

Patient Information

**ARNUITY ELLIPTA (ar-NEW-i-te e-LIP-ta)
(fluticasone furoate inhalation powder)
for oral inhalation use**

What is ARNUITY ELLIPTA?

- ARNUITY ELLIPTA is an inhaled corticosteroid (ICS) medicine used for the control and prevention of asthma in adults and children aged 5 years and older.
- ARNUITY ELLIPTA helps to prevent and control symptoms of asthma.
- **ARNUITY ELLIPTA is not for use to treat sudden symptoms of an asthma attack, wheezing, cough, shortness of breath, and chest pain or tightness.** Always have a rescue inhaler (an inhaled, short-acting bronchodilator) with you to treat sudden symptoms. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.
- It is not known if ARNUITY ELLIPTA is safe and effective in children younger than 5 years.

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 albuterol, during a sudden asthma attack.
- if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- if you are allergic to fluticasone furoate or any of the ingredients in ARNUITY ELLIPTA. See the end of this leaflet for a complete list of ingredients in ARNUITY ELLIPTA.

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

- have liver problems.
- have weak bones (osteoporosis).
- have an immune system problem.
- have eye problems such as glaucoma or cataracts.
- are allergic to milk proteins.
- have any type of viral, bacterial, fungal, or parasitic infection.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if ARNUITY ELLIPTA may harm your unborn baby.
- are breastfeeding. It is not known if the medicine in ARNUITY 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. ARNUITY ELLIPTA and certain other medicines may interact with each other. This may cause serious side effects. Especially, tell your healthcare provider if you take antifungal, anti-HIV, or any other corticosteroid medicines.

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 ARNUITY ELLIPTA?

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

- **Do not** use ARNUITY ELLIPTA unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- ARNUITY ELLIPTA comes in 3 different strengths. Your healthcare provider prescribed the strength that is best for you.
- Use ARNUITY ELLIPTA exactly as your healthcare provider tells you to use it. **Do not** use ARNUITY ELLIPTA more often than prescribed.
- Children and adolescents may need help to use ARNUITY ELLIPTA.
- Use 1 inhalation of ARNUITY ELLIPTA 1 time each day. Use ARNUITY ELLIPTA at the same time each day.
- If you miss a dose of ARNUITY 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.
- Do not stop using ARNUITY ELLIPTA unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- **ARNUIITY ELLIPTA does not relieve sudden symptoms of asthma and you should not take extra doses of ARNUITY 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.
 - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.

What are the possible side effects of ARNUITY ELLIPTA?

ARNUIITY ELLIPTA can cause serious side effects, including:

- **fungal infection in your mouth or throat (thrush).** Rinse your mouth with water without swallowing after using ARNUITY ELLIPTA to help reduce your chance of getting thrush.
- **weakened immune system and increased chance of getting infections (immunosuppression).**
- **reduced adrenal function (adrenal insufficiency).** Adrenal insufficiency is a condition where the adrenal glands do not make enough steroid hormones. This can happen when you stop taking oral corticosteroid medicines (such as prednisone) and start taking a medicine containing an inhaled corticosteroid (such as ARNUITY ELLIPTA). During this transition period, when your body is under stress from fever, trauma (such as a car accident), infection, surgery, or worse asthma symptoms, adrenal insufficiency can get worse and may cause death.

Symptoms of adrenal insufficiency include:

- feeling tired
 - lack of energy
 - weakness
 - nausea and vomiting
 - low blood pressure
- **sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop taking ARNUITY ELLIPTA and call your healthcare provider right away.
 - **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the

following symptoms of a serious allergic reaction:

- o rash
- o hives
- o swelling of your face, mouth, and tongue
- o breathing problems

- **bone thinning or weakness (osteoporosis).**
- **slow growth in children and adolescents.** A child's or adolescent's growth should be checked often.
- **eye problems including glaucoma and cataracts.** You should have regular eye exams while using ARNUITY ELLIPTA.

Common side effects of ARNUITY ELLIPTA include:

- runny nose and sore throat
- headache
- breathing problems (bronchitis)
- flu

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

- Store ARNUITY 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 ARNUITY ELLIPTA in the unopened tray and only open when ready for use.
- Safely throw away ARNUITY ELLIPTA in the trash 6 weeks after you open the tray or when the counter reads "0", whichever comes first. Write the date you open the tray on the label on the inhaler.

Keep ARNUITY ELLIPTA and all medicines out of the reach of children.

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ARNUITY ELLIPTA for a condition for which it was not prescribed. Do not give ARNUITY 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 ARNUITY ELLIPTA that is written for health professionals.

What are the ingredients in ARNUITY ELLIPTA?

Active ingredients: fluticasone furoate

Inactive ingredients: lactose monohydrate (contains milk proteins)



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

Trademarks are owned by or licensed to the GSK group of companies.

GlaxoSmithKline, Research Triangle Park, NC 27709

©2018 GSK group of companies or its licensor.

ARN:3PIL

This Patient Information has been approved by the U.S. Food and Drug Administration

Revised: May 2018

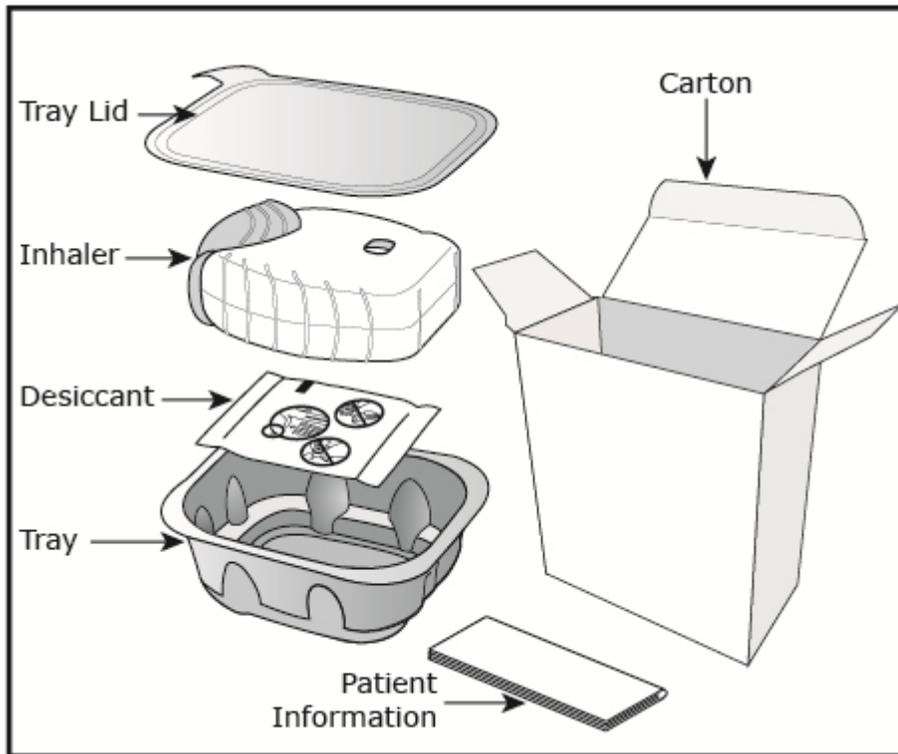
INSTRUCTIONS FOR USE

ARNUIITY ELLIPTA (ar-NEW-i-te e-LIP-ta) (fluticasone furoate inhalation powder) for oral inhalation use

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 ARNUITY ELLIPTA inhaler



How to use your inhaler

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

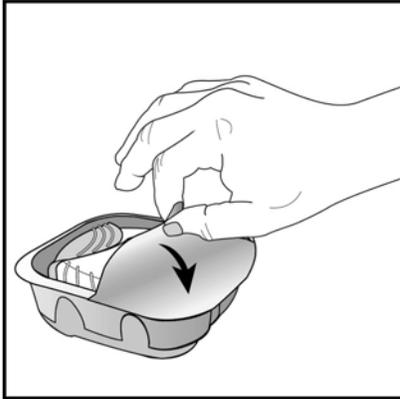


Figure A

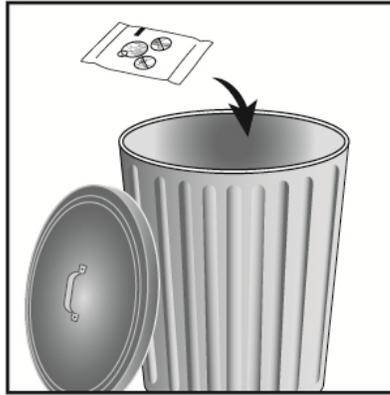


Figure B

Important Notes:

- Your inhaler contains 30 doses (14 doses if you have a 100-mcg or 200-mcg strength 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.

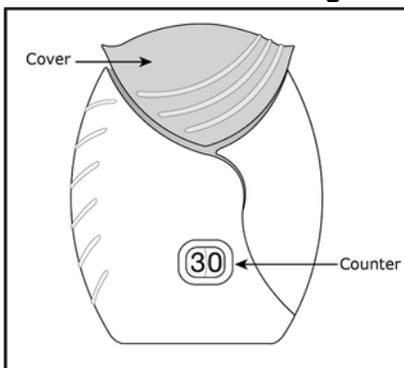


Figure C

- Before the inhaler is used for the first time, the counter should show the number 30 (14 if you have a 100-mcg or 200-mcg strength 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.

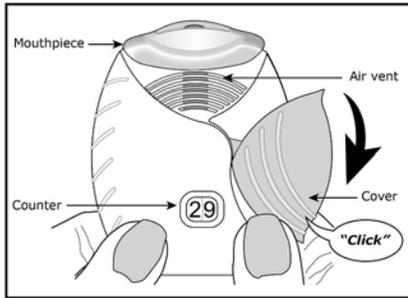


Figure D

Step 1. Open the cover of the inhaler. See Figure D.

- Slide the cover down to 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.

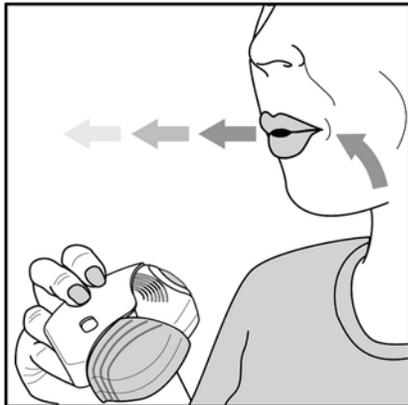


Figure E

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.

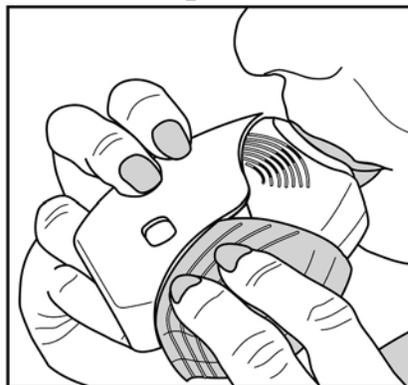


Figure F

Do not block the air vent with your fingers.

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.



Figure G

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

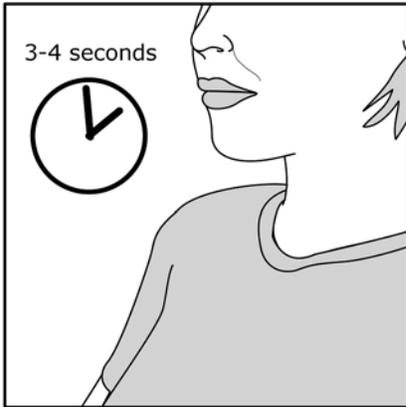


Figure H

- **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.**

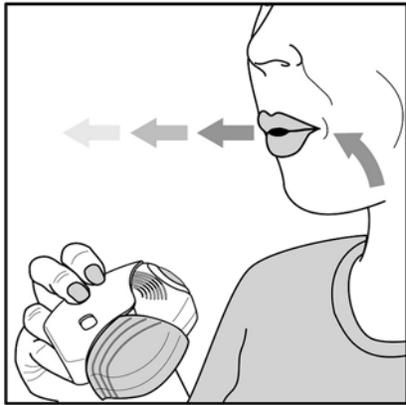


Figure I

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.

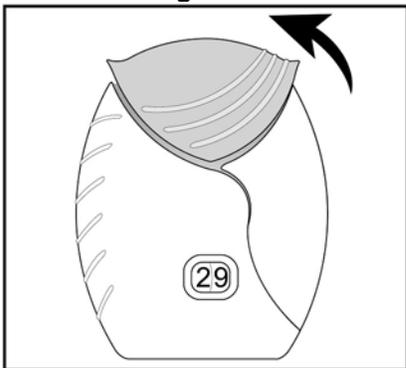


Figure J

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 K

Step 6. Rinse your mouth. See Figure K.

- Rinse your mouth with water after you have used the inhaler and spit the water out. **Do not** swallow the water.

Important Note: When should you get a refill?

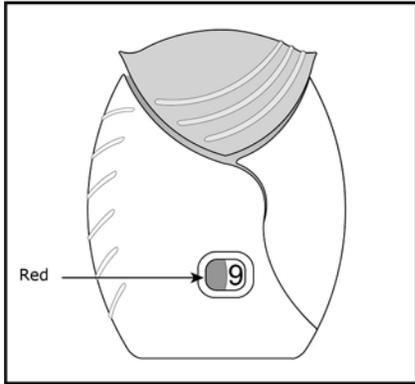


Figure L

- **When you have fewer than 10 doses remaining** in your inhaler, the left half of the counter shows red as a reminder to get a refill. **See Figure L.**
- 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.



For more information about ARNUITY ELLIPTA or how to use your inhaler, call 1-888-825-5249 or visit our website at www.ARNUIITY.com.

Trademarks are owned by or licensed to the GSK group of companies.

GlaxoSmithKline, Research Triangle Park, NC 27709

©2018 GSK group of companies or its licensor.

ARN:1IFU

This Instructions for Use has been approved by the U.S. Food and Drug Administration

Revised: May 2018