PATIENT INFORMATION

INCRUSE ELLIPTA [(IN-cruise e-LIP-ta)
(umeclidinium inhalation powder)
for oral inhalation

What is INCRUSE ELLIPTA?

- INCRUSE ELLIPTA is an anticholinergic medicine. Anticholinergic 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.
- INCRUSE ELLIPTA is a prescription medicine used to treat chronic obstructive pulmonary disease (COPD). COPD is a long-term (chronic) lung disease that includes chronic bronchitis, emphysema, or both. INCRUSE ELLIPTA is used long term as 1 inhalation 1 time each day to improve symptoms of COPD for better breathing.
- INCRUSE ELLIPTA is not used to relieve sudden breathing problems and will not replace a rescue inhaler.
- INCRUSE ELLIPTA should not be used in children. It is not known if INCRUSE ELLIPTA is safe and effective in children.

Do not use INCRUSE ELLIPTA if you:

- have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- are allergic to umeclidinium or any of the ingredients in INCRUSE ELLIPTA. See the end of this leaflet for a complete list of ingredients in INCRUSE ELLIPTA.

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

- have heart problems.
- have eye problems such as glaucoma. INCRUSE ELLIPTA may make your glaucoma worse.
- have prostate or bladder problems, or problems passing urine. INCRUSE ELLIPTA may make these problems worse.
- are allergic to any of the ingredients in INCRUSE ELLIPTA, any other medicines, or food products. See “What are the ingredients in INCRUSE ELLIPTA?” below for a complete list of ingredients.
- are pregnant or plan to become pregnant. It is not known if INCRUSE ELLIPTA may harm your unborn baby.
- are breastfeeding. It is not known if the medicine in INCRUSE ELLIPTA passes into your breast milk and if it 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. INCRUSE 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

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 INCRUSE ELLIPTA?

Read the step-by-step instructions for using INCRUSE ELLIPTA at the end of this Patient Information.

- Do not use INCRUSE ELLIPTA unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
Use INCRUSE ELLIPTA exactly as your healthcare provider tells you to use it. Do not use INCRUSE ELLIPTA more often than prescribed.

Use 1 inhalation of INCRUSE ELLIPTA 1 time each day. Use INCRUSE ELLIPTA at the same time each day.

If you miss a dose of INCRUSE ELLIPTA, take it as soon as you remember. Do not take more than 1 inhalation each day. Take your next dose at your usual time. Do not take 2 doses at 1 time.

If you take too much INCRUSE 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 an anticholinergic for any reason. Ask your healthcare provider or pharmacist if any of your other medicines are anticholinergic medicines.

Do not stop using INCRUSE ELLIPTA, even if you are feeling better, unless your healthcare provider tells you to.

Talk to your healthcare provider right away if you stop using INCRUSE ELLIPTA.

INCRUSE ELLIPTA does not relieve sudden symptoms of COPD and you should not take extra doses of INCRUSE ELLIPTA to relieve these sudden symptoms. 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 INCRUSE ELLIPTA?

INCRUSE ELLIPTA can cause serious side effects, including:

- **sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop taking INCRUSE ELLIPTA and call your healthcare provider right away.

- **serious allergic reactions (anaphylaxis).** Stop using INCRUSE ELLIPTA and call your healthcare provider or go to the nearest emergency room right away if you get any of the following symptoms of a serious allergic reaction:
  - rash
  - hives
  - severe itching
  - swelling of your face, lips, mouth, or tongue
  - breathing problems

- **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
  - urine in a weak stream or drips

If you have these symptoms, call your healthcare provider right away before taking another dose.

- **urinary retention.** People who take INCRUSE 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 INCRUSE ELLIPTA, and call your healthcare provider right away before taking another dose.
Common side effects of INCRUSE ELLIPTA include:

- upper respiratory tract infection
- muscle pain
- stuffy or runny nose
- tooth pain
- cough
- stomach pain
- mouth and throat pain
- bruising or dark areas of skin
- joint pain
- fast or irregular heartbeat
- change in taste

These are not all the possible side effects of INCRUSE 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 INCRUSE ELLIPTA?

- Store INCRUSE 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 INCRUSE ELLIPTA in the unopened foil tray and only open when ready for use.
- Safely throw away INCRUSE 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 INCRUSE ELLIPTA and all medicines out of the reach of children.

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information. Do not use INCRUSE ELLIPTA for a condition for which it was not prescribed. Do not give INCRUSE ELLIPTA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about INCRUSE ELLIPTA that was written for health professionals.

What are the ingredients in INCRUSE ELLIPTA?

Active ingredient: umeclidinium

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

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

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(umeclidinium inhalation powder)
for oral inhalation

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 to be inhaled.
• It is not possible to accidentally take a double dose or an extra dose in 1 inhalation.

Your INCRUSE ELLIPTA inhaler

- INCRUSE ELLIPTA comes in a foil tray.
- Peel back the lid to open the tray. **See Figure A.**
- The tray contains a desiccant to reduce moisture. Do not eat or breathe in (inhale). Throw it away in the household trash out of reach of children and pets. **See Figure B.**

**Important Notes:**
- Your inhaler contains 30 doses (7 doses if you have a sample or institutional pack).
- Each time you fully open the cover of the inhaler (you will hear a clicking sound), a dose is ready to be inhaled. This is shown by a decrease in the number on the counter.
- If you open and close the cover without inhaling the medicine, you will lose the dose. The lost dose will be held in the inhaler, but it will no longer be available to be inhaled. It is not possible to accidentally take a double dose or an extra dose in 1 inhalation.
- **Do not** open the cover of the inhaler until you are ready to use it. To avoid wasting doses after
the inhaler is ready, do not close the cover until after you have inhaled the medicine.

- Write the “Tray opened” and “Discard” dates on the inhaler label. The “Discard” date is 6 weeks from the date you open the tray.

Check the counter. See Figure C.

- Before the inhaler is used for the first time, the counter should show the number 30 (7 if you have a sample or institutional pack). This is the number of doses in the inhaler.
- Each time you open the cover, you prepare 1 dose of medicine.
- The counter counts down by 1 each time you open the cover.

Prepare your dose:

Wait to open the cover until you are ready to take your dose.

Step 1. Open the cover of the inhaler. See Figure D.
- Slide the cover down to show (expose) the mouthpiece. You should hear a “click.” The counter will count down by 1 number. You do not need to shake this kind of inhaler. Your inhaler is now ready to use.
- If the counter does not count down as you hear the click, the inhaler will not deliver the medicine. Call your healthcare provider or pharmacist if this happens.

Step 2. Breathe out. See Figure E.
- While holding the inhaler away from your mouth, breathe out (exhale) fully. Do not breathe out into the mouthpiece.
Step 3. Inhale your medicine. See Figure F.

- Put the mouthpiece between your lips, and close your lips firmly around it. Your lips should fit over the curved shape of the mouthpiece.
- Take 1 long, steady, deep breath in through your mouth. Do not breathe in through your nose.

- Do not block the air vent with your fingers. See Figure G.

- Remove the inhaler from your mouth and hold your breath for about 3 to 4 seconds (or as long as comfortable for you). See Figure H.
Step 4. Breathe out slowly and gently. See Figure I.
- You may not taste or feel the medicine, even when you are using the inhaler correctly.
- Do not take another dose from the inhaler even if you do not feel or taste the medicine.

![Figure I](image)

Step 5. Close the inhaler. See Figure J.
- You can clean the mouthpiece if needed, using a dry tissue, before you close the cover. Routine cleaning is not required.
- Slide the cover up and over the mouthpiece as far as it will go.

![Figure J](image)

Important Note: When should you get a refill?
- When you have less than 10 doses remaining in your inhaler, the left half of the counter shows red as a reminder to get a refill. See Figure K.
- After you have inhaled the last dose, the counter will show “0” and will be empty.
- Throw the empty inhaler away in your household trash out of reach of children and pets.

![Figure K](image)