

PART III: CONSUMER INFORMATION

ARNUITY ELLIPTA fluticasone furoate dry powder for oral inhalation

This leaflet is part III of a three-part "Product Monograph" published when ARNUITY 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 ARNUITY ELLIPTA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ARNUITY ELLIPTA is an inhaled corticosteroid used for the long-term treatment of asthma in people aged 12 years and older.

What it does:

ARNUITY ELLIPTA contains fluticasone furoate. Fluticasone furoate is an inhaled corticosteroid. 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.

When it should not be used:

Do not use ARNUITY ELLIPTA:

- To treat sudden symptoms of asthma. **ARNUITY 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.
- 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 under 12 years of age.

What the medicinal ingredient is:

Fluticasone furoate.

What the nonmedicinal ingredients are:

Lactose monohydrate (which contains milk proteins).

What dosage forms it comes in:

Dry Powder for Oral Inhalation: 100 mcg and 200 mcg

The dry powder is contained in a series of separate blisters and is delivered by the ELLIPTA inhaler.

Each inhaler contains 30 doses (one inhalation per day for 30 days).

If a sample is given to you by your doctor, it will contain 14 doses (one inhalation per day for 14 days).

WARNINGS AND PRECAUTIONS

BEFORE you use ARNUITY ELLIPTA talk to your doctor or pharmacist if you:

- have liver disease, as you may be more likely to have side effects;
- have weak bones (osteoporosis);
- have eye problems such as glaucoma, cataracts, blurry vision or other changes in vision;
- are pregnant or planning to become pregnant;
- are breastfeeding;
- have ever had thrush or a yeast infection in your mouth;
- 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 an immune system problem;
- have ever had herpes simplex of the eye, a history of tuberculosis infections, or any type of viral, bacterial, fungal (yeast), or parasitic infection.

If you have moderate to severe liver problems, your doctor may do blood tests to monitor your liver function.

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.

You should avoid coming into contact with people who have measles or chicken pox while taking ARNUITY ELLIPTA. If you are exposed, tell your doctor right away.

Drugs 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.

Pregnancy:
ARNUIITY ELLIPTA is not usually recommended for use during pregnancy.

Before prescribing ARNUITY ELLIPTA your doctor will consider the benefit to you and the risk to your unborn baby.

Breastfeeding/Lactation:

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

Tell your doctor immediately if:

- 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.

These could be warning signs that your condition may be worsening.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Drugs that may interact with ARNUITY ELLIPTA include:

- Ketoconazole used to treat fungal infections;
- Anti-HIV medicines;
- Clarithromycin used to treat bacterial infections;
- Any other corticosteroid medicines.

PROPER USE OF THIS MEDICATION

ARNUIITY 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.

Your doctor will determine the dose of ARNUITY ELLIPTA based on the severity of your asthma and if you have liver disease.

It is important to continue using ARNUITY ELLIPTA even if you do not have any symptoms.

Do not stop taking ARNUITY ELLIPTA without talking to your doctor.

Take ARNUITY ELLIPTA:

- exactly as prescribed;
- every day;
- every 24 hours, at about the same time each day

Rinse your mouth with water after each inhalation. Do not swallow the water

Usual dose: One inhalation through the mouth once a day.

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

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

Do not take more than the recommended dose.

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.

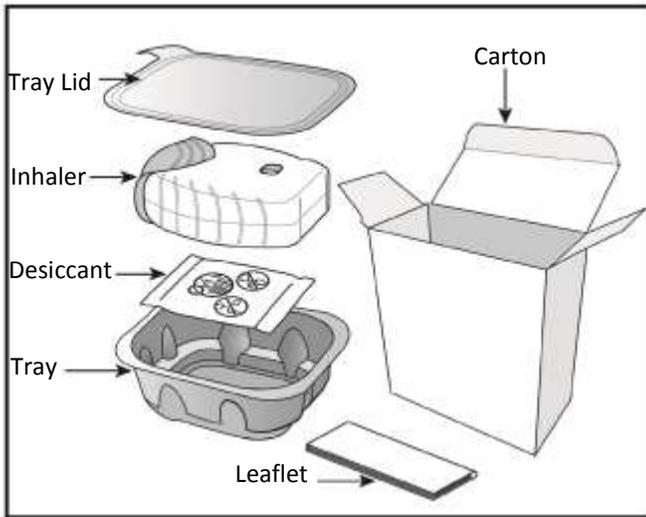
If you have taken larger doses than instructed for a long period of time, you should ask your doctor or pharmacist for advice.

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.

About your ARNUITY ELLIPTA Inhaler:

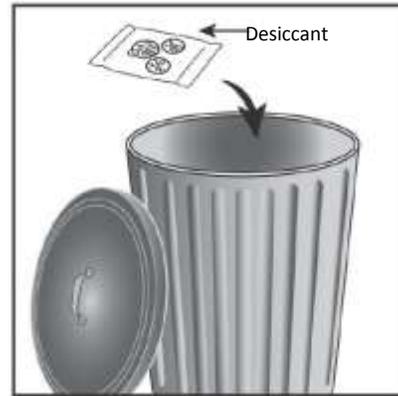
Your ELLIPTA inhaler carton contains:



The plastic ELLIPTA inhaler is packaged in a tray, with a peelable foil lid. **Do not remove the foil 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, 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.

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.

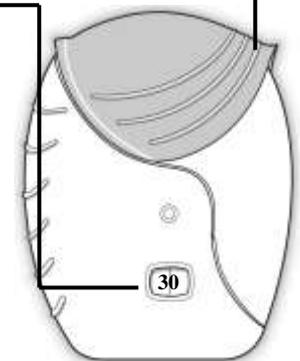
Before the inhaler has been used, it shows exactly 30 doses (14 for sample and hospital packs).

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 to remind you to refill your prescription.

After you have inhaled the last dose, the counter shows 0. 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 ARNUITY ELLIPTA:

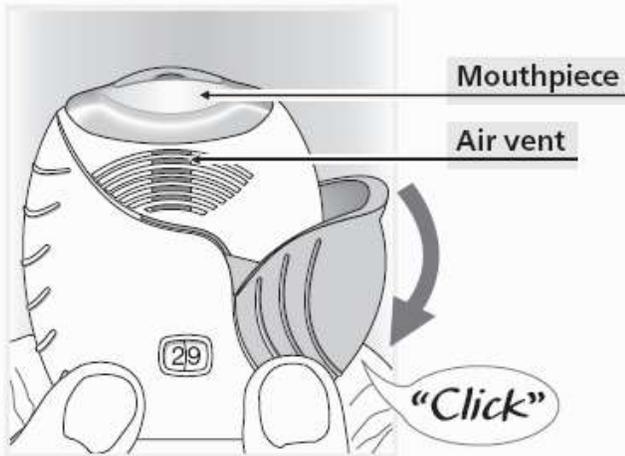
Please follow the instructions ‘**OPEN, INHALE, and CLOSE**’ to use your ELLIPTA inhaler. The instructions shown below apply to both the 30-dose and 14-dose ELLIPTA inhaler.

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:

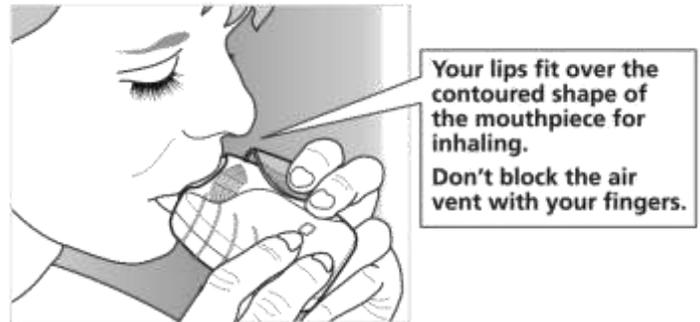
1. When you are ready, activate the inhaler by sliding the orange cover down until you hear a ‘click’ to prepare a dose.
2. The dose counter will now count down by one number (“1”). *It is unlikely the dose counter will not count down as you hear the ‘click’.* *If this happens, it may mean the inhaler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

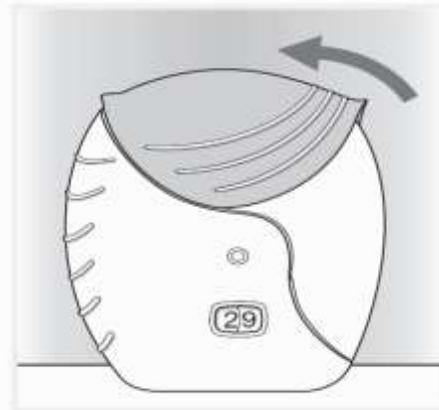
1. Put the mouthpiece between your lips, and close your lips firmly around it. *Don’t block the air vent with your fingers.*



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.



SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Sore, raised patches in the mouth or throat caused by a yeast infection (*candidiasis*/thrush). After using ARNUITY ELLIPTA, rinse your mouth out with water immediately (do not swallow) as it may help stop this side effect from occurring.
- 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 and diarrhea

If any of these affects you severely, tell your doctor, nurse or pharmacist.

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 seek immediate medical help
		Only if severe	In all cases	
Unknown	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).		✓	
	Asthma exacerbations		✓	
	Decreased Adrenal Function: Tiredness, weakness, nausea and vomiting, low blood pressure.		✓	
	Glaucoma: New or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes		✓	
	Cataract: clouding of the lens in the eye, blurry vision and/or eye pain.		✓	

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 seek immediate medical help
		Only if severe	In all cases	
Common	Thrush (yeast infection): White patches in the mouth and on the tongue, sore throat		✓	
	Bronchitis (inflammation of the lungs).		✓	
	Flu: sore throat, fever, headache, sore muscles, cough		✓	

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 seek immediate medical help
	Only if severe	In all cases	
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 of consciousness).			✓
Bone Fractures or Osteoporosis: In situations where healthy people would not normally break a bone you may have sudden pain in any location and especially in the wrist, spine or hip. This may be a fracture.		✓	

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

HOW TO STORE IT

- **Keep out of the reach and sight 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 ARNUITY ELLIPTA above 25°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 container 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 ARNUITY ELLIPTA when the dose counter reads “0” or 6 weeks after you open the lid of the tray, whichever comes first. **ARNUITY 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, GlaxoSmithKline Inc., at:
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Mississauga, Ontario
Canada L5N 6L4
1-800-387-7374

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