

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{PR}ANORO ELLIPTA

umeclidinium and vilanterol dry powder for oral inhalation

Read this carefully before you start taking **ANORO ELLIPTA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ANORO ELLIPTA**.

Serious Warnings and Precautions

ASTHMA-RELATED DEATH

ANORO ELLIPTA should only be used to treat COPD.

ANORO ELLIPTA should not be used to treat asthma.

Long-acting beta₂-agonist (LABA) medicines may increase the chance of death from asthma. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma problems compared with patients who did not use that LABA medicine. This finding may also apply to ANORO ELLIPTA.

What is ANORO ELLIPTA used for?

ANORO ELLIPTA is used in adults as a long-term, once a day maintenance treatment. It can make breathing easier for people who experience breathing difficulties (i.e., shortness of breath) due to a lung disease called Chronic Obstructive Pulmonary Disease or COPD, including chronic bronchitis and emphysema.

If you are a smoker, it is important to quit smoking. This will help decrease the symptoms of COPD and potentially increase your lifespan.

How does ANORO ELLIPTA work?

ANORO ELLIPTA contains 2 medicinal ingredients:

- umeclidinium is a long-acting muscarinic antagonist (LAMA)
- vilanterol is a long-acting beta agonist (LABA).

Both ingredients belong to a group of medicines called bronchodilators. Bronchodilators help to open and relax the muscles of the airways. This allows more air to get in and out of the lungs. This makes it easier for patients with COPD to breathe and helps prevent shortness of breath and wheezing.

There is no cure for COPD, but ANORO ELLIPTA helps to control it. It is therefore important that you continue to take ANORO ELLIPTA regularly even if you feel fine.

What are the ingredients in ANORO ELLIPTA?

Medicinal ingredients: umeclidinium (as bromide) and vilanterol (as trifenate).

Non-medicinal ingredients: lactose monohydrate (which contains milk proteins) and magnesium stearate.

ANORO ELLIPTA comes in the following dosage forms:

Dry powder for oral inhalation delivered by the ELLIPTA inhaler. Each dose contains 62.5 mcg umeclidinium (as bromide) and 25 mcg vilanterol (as trifenate).

Do not use ANORO ELLIPTA:

- if you are allergic to umeclidinium, vilanterol or any of the non-medicinal ingredients in ANORO ELLIPTA (see **What are the ingredients in ANORO ELLIPTA?**)
- to treat sudden severe symptoms of COPD such as sudden shortness of breath or wheezing. Always have a rescue inhaler with you to treat sudden symptoms (“flare ups”). If you do not have a rescue inhaler, ask your healthcare professional to prescribe one for you.
- to treat asthma
- if you have a severe milk protein allergy as ANORO ELLIPTA contains lactose.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ANORO ELLIPTA. Talk about any health conditions or problems you may have, including if you:

- have heart problems, such as
 - heart disease
 - rapid or irregular heart beat or any problems with how your heart beats
 - a condition called “QT prolongation”
- have high blood pressure
- have eye problems such as increased pressure in the eye, or glaucoma
- have prostate or bladder problems, or problems passing urine
- have diabetes
- have ever had seizures
- have thyroid problems
- have low levels of potassium in your blood
- are taking similar medicines for your lung disease
- are pregnant or planning to become pregnant. Talk to your healthcare professional if you become pregnant while taking ANORO ELLIPTA. Your healthcare professional will consider the benefit to you and the risk to your unborn baby.
- are breastfeeding. It is not known if ANORO ELLIPTA can pass into breastmilk.

Other warnings you should know about:

Driving and Using Machines:

If you experience side effects such as headache, dizziness or blurred vision, you should avoid driving or operating machinery.

COPD flare-up:

ANORO ELLIPTA must not be used to relieve a COPD flare-up. If you experience this sort of attack you must use your rescue inhaler (short acting bronchodilator such as salbutamol). Rescue inhalers should only be used as rescue medication while you are taking ANORO ELLIPTA. Your healthcare professional will tell you how to discontinue their **regular** use when you start taking ANORO ELLIPTA.

If you notice any of the following symptoms, talk to your healthcare professional immediately. They could be warning signs that you are having a COPD flare-up or your condition is worsening:

- unusual increase in the severity of breathlessness, cough, wheezing, or fatigue
- unusual colour, amount or thickness of mucus

- tightness in the chest or symptoms of a cold
- you need to use your rescue inhaler more often than usual
- your rescue inhaler does not work as well to relieve your symptoms

Monitoring and Laboratory Tests:

ANORO ELLIPTA can cause abnormal blood test results such as low blood levels of potassium and high blood sugar. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ANORO ELLIPTA:

- Other medications that contain a LABA or a LAMA such as, ipratropium, tiotropium, glycopyrronium, aclidinium
- Beta blockers used in the treatment of high blood pressure or other heart problems such as, propranolol
- Eye drops, such as timolol, used to treat glaucoma
- Medicines used to treat fungal infections such as, ketoconazole, itraconazole, voriconazole
- Clarithromycin, an antibiotic used to treat bacterial infections
- Medicines used to treat HIV infection such as, ritonavir, indinavir, lopinavir, nelfinavir, saquinavir
- Medicines used in the treatment of depression such as, tricyclic antidepressants, monoamine oxidase inhibitors
- Medicines that lower the level of potassium in your blood. These include certain types of diuretics (also known as “water pills”) used to treat high blood pressure and heart problems, and oral corticosteroids, such as prednisone.

How to take ANORO ELLIPTA:

Take ANORO ELLIPTA:

- Exactly as recommended by your healthcare professional. Talk to your healthcare professional if you are unsure.
- Only once a day.
- At the same time each day.
- By inhaling it into the lungs through the mouth.

Unless you talk to your healthcare professional first, **DO NOT:**

- Stop taking ANORO ELLIPTA (even if you feel better).
- Use it more frequently than once a day.
- Increase the dose.

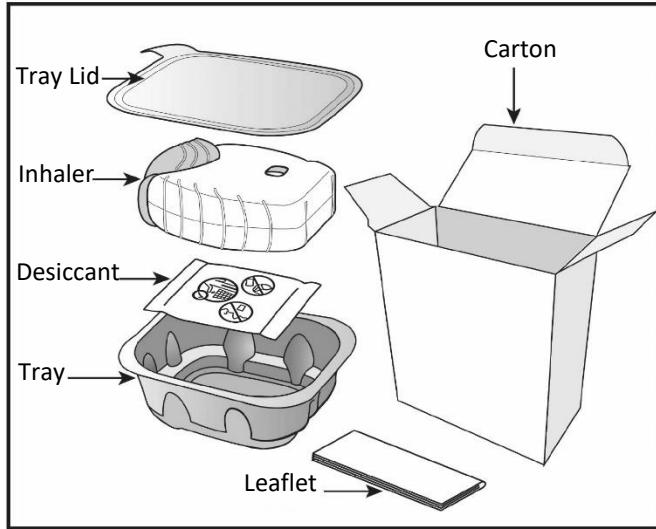
ANORO ELLIPTA has been prescribed for you and should not be given to other people.

Usual dose:

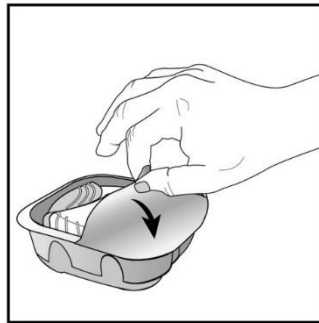
One inhalation through the mouth once a day, preferably at the same time each day.

About your ANORO ELLIPTA Inhaler:

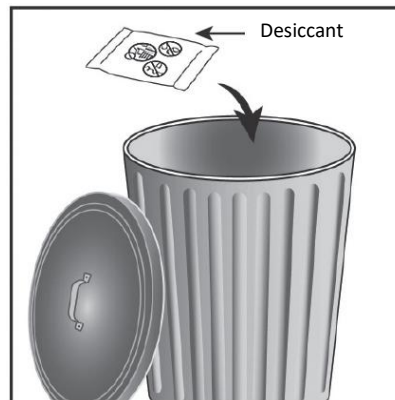
Your ELLIPTA inhaler carton contains:



The plastic ELLIPTA inhaler is packaged in a tray, with a peelable foil lid. **Do not remove the foil lid until you are ready to use the inhaler.** Peel back the lid to open the tray.



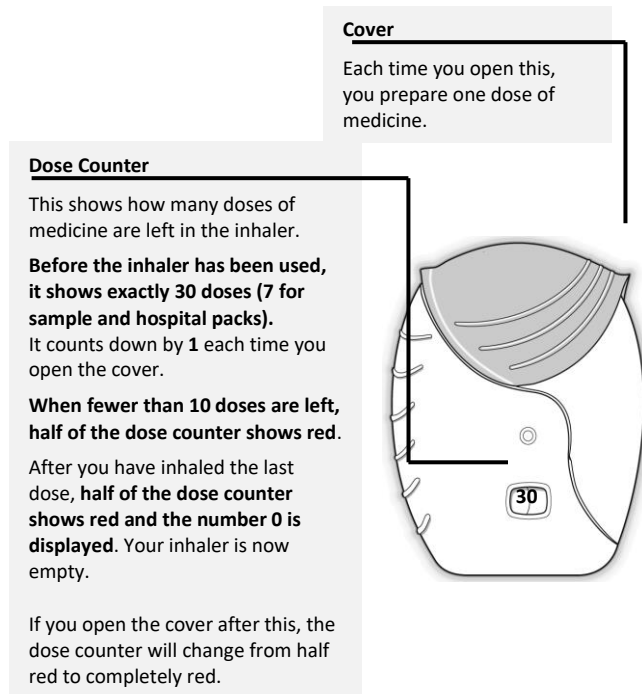
In the tray, you will find a small desiccant sachet containing a drying agent. The desiccant sachet helps to prevent moisture from forming inside the tray. **Keep it away from children and pets.** Do **not** open, eat or inhale the desiccant sachet and **throw it away** once you have opened the lid of the tray. It is dangerous to eat or inhale the contents of the desiccant sachet.



When you take your ELLIPTA inhaler out of its tray it will be in the closed position. 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.

The plastic ELLIPTA inhaler has a light grey body, a red mouthpiece cover, and a dose counter. The mouthpiece and the air vent are hidden by the cover and can only be seen when the cover is opened. The ELLIPTA inhaler is ready-to-use. You will not need to prime it before using it for the first time.



IMPORTANT:

If you open and close the cover of the ELLIPTA inhaler without inhaling the medicine, you will lose a dose. The 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 take a double dose in one inhalation.

Never try to alter the numbers on the counter or detach the counter on the front of the ELLIPTA inhaler. The counter cannot be reset and is permanently attached to the inhaler.

How to use ANORO ELLIPTA:

Please follow the instructions ‘**OPEN, INHALE and CLOSE**’ to use your ELLIPTA inhaler. The instructions shown below apply to both the 30-dose and 7-dose ELLIPTA inhaler.

Keep the cover closed until you are ready to inhale a dose. Do not shake the ELLIPTA inhaler at any point during use as this is not necessary.

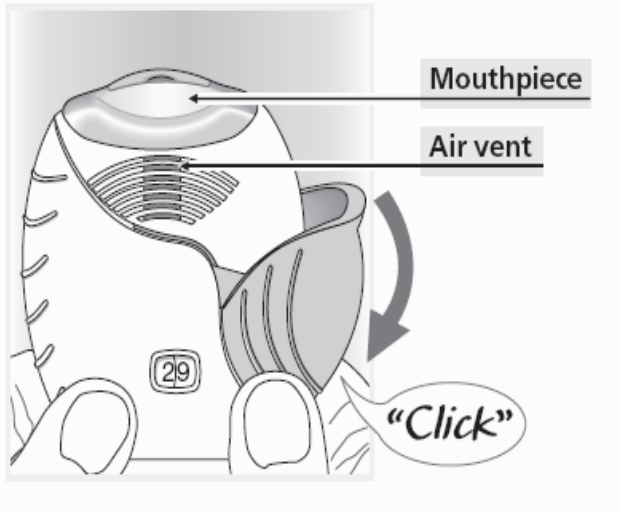
Sit down or stand in a comfortable position.

OPEN:

1. When you are ready, activate the inhaler by sliding the red cover down until you hear a ‘click’ to prepare a dose.
2. The dose counter will now count down by one number (“1”). *It is unlikely the dose counter will not*

count down as you hear the 'click'. If this happens, it may mean the inhaler did not load the medicine. Bring it back to your pharmacist for advice.

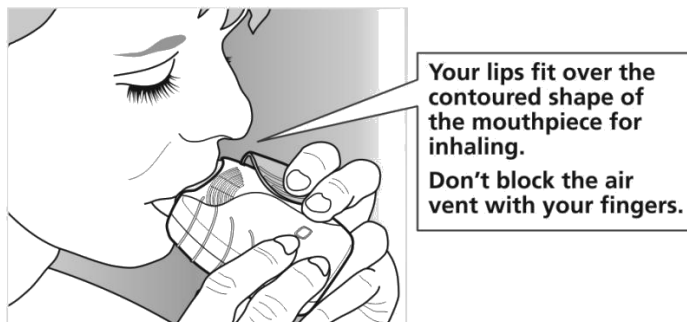
3. While holding the inhaler away from your mouth, exhale a complete breath (i.e. breathe out as far as is comfortable). *Don't breathe out into the inhaler.*



You are now ready to inhale a dose.

INHALE:

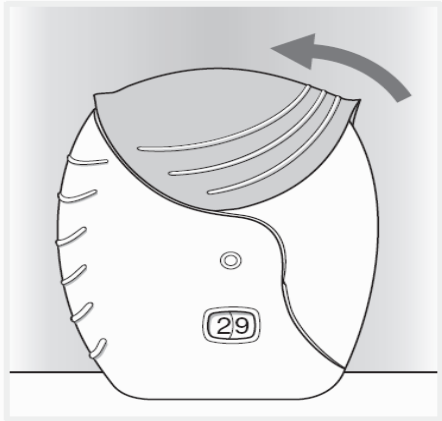
1. Put the mouthpiece between your lips, and close your lips firmly around it. *Don't block the air vent with your fingers.*



2. Take one long, steady, deep breath in. Hold this breath for as long as possible (minimum 3-4 seconds).

CLOSE:

1. Remove the inhaler from your mouth. Exhale slowly and gently. Continue to breathe normally.
2. You can clean the mouthpiece of the inhaler with a clean dry tissue after you have inhaled the medicine.
3. Close the inhaler by sliding the cover upwards as far as it will go to cover the mouthpiece.



You may not be able to taste or feel the medicine (this is normal), even when you are using the inhaler correctly.

Overdose:

If you think you, or a person you are caring for, have taken too much ANORO ELLIPTA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

If you accidentally take more ANORO ELLIPTA than recommended by your healthcare professional, you may feel shaky, have a headache, dry mouth, blurred vision, or feel like your heart is beating faster than usual. Talk to your healthcare professional right away if this occurs.

Missed Dose:

If you miss a dose, take your next dose at the usual time the next day. Do not take an extra dose to make up for a missed one.

What are possible side effects from using ANORO ELLIPTA?

These are not all the possible side effects you may have when taking ANORO ELLIPTA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- sore throat
- cough
- diarrhea, constipation, stomach pain
- pain in arms and legs, muscle spasms, neck pain, back pain
- headache
- feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis)
- dry mouth, taste disturbance
- feeling dizzy, tired, unwell
- swollen painful joints
- tremor
- nervousness, feeling anxious
- difficulty sleeping (insomnia)
- nausea, vomiting

- common cold
- hoarseness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Pneumonia (infection of the lungs): fever, chills, increase in sputum production, change in sputum colour, increased cough or an increase in breathing difficulties (shortness of breath, chest pain)		✓	
Low blood potassium: irregular heartbeats, muscle weakness or spasms and generally feeling unwell		✓	
Chest pain			✓
Fast or irregular heartbeat		✓	
Allergic reaction: skin rash, hives, redness, swelling of the face, lips, tongue or throat (angioedema), becoming very wheezy, coughing or difficulty swallowing or breathing, suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)			✓
RARE			
High or Low blood pressure: headache, ringing in the ears, lightheadedness, dizziness, fainting		✓	
Paradoxical bronchospasm (worsening of symptoms related to breathing): tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation of ANORO ELLIPTA			✓
Difficulty urinating or urinary infection: difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips		✓	
Eye problems: decrease in vision or new or worsened pressure in			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
your eyes (possible signs of glaucoma), eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes			
UNKNOWN			
High blood sugar: frequent urination, thirst, and hunger		✓	
Heart palpitations: awareness of heartbeat		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep out of sight and reach of children. Your medicine may harm them.**
- **Keep your inhaler in a cool dry place away from direct heat or sunlight.** Keep it closed when not in use.
- Do not store ANORO ELLIPTA in areas above 30°C. If you store in a refrigerator, **allow the inhaler to return to room temperature for at least an hour** before use.
- Store in the original package in order to protect from moisture and do not open the foil lid until ready for first use.
- Once the tray is opened:
 - You can use the inhaler for up to 6 weeks, starting from the date you opened the lid of the tray.
 - Write the date the inhaler should be discarded on the inhaler in the space provided.
- Safely discard ANORO ELLIPTA when the dose counter reads “0” or 6 weeks after you open the lid of the tray, whichever comes first. **ANORO ELLIPTA expires 6 weeks after you have opened**

the lid of the tray.

If you want more information about ANORO ELLIPTA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

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