

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### PrARNUIITY ELLIPTA

#### fluticasone furoate dry powder for oral inhalation

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

#### What is ARNUITY ELLIPTA used for?

ARNUIITY ELLIPTA is used in adults and children (12 years of age and older) for the long-term maintenance treatment of asthma.

#### How does ARNUITY ELLIPTA work?

ARNUIITY ELLIPTA contains fluticasone furoate and belongs to a group of medicines known as “inhaled corticosteroids”. It reduces inflammation in the airways of the lungs, which can ease breathing problems.

This medicine does not cure asthma but helps to prevent and control its symptoms.

#### What are the ingredients in ARNUITY ELLIPTA?

Medicinal ingredient: Fluticasone furoate.

Non-medicinal ingredient: Lactose monohydrate (which contains milk proteins).

#### ARNUIITY ELLIPTA comes in the following dosage forms:

Dry powder for oral inhalation (delivered by the ELLIPTA inhaler): 100 mcg or 200 mcg of fluticasone furoate for each dose.

#### Do not use ARNUITY ELLIPTA if:

- you are allergic to fluticasone furoate or any of the other ingredients in ARNUITY ELLIPTA.
- you have a severe milk protein allergy. ARNUITY ELLIPTA contains a lactose (milk protein) component.
- you have a sudden asthma attack. **ARNUIITY ELLIPTA is NOT a rescue inhaler and should NOT be used to give you fast relief from your asthma attack.** Always use a rescue inhaler, such as salbutamol, during a sudden asthma attack.

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

- have liver problems.
- have or at a higher risk of having weak bones or low bone mineral content (osteoporosis). This can include if you:
  - are immobilized for prolonged periods;
  - have a family history of osteoporosis;

- have gone through menopause;
  - use tobacco;
  - have poor nutrition or diet;
  - are at an advanced age; or
  - have been taking medicines that can reduce bone mass for a long period of time (e.g., anticonvulsants and oral corticosteroids).
- have eye problems (e.g., glaucoma, cataracts, blurry vision, or other changes in vision).
  - are pregnant or planning to become pregnant. ARNUITY ELLIPTA is not usually recommended for use during pregnancy. Your healthcare professional will consider the benefit to you and the risk to your unborn baby.
  - are breastfeeding or planning to breastfeed. It is not known if ARNUITY ELLIPTA can pass into breastmilk.
  - have ever had to stop taking another medication for your breathing problems because you were allergic to it or it caused problems.
  - have been taking other corticosteroids by mouth or inhalation.
  - have not had chickenpox or measles, or have not been vaccinated against these diseases.
  - have or have previously had any type of viral, bacterial, fungal, or parasitic infection (e.g., herpes simplex of the eye, tuberculosis infections, and thrush or yeast infection in your mouth).

**Other warnings you should know about:**

ARNUITY ELLIPTA does not relieve 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.

If you experience sudden shortness of breath or wheezing, or develop any other symptoms of an asthma attack, you should use your rapid onset, short duration, inhaled bronchodilator (e.g., salbutamol) and seek medical attention.

**Measles and chickenpox:** You should avoid coming into contact with people who have measles or chicken pox while taking ARNUITY ELLIPTA. If you are exposed, tell your healthcare professional right away.

**Eye problems:** Medicines like ARNUITY ELLIPTA can cause eye disorders:

- Cataracts: Clouding of the lens in the eye, blurry vision, eye pain;
- Glaucoma: An increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss;
- Central serous chorioretinopathy (CSCR): Blurry vision or other changes in vision.

Contact your healthcare professional if you experience blurry vision or other vision problems. You should have regular eye exams.

**Worsening of your condition:** If you notice any of the following symptoms, tell your healthcare professional right away. They could be warning signs that your condition may be worsening.

- There is a change in your symptoms such as more coughing, attacks of wheezing, chest tightness, or an unusual increase in the severity of the breathlessness.
- You wake up at night with chest tightness, wheezing or shortness of breath.
- You are using increasing amounts of your rescue inhaler.

**Monitoring and testing:** Your healthcare professional will monitor your health throughout your treatment with ARNUITY ELLIPTA. They may do specific tests to monitor your growth (for children and adolescents), liver function, bones, eyes and eye sight.

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

**The following may interact with ARNUITY ELLIPTA:**

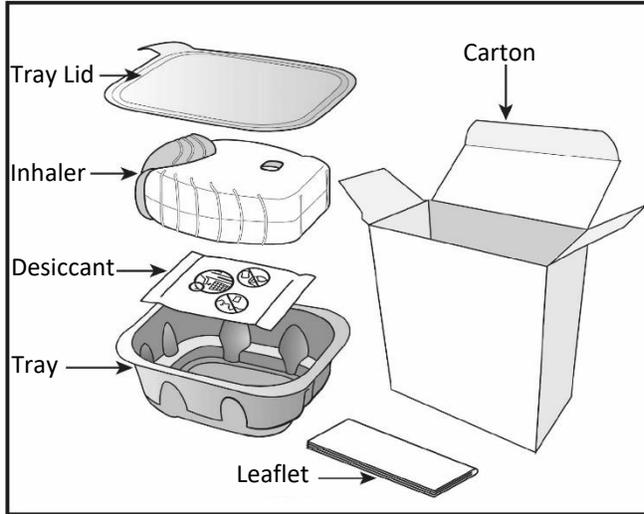
- antifungals, medicines used to treat fungal infections (e.g., ketoconazole, itraconazole, and voriconazole);
- antiretrovirals, medicines use to treat HIV/AIDS (e.g., ritonavir, indinavir, lopinavir, nelfinavir, and saquinavir);
- antibiotics, medicines used to treat bacterial infections (e.g., clarithromycin, telithromycin, and troleandomycin);
- conivaptan, a medicine used to treat low sodium levels;
- nefazodone, a medicine used to treat depression;
- any other corticosteroid medicines.

**How to take ARNUITY ELLIPTA:**

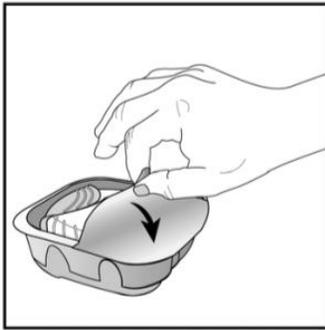
- ARNUITY ELLIPTA is for oral inhalation only.
- Use ARNUITY ELLIPTA exactly as recommended by your healthcare professional.
- Rinse your mouth with water after each inhalation to reduce the risk of an infection. Do NOT swallow the water.
- It is important to continue using ARNUITY ELLIPTA regularly even if you do not have any symptoms.
- Do NOT stop using ARNUITY ELLIPTA without talking to your healthcare professional.

**About your ARNUITY ELLIPTA Inhaler:**

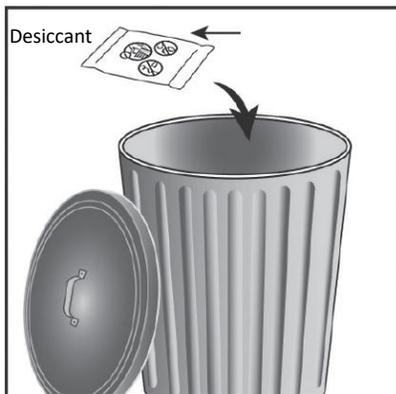
The ELLIPTA inhaler is the device used to deliver your medication. Your ELLIPTA inhaler carton contains:



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

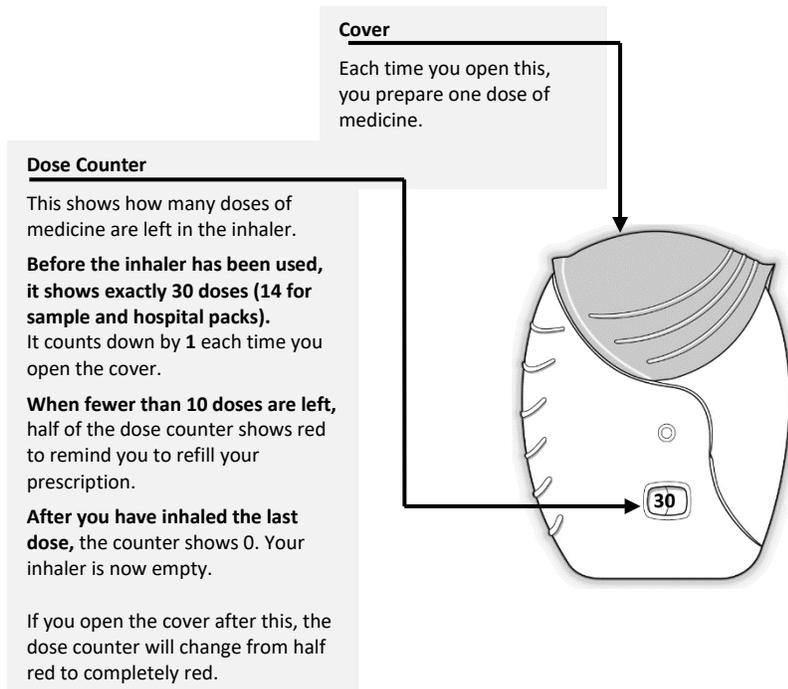


In the tray, you will find a small desiccant sachet containing a drying agent. The desiccant sachet helps to prevent moisture from forming inside the tray. **Keep it away from children and pets.** Do NOT open, eat or inhale the desiccant sachet. **Throw it away in the household trash** once you have 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, an orange 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.

**Instructions for use of ARNUITY ELLIPTA:**

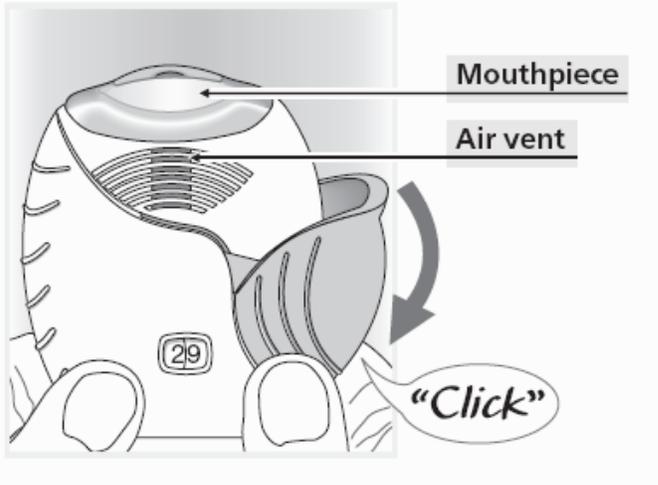
Please follow the instructions ‘**OPEN, INHALE, and CLOSE**’ to use your ELLIPTA inhaler. The instructions shown below apply to both the 30-dose and 14-dose ELLIPTA inhaler.

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:**

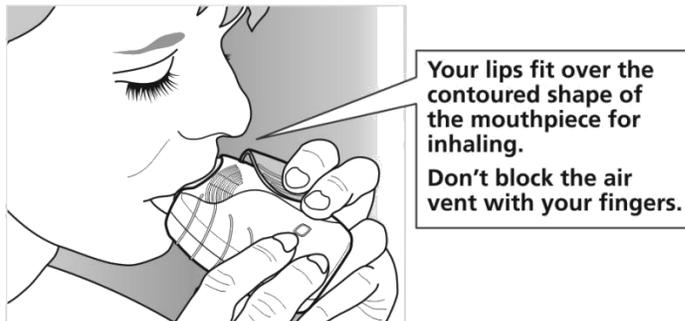
1. When you are ready, activate the inhaler by sliding the orange cover down until you hear a 'click' to prepare a dose.
2. The dose counter will now count down by one number ("1"). *It is unlikely the dose counter will not count down as you hear the 'click'. If this happens, it may mean the inhaler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

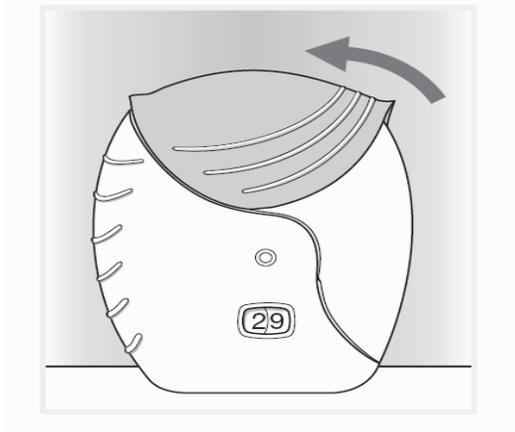
1. Put the mouthpiece between your lips, and close your lips firmly around it. *Don't block the air vent with your fingers.*



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.

4. Rinse your mouth with water. **Do not** swallow.



**Usual dose:**

Your healthcare professional will determine the right dose of ARNUITY ELLIPTA for you. This may be based on the severity of your asthma, if you have liver problems, other medicines/treatments you take, and how you respond to ARNUITY ELLIPTA.

The usual dose is one inhalation of ARNUITY ELLIPTA (100 mcg or 200 mcg) through the mouth once a day at about the same time each day.

If you have severe asthma, your healthcare professional may decide that you should use the higher strength of ARNUITY ELLIPTA (200 mcg).

If you have liver problems, your healthcare professional may decide that you should use the lower strength of ARNUITY ELLIPTA (100 mcg).

Do **NOT** take more than the recommended dose, once every 24 hours.

**Overdose:**

If you have taken larger doses than instructed for a long period of time, you should ask your healthcare professional right away for advice.

If you think you, or a person you are caring for, have taken too much ARNUITY 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, carry-on and take your next dose at the usual time the next day. **Do NOT** take an extra dose to make up for the missed one.

**What are possible side effects from using ARNUITY ELLIPTA?**

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

Side effects may include:

- infection or inflammation of the nose or throat;
- feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis);
- pain and irritation in the back of the mouth and throat;
- headache;
- back pain;
- cough;
- hoarseness and voice changes;
- respiratory tract infection;
- stomach pain;
- diarrhea.

**If any of these affects you severely, tell your healthcare professional.**

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	
<b>COMMON</b>			
<b>Bronchitis</b> (inflammation of the lungs).		✓	
<b>Flu:</b> sore throat, fever, headache, sore muscles, or cough.		✓	
<b>Thrush</b> (yeast infection): white patches in the mouth and on the tongue, sore throat.		✓	
<b>UNKNOWN FREQUENCY</b>			
<b>Allergic reaction:</b> skin rash, hives, redness, swelling of the face, lips, tongue or throat (angioedema), wheezing, coughing, difficulty swallowing, difficulty breathing, or suddenly feeling weak or light headed (may lead to collapse of consciousness).			✓
<b>Asthma exacerbations</b>		✓	

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	
<b>Bone fractures or osteoporosis</b> (thin, fragile bones): broken bones, sudden pain in any location of the body (especially in the wrist, spine, or hip), or back pain that gets worse when standing or walking.		✓	
<b>Cataracts:</b> clouding of the lens in the eye, blurry vision, dim vision, or eye pain.		✓	
<b>Decreased adrenal function:</b> tiredness, weakness, nausea and vomiting, low blood pressure.		✓	
<b>Glaucoma:</b> new or worsened pressure in your eyes, eye pain, eye discomfort, blurred vision, seeing halos or rainbows around items, or redness in or around the eye.		✓	
<b>Pneumonia</b> (infection in the lungs): fever, chills, increase in mucus production, change in mucus colour, increased cough, an increase in breathing difficulties, shortness of breath, or chest pain.		✓	

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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

- Store ARNUITY ELLIPTA at or below 25°C. **Keep your inhaler in a cool dry place away from direct heat or sunlight.** Keep it closed when not in use.
- If you store ARNUITY ELLIPTA in a refrigerator, **allow the inhaler to return to room temperature for at least an hour** before use.
- Store in the original package container in order to protect from moisture and do not open the foil lid until ready for first use.
- ARNUITY ELLIPTA **expires 6 weeks after you have opened the lid of the tray.** After 6 weeks or when the dose counter displays “0”, whichever comes first, safely discard ARNUITY ELLIPTA. To help you remember when to discard ARNUITY ELLIPTA, write the date the inhaler should be discarded on the inhaler in the space provided after opening.

Keep out of the sight and reach of children. Your medicine may harm them.

**If you want more information about ARNUITY 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](http://www.gsk.ca)), or by calling 1-800-387-7374.

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