

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrINCRUSE ELLIPTA

umeclidinium dry powder for oral inhalation

Read this carefully before you start taking **INCRUSE 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 **INCRUSE ELLIPTA**.

What is INCRUSE ELLIPTA used for?

INCRUSE 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 INCRUSE ELLIPTA work?

INCRUSE ELLIPTA is a long-acting muscarinic antagonist (LAMA).

INCRUSE ELLIPTA helps open and relax the muscles of the airways, which 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 INCRUSE ELLIPTA helps to control it. It is therefore important that you continue to take INCRUSE ELLIPTA regularly even if you feel fine.

What are the ingredients in INCRUSE ELLIPTA?

Medicinal ingredients: Umeclidinium (as bromide).

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

INCRUSE 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).

Do not use INCRUSE 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.
- If you are allergic to umeclidinium, or any of the nonmedicinal ingredients in INCRUSE ELLIPTA.
- If you have a lactose or severe milk protein allergy, as INCRUSE ELLIPTA contains lactose.

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

- have heart problems.
- have eye problems such as increased pressure in the eye, or glaucoma.

- have prostate or bladder problems, or problems passing urine.
- have any allergies to food or drugs.
- are pregnant or planning to become pregnant. Talk to your healthcare professional if you become pregnant while taking INCRUSE ELLIPTA. Your healthcare professional will consider the benefit to you and the risk to your unborn baby.
- are breastfeeding. It is not known if INCRUSE ELLIPTA can pass into breastmilk.

Other warnings you should know about:

Driving and Using Machines:

INCRUSE ELLIPTA can cause dizziness or blurred vision. Use caution when driving and using machines until you know how INCRUSE ELLIPTA affects you.

COPD flare-up:

INCRUSE ELLIPTA should 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 INCRUSE ELLIPTA. Your healthcare professional will tell you how to discontinue their regular use when you start taking INCRUSE ELLIPTA. If you notice any of the following symptoms, tell 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 medication more often than usual.
- your rescue medication does not work as well to relieve your symptoms.

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 INCRUSE ELLIPTA:

- Other medications that contain a short- or long-acting muscarinic antagonist (e.g., ipratropium, tiotropium, glycopyrronium, aclidinium).

How to take INCRUSE ELLIPTA:

One dose of INCRUSE ELLIPTA lasts a full 24 hours.

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

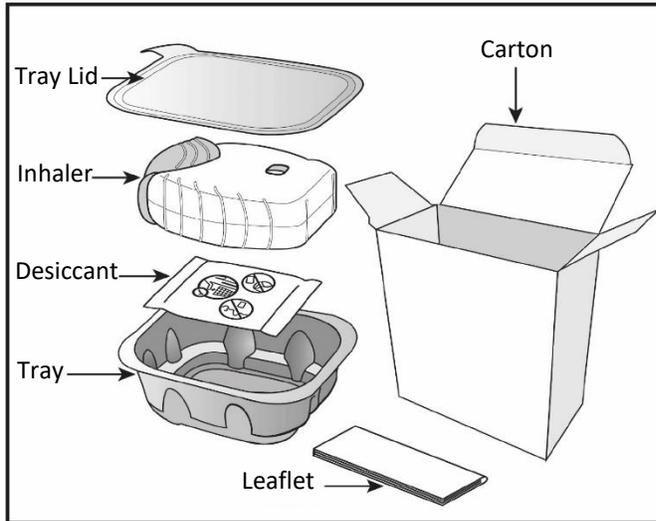
INCRUSE ELLIPTA has been prescribed for you and should not be given to other people.

Usual dose:

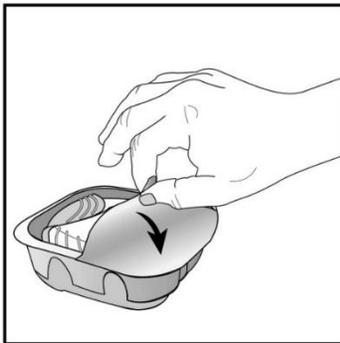
One inhalation through the mouth once a day, preferably at the same time each day.

About your INCRUSE ELLIPTA Inhaler:

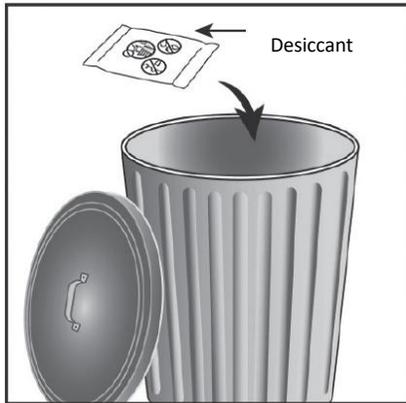
Your ELLIPTA inhaler carton contains:



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.

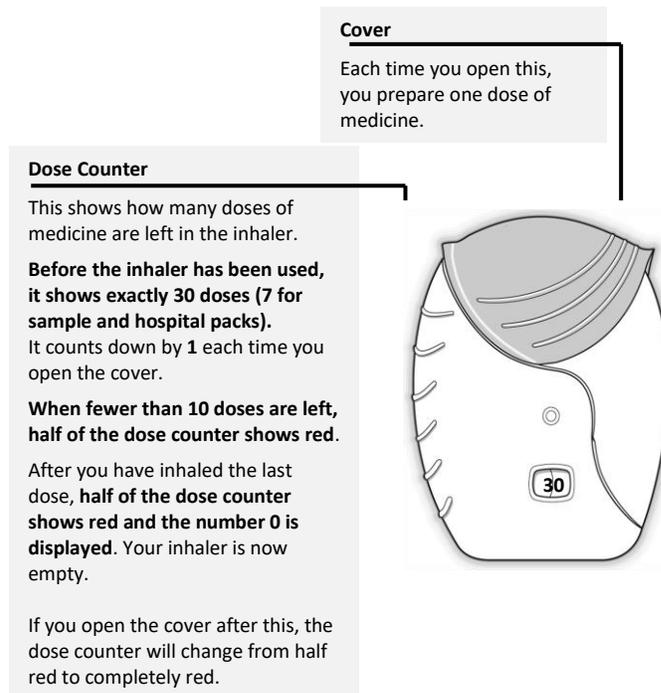


In the tray, you will find a small desiccant sachet containing a drying agent. The desiccant sachet helps to prevent moisture from forming inside the tray. **Keep it away from children and pets.** Do **not** open, eat or inhale the desiccant sachet and **throw it away** once you have opened the lid of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

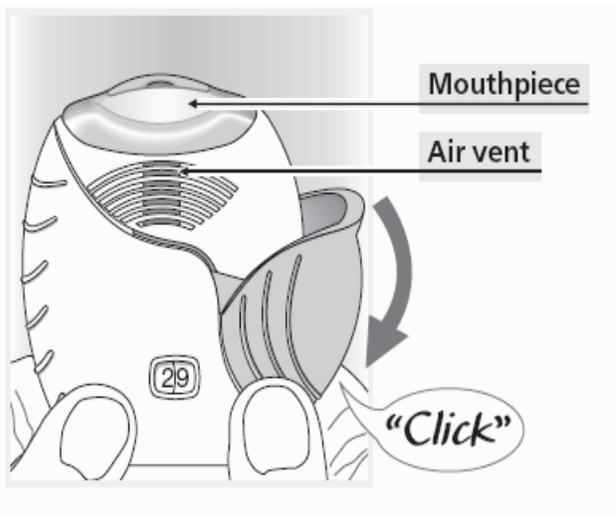
Please follow the instructions '**OPEN, INHALE, and CLOSE**' to use your ELLIPTA inhaler. The instructions shown below apply to both the 30-dose and 7-dose ELLIPTA inhaler.

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:

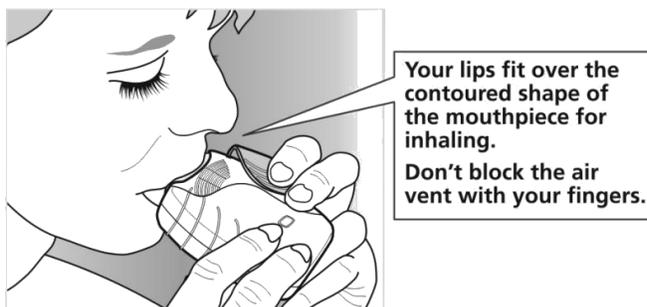
1. When you are ready, activate the inhaler by sliding the light green cover down until you hear a 'click' to prepare a dose.
2. The dose counter will now count down by one number ("1"). *It is unlikely the dose counter will not count down as you hear the 'click'. If this happens, it may mean the inhaler 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:

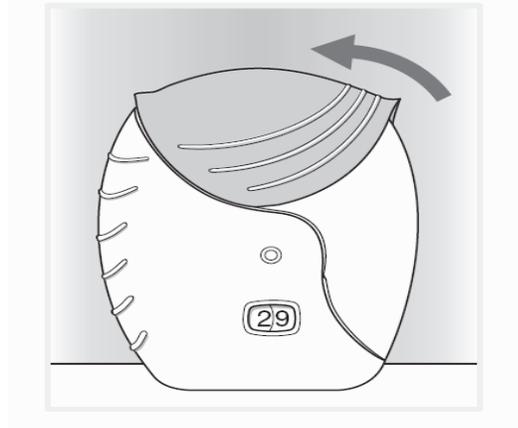
1. Put the mouthpiece between your lips, and close your lips firmly around it. *Don't block the air vent with your fingers.*



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 accidentally take more INCRUSE ELLIPTA than recommended by your healthcare professional, you may 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.

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

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 INCRUSE ELLIPTA?

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

Side effects may include:

- Cough, hoarseness
- diarrhea, stomach pain

- constipation
- pain in arms and legs, 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), runny nose, sore throat, mouth and throat pain
- dry mouth, toothache, taste disturbance
- feeling dizzy
- joint pain, muscle pain
- nausea
- depression
- common cold
- bruising

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	
COMMON			
Fast heartbeat		✓	
UNCOMMON			
Pneumonia (an infection of the lungs): fever, chills, increase in mucus production, change in mucus colour, increased cough or an increase in breathing difficulties (shortness of breath, chest pain).		✓	
Irregular heartbeat		✓	
Allergic reaction: skin rash, hives, redness, swelling of the face, lips, tongue or throat, becoming very wheezy, coughing or difficulty swallowing or breathing; suddenly feeling weak or light-headed (may lead to collapse or loss of consciousness).			✓
UNKNOWN			
Eye problems: decrease in vision, or new or worsened pressure in your eyes (possible signs of glaucoma), eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes.			✓
Paradoxical bronchospasm (worsening of symptoms related to breathing): tightness of the chest			✓

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	
associated with coughing, or breathlessness immediately after inhalation of INCRUSE ELLIPTA.			
Difficulty urinating or urinary infection: difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips.		✓	

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/adverse-reaction-reporting.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 INCRUSE 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 INCRUSE ELLIPTA when the dose counter reads “0” or 6 weeks after you open the lid of the tray, whichever comes first. **INCRUSE ELLIPTA expires 6 weeks after you have opened the lid of the tray.**

If you want more information about INCRUSE 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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