

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

- Keep this leaflet for future reference.

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

- This leaflet 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 ELLIPTA is and what it is used for

What ANORO ELLIPTA is

ANORO ELLIPTA is and what it is for

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

What ANORO ELLIPTA is used for

ANORO ELLIPTA is used to treat chronic obstructive pulmonary disease (COPD) in adults. COPD is a long-term condition characterised by breathing difficulties that start when 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 your doctor.

**2. What you need to know before you use ANORO ELLIPTA****Do not use ANORO ELLIPTA:**

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

- if you have any other medical conditions that mean you should not 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 ELLIPTA to treat asthma)- if you have **heart problems or high blood pressure**- if you have **eye problems 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 **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 ELLIPTA inhaler:

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

Tell your doctor or pharmacist about this medicine if you are below the age of 18 years.

**Other medicines and ANORO ELLIPTA:**

Tell your doctor or pharmacist if you are taking any other medicines. If you are not sure what your medicine contains talk to your doctor or pharmacist.

Some medicines may affect this medicine, 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**

- medicines that affect the amount of potassium in your blood, such as some diuretics (water tablets) or some medicines used to treat asthma (such as methyldantoin or steroids)

- other long-acting medicines similar to this medicine that are used to treat breathing problems, e.g. tiotropium, indacaterol. Don't use ANORO ELLIPTA if you are taking these medicines.

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

**Pregnancy and breast-feeding:**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 ELLIPTA can pass into breast milk. If you are **breast- feeding**, you must **check with your doctor** before you use this medicine. 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 ELLIPTA will affect your ability to drive or use machines.

**ANORO ELLIPTA 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 ELLIPTA:**

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 ELLIPTA regularly**.

It is very important that you use ANORO ELLIPTA every day, as instructed by your doctor. 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 inhaler:**

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

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

**If your symptoms do not improve:**

If you are still having symptoms of 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 ELLIPTA 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 feel sick.**If you forget to use ANORO ELLIPTA:**

Don't inhal an extra dose to make up for a forgotten dose. Just inhale 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 ELLIPTA:**

Use ANORO ELLIPTA as directed by your doctor. 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:**If you have any of the following symptoms after taking ANORO ELLIPTA **stop using this medicine and tell your doctor immediately**.

- Uncommon side effects (may affect up to 1 in 100 people):

- skin rash (hives) or redness

- hives (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)

**Immediate breathing difficulties:**

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:**

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

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

- Uncommon side effects (may affect up to 1 in 10 people):

- pain 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** (may affect up to 1 in 100 people)

- irregular heart beat

- faster heart beat

- awareness of heart beat (palpitations)

- rash

- muscle spasms

- tremor

- taste disturbance

- hairiness.

**Rare** (may affect up to 1 in 1,000 people)

- blurring of 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.

**Not known** (frequency cannot be estimated from the available data)**5. How to store ANORO ELLIPTA:**

Keep this medicine out of the sight and reach of children.

Do not store 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.

Keep the inhaler in the sealed tray in order to protect from moisture and only remove immediately before 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 thrown away 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 stored 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. Details of the pack and other information:****What ANORO ELLIPTA contains:**

The active substances are umeclidinium bromide and vilanterol (as trifenatate). This corresponds to a pre-dispersed dose of 74.2 micrograms umeclidinium bromide equivalent to 65 micrograms of umeclidinium and 22 micrograms of vilanterol (as trifenatate).

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

**ANORO ELLIPTA is an inhalation powder, pre-dispersed.**

The ELLIPTA inhaler 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 (30 doses of 30) doses are also available. Not all pack sizes may be marketed.

**Packed in:****Pharmaline - Lebanon****Licensed by:****GSKSmithKline Export Limited - UK**

Trade name(s) used by the company in the GSK group of companies.

ANORO ELLIPTA was developed in collaboration with Innova, Inc.

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**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medications out of reach of children.

**Council of Arab Health Ministers****Union of Arab Pharmacists****Step-by-step instructions:**

What is the 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.

Your ANORO ELLIPTA inhaler carton contains:

- Tray Lid

- Inhaler

- Desiccant

- Tray

- This leaflet

The inhaler is packaged in a tray. **Don't open the tray until you are ready to start using your new inhaler.** When