

PART III: CONSUMER INFORMATION

PrINCRUSE ELLIPTA

umeclidinium (as bromide) dry powder for oral inhalation

This leaflet is part III of a three-part "Product Monograph" published when INCRUSE ELLIPTA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INCRUSE ELLIPTA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

INCRUSE ELLIPTA is used 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.

What it does:

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

INCRUSE ELLIPTA relaxes the muscles in the walls of small airways in the lungs. This medicine works to help open the airways and make it easier for air to get in and out of the lungs. When taken regularly, INCRUSE ELLIPTA helps keep the airways open, which can help 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.

When it should not be used:

Do not use INCRUSE ELLIPTA:

- To treat sudden severe symptoms of COPD such as sudden shortness of breath or wheezing. If you experience this sort of attack you must use a rapid onset, short duration, inhaled bronchodilator such as salbutamol (rescue medication). Keep this rescue medication with you at all times.
- If you are allergic to any of the medicinal or nonmedicinal ingredients contained in the product.

- If you have a lactose or severe milk protein allergy.
- If you are younger than 18 years of age.

What the medicinal ingredient is:

Umeclidinium.

What the nonmedicinal ingredients are:

Lactose monohydrate (which contains milk proteins) and magnesium stearate.

What dosage forms it comes in:

Dry powder for oral inhalation delivered by the ELLIPTA inhaler. Each dose contains 62.5 mcg umeclidinium per blister.

Each inhaler contains one month's supply (one dose per day for 30 days).

If a sample is given to you by your doctor, it will contain one week's supply (one dose per day for 7 days).

WARNINGS AND PRECAUTIONS

BEFORE you use INCRUSE ELLIPTA talk to your doctor or pharmacist if you have any of the following:

- Heart problems.
- Eye problems such as increased pressure in the eye, or glaucoma.
- Prostate or bladder problems, or problems passing urine.
- Any allergies to food or drugs.

Pregnancy and breast-feeding:

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take INCRUSE ELLIPTA without asking your doctor. Your doctor will consider the benefit to you and the risk to your unborn baby.

It is not known whether the ingredients of INCRUSE ELLIPTA can pass into breast milk. If you are breast-feeding, check with your doctor before you take INCRUSE ELLIPTA.

Driving and Using Machines:

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

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 a rapid onset, short duration, inhaled bronchodilator such as salbutamol (i.e. rescue medication).

If you notice any of the following symptoms, tell your doctor 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.

Short-acting bronchodilators should only be used as rescue medication while you are taking INCRUSE ELLIPTA. Your doctor will instruct you on how to discontinue their **regular** use when you start taking INCRUSE ELLIPTA.

This medication has been prescribed for you and should not be given to other people.

INTERACTIONS WITH THIS MEDICATION

Be sure to tell your doctor or pharmacist:

- About any medicines you are currently taking, or have taken recently, including medications that did not require a prescription, e.g. alternative medicines, vitamins and minerals.
- If you start any new medications.

Drugs that may interact with INCRUSE ELLIPTA include:

- Other medications that contain a short- or long-acting muscarinic antagonist (e.g. ipratropium, tiotropium, glycopyrronium, aclidinium). Ask your doctor or pharmacist if any of your other medicines are ipratropium or LAMA containing medicines.

PROPER USE OF THIS MEDICATION

If you have any difficulties or you are unsure about how or when to take INCRUSE ELLIPTA, check with your doctor or pharmacist.

One dose of INCRUSE ELLIPTA lasts a full 24 hours.

Take INCRUSE ELLIPTA:

- Exactly as recommended by your doctor
- Only once a day
- At the same time each day
- By inhaling it into the lungs through the mouth

Unless you talk to your doctor first, **DO NOT**:

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

Usual Adult Dose:

One inhalation through the mouth once a day.

Taking INCRUSE ELLIPTA at the same time every day will help you remember to use it.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

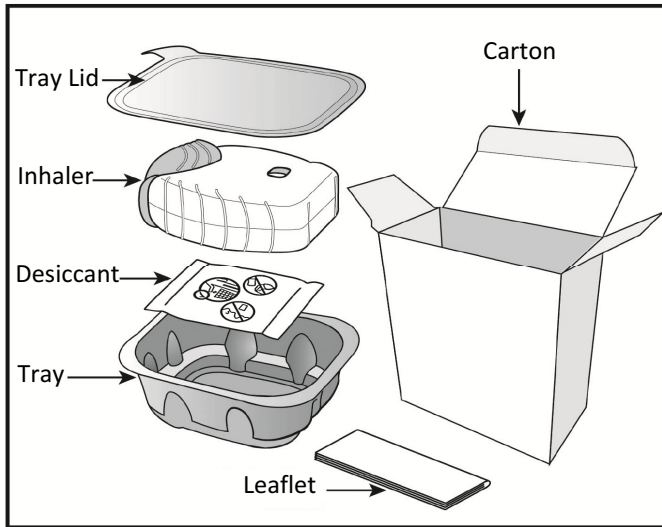
If you accidentally take a larger dose of INCRUSE ELLIPTA (i.e., more drug than recommended by your doctor), you may have a headache, dry mouth, blurred vision, or feel like your heart is beating faster than usual. Talk to your doctor or pharmacist right away if this occurs.

Missed Dose:

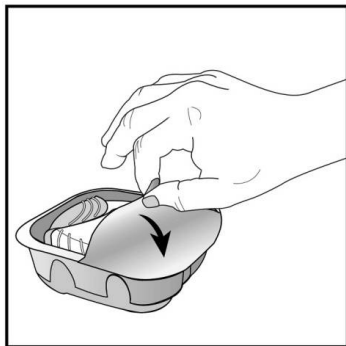
If you miss a dose, take your next dose at the usual time the next day. Do not take an extra dose to make up for a missed one.

About your INCRUSE ELLIPTA Inhaler:

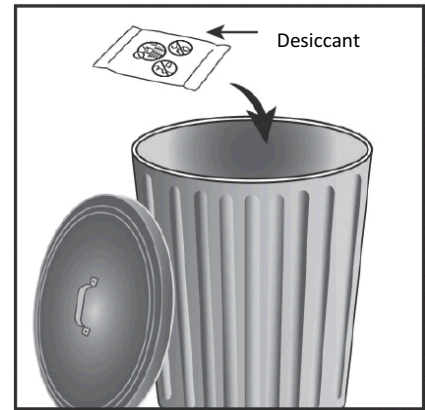
Your ELLIPTA inhaler carton contains:



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.

Cover

Each time you open this, you prepare one dose of medicine.

Dose Counter

This shows how many doses of medicine are left in the inhaler.

Before the inhaler has been used, it shows exactly 30 doses (7 for sample and hospital packs).

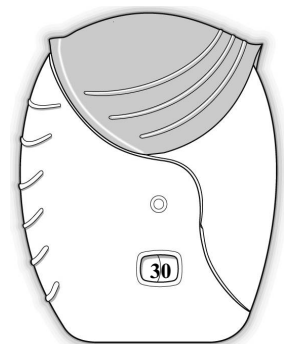
It counts down by 1 each time you open the cover.

When fewer than 10 doses are left, half of the dose counter shows red.

After you have inhaled the last dose, **half of the dose counter shows red and the number 0 is displayed.**

Your inhaler is now empty.

If you open the cover after this, the dose counter will change from half red to completely red.



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

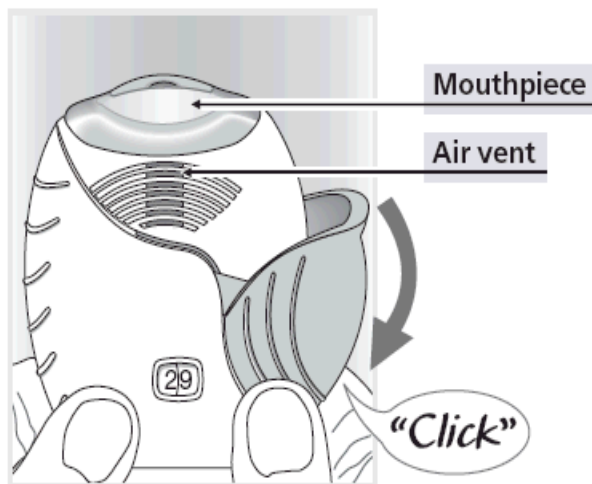
Please follow the instructions ‘**OPEN, INHALE, and CLOSE**’ to use your ELLIPTA inhaler. The instructions shown below apply to both the 30-dose and 7-dose ELLIPTA inhaler.

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.*

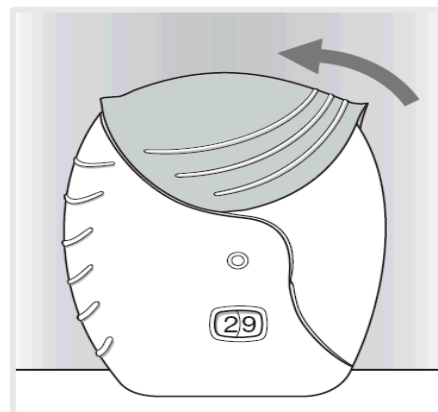


Your lips fit over the contoured shape of the mouthpiece for inhaling. Don't block the air vent with your fingers.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- cough
- 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
- dry mouth, toothache, taste disturbance
- feeling dizzy

- joint pain, muscle pain
- nausea
- depression
- common cold
- bruising

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Fast heartbeat		✓	
Uncommon	Pneumonia (an 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).		✓	
	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).			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown	Eye disorders: 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 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		✓	

This is not a complete list of side effects. For any unexpected effects while taking INCRUSE ELLIPTA, contact your doctor or pharmacist.

HOW TO STORE IT

- 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.**

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

You may need to read this package insert again. **Please do not throw it away** until you have finished your medicine.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca> or by contacting the sponsor,

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