sachet. – it must not be opened, eaten, or inhaled.

When you remove the inhaler from the tray, it is in the 'closed' position. Do not open the inhaler until you are ready to inhale a dose of the medicine. Once the tray is opened, write the 'Discard by' date on the inhaler label in the designated space. The 'Discard by' date is 6 weeks after the date the tray was opened. From this date, you should no longer use the inhaler. You may discard the tray after first opening.

If the inhaler is stored in the refrigerator, allow it to return to room temperature for at least one hour before use.

The step-by-step instructions for using the inhaler below apply to both the inhaler with 30 doses (supply for 30 days) and the inhaler with 7 doses (supply for 7 days).

1) Read this before you start

If you open and close the cap without inhaling the medicine, the dose is lost.

The lost dose is safely retained in the inhaler but is no longer available.

It is not possible to accidentally take extra medicine or a double dose during one inhalation.

2) Prepare a dose

Wait to open the protective cap until you are ready to inhale your dose. The inhaler do not shake.

Slide the protective cap down until you hear a 'click'.

Your medicine can now be inhaled.

The dose counter will count down by 1 to confirm this.

If the dose counter does not count down when you hear the 'click', the inhaler will not deliver any medicine.

Return it to your pharmacist for advice.

3) Your medicine inhale

Breathe out as deeply as possible while keeping the inhaler away from your mouth. Do not exhale into the inhaler.

Place the mouthpiece between your lips and close your lips firmly around it.

Do not block the air vent with your fingers.

Take one long, steady, and deep breath. Hold your 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 taste or feel the medicine, even if you use the inhaler correctly.kt.

If you want to clean the mouthpiece, use a dry cloth before closing the protective cap.

4) Close the inhaler

Slide the protective cap up as far as possible to cover the mouthpiece.

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