MEDICATION GUIDE

ANORO® ELLIPTA® [*a-nor′oh e-LIP-ta*]

(umeclidinium and vilanterol inhalation powder)

for oral inhalation

What is the most important information I should know about ANORO ELLIPTA?

ANORO ELLIPTA is only approved for use in chronic obstructive pulmonary disease (COPD). ANORO ELLIPTA is NOT approved for use in asthma.

ANORO ELLIPTA can cause serious side effects, including:

- **People with asthma who take long-acting beta$_2$-adrenergic agonist (LABA) medicines, such as vilanterol (one of the medicines in ANORO ELLIPTA), have an increased risk of death from asthma problems.**
- **It is not known if LABA medicines such as vilanterol increase the risk of death in people with COPD.**
- **Call your healthcare provider if breathing problems worsen over time while using ANORO ELLIPTA.** You may need different treatment.
- **Get emergency medical care if:**
  - your breathing problems worsen quickly.
  - you use your rescue inhaler, but it does not relieve your breathing problems.

What is ANORO ELLIPTA?

- ANORO ELLIPTA combines an anticholinergic, umeclidinium, and a LABA medicine, vilanterol.
- Anticholinergic and LABA medicines help the muscles around the airways in your lungs stay relaxed to prevent symptoms such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- ANORO ELLIPTA is a prescription medicine used to treat COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. ANORO ELLIPTA is used long term as 1 inhalation, 1 time each day, to improve symptoms of COPD for better breathing.
- **ANORO ELLIPTA is not for use to treat sudden symptoms of COPD.** Always have a rescue inhaler (an inhaled, short-acting bronchodilator) with you to treat sudden symptoms. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.
- **ANORO ELLIPTA is not for the treatment of asthma. It is not known if ANORO ELLIPTA is safe and effective in people with asthma.**
- ANORO ELLIPTA should not be used in children. It is not known if ANORO ELLIPTA is safe and effective in children.

Do not use ANORO ELLIPTA if you:

- have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- are allergic to umeclidinium, vilanterol, or any of the ingredients in ANORO ELLIPTA. See “What are the ingredients in ANORO ELLIPTA?” below for a complete list of ingredients.

Before using ANORO ELLIPTA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have high blood pressure.
- have seizures.
- have thyroid problems.

- have diabetes.
- have liver problems.
- have eye problems such as glaucoma. ANORO ELLIPTA may make your glaucoma worse.
- have prostate or bladder problems, or problems passing urine. ANORO ELLIPTA may make these problems worse.
- are allergic to any of the ingredients in ANORO ELLIPTA, any other medicines, or food products. See "What are the ingredients in ANORO ELLIPTA?" below for a complete list of ingredients.
- are pregnant or planning to become pregnant. It is not known if ANORO ELLIPTA may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in ANORO ELLIPTA pass into your milk and if they can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ANORO ELLIPTA and certain other medicines may interact with each other. This may cause serious side effects.

Especially tell your healthcare provider if you take:

- anticholinergics (including tiotropium, ipratropium, aclidinium)
- atropine
- antifungal or anti-HIV medicines

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use ANORO ELLIPTA?

Read the step-by-step instructions for using ANORO ELLIPTA at the end of this Medication Guide.

- **Do not** use ANORO ELLIPTA unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- Use ANORO ELLIPTA exactly as your healthcare provider tells you to use it. **Do not** use ANORO ELLIPTA more often than prescribed.
- Use 1 inhalation of ANORO ELLIPTA 1 time each day. Use ANORO ELLIPTA at the same time each day.
- If you miss a dose of ANORO ELLIPTA, take it as soon as you remember. Do not take more than 1 inhalation per day. Take your next dose at your usual time. Do not take 2 doses at 1 time.
- If you take too much ANORO ELLIPTA, call your healthcare provider or go to the nearest hospital emergency room right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.
- **Do not use other medicines that contain a LABA or an anticholinergic for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA or anticholinergic medicines.
- Do not stop using ANORO ELLIPTA unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- **ANORO ELLIPTA does not relieve sudden breathing problems.** Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.
- Call your healthcare provider or get medical care right away if:
  - your breathing problems get worse.
  - you need to use your rescue inhaler more often than usual.
  - your rescue inhaler does not work as well to relieve your symptoms.

What are the possible side effects of ANORO ELLIPTA?

ANORO ELLIPTA can cause serious side effects, including:

- **See "What is the most important information I should know about ANORO ELLIPTA?"**
- **sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop using ANORO ELLIPTA and call your healthcare provider right away.
- **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following symptoms of a serious allergic reaction:
  - rash
  - hives
  - swelling of your face, mouth, and tongue
  - breathing problems
- **effects on heart**
  - increased blood pressure
  - a fast or irregular heartbeat, awareness of heartbeat
  - chest pain
- **effects on nervous system**
  - tremor
  - nervousness
- **new or worsened eye problems including acute narrow-angle glaucoma.** Acute narrow-angle glaucoma can cause permanent loss of vision if not treated. Symptoms of acute narrow-angle glaucoma may include:
  - eye pain or discomfort
  - nausea or vomiting
  - blurred vision
  - seeing halos or bright colors around lights
  - red eyes

  If you have these symptoms, call your healthcare provider right away before taking another dose.
- **urinary retention.** People who take ANORO ELLIPTA may develop new or worse urinary retention. Symptoms of urinary retention may include:
  - difficulty urinating
  - painful urination
  - urinating frequently
  - urination in a weak stream or drips

  If you have these symptoms of urinary retention, stop taking ANORO ELLIPTA and call your healthcare provider right away before taking another dose.
- **changes in laboratory blood levels**, including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia)

Common side effects of ANORO ELLIPTA include:

- sore throat
- sinus infection
- lower respiratory infection
- common cold symptoms
- constipation
- diarrhea
- pain in your arms or legs
- muscle spasms
- neck pain
- chest pain

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with ANORO ELLIPTA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ANORO ELLIPTA?

- Store ANORO ELLIPTA at room temperature between 68°F and 77°F (20°C and 25°C). Keep in a dry place away from heat and sunlight.
- Store ANORO ELLIPTA in the unopened foil tray and only open when ready for use.
- Safely throw away ANORO ELLIPTA in the trash 6 weeks after you open the foil tray or when the counter reads “0”, whichever comes first. Write the date you open the tray on the label on the inhaler.
- **Keep ANORO ELLIPTA and all medicines out of the reach of children.**

General information about the safe and effective use of ANORO ELLIPTA.

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use ANORO ELLIPTA for a condition for which it was not prescribed. Do not give your ANORO ELLIPTA to other people, even if they have the same condition that you have. It may harm them.

This Medication Guide summarizes the most important information about ANORO ELLIPTA. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about ANORO ELLIPTA that was written for healthcare professionals.

What are the ingredients in ANORO ELLIPTA?

Active ingredients: umeclidinium, vilanterol

Inactive ingredients: lactose monohydrate (contains milk proteins), magnesium stearate

For more information about ANORO ELLIPTA, call 1-888-825-5249 or visit our website at www.ANORO.com.

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ANORO ELLIPTA was developed in collaboration with INNOVIVA.

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