

## Instructions for Use

### PYQUVI (Pik'-YOO-vee) (deflazacort) oral suspension

Read this Instructions for Use before you start using PYQUVI oral suspension and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

#### Important information before you use PYQUVI oral suspension:

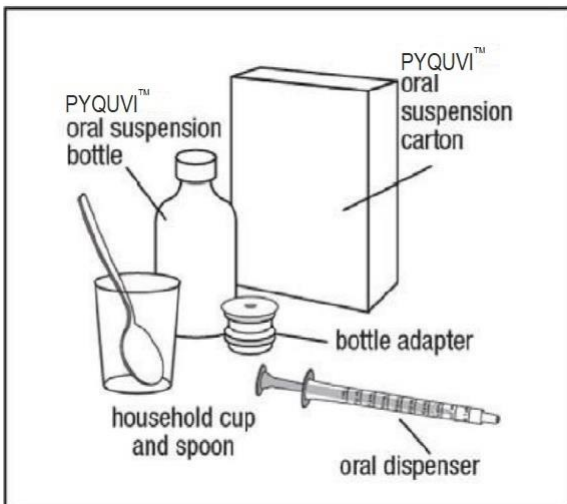
- Only use the oral dispenser (see Figure A below) that comes in your PYQUVI carton when using this medicine.
- PYQUVI oral suspension can be taken with or without food.
- Take your dose of PYQUVI oral suspension with juice or milk. **Do not** take PYQUVI with grapefruit juice.
- Throw away (discard) any unused PYQUVI oral suspension after 1 month of first opening the bottle.
- **Do not** stop taking PYQUVI oral suspension without talking to your healthcare provider first.

#### Preparing for your PYQUVI oral suspension dose:

You will need the following supplies: See Figure A.

- 1 PYQUVI oral suspension bottle
- 1 bottle adapter
- 1 oral dispenser (2 oral dispensers are included in the PYQUVI oral suspension carton. 1 is to be used to give (administer) the product and 1 extra oral dispenser is included as a spare, if needed.)
- 1 household cup filled with 3 to 4 ounces of juice or milk
- 1 spoon

Figure A

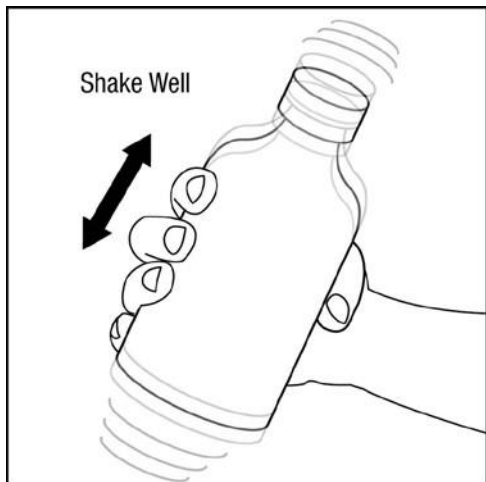


#### How to prepare your dose of PYQUVI oral suspension:

**Step 1.** Remove the PYQUVI oral suspension bottle, bottle adapter and 1 of the oral dispensers from the carton.

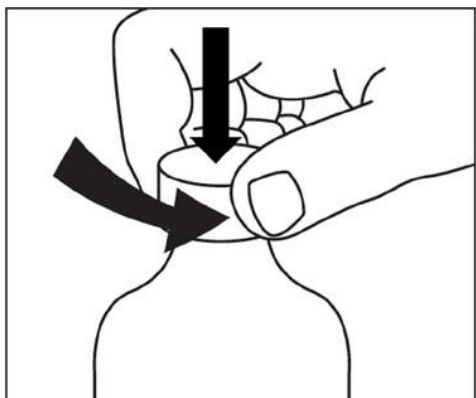
**Step 2.** Make sure the bottle cap is put on tightly and shake well before each use. **See Figure B.**

**Figure B**



**Step 3.** Remove the cap from the bottle by pushing down firmly on the cap and turning the cap in a counter-clockwise direction (to the left). **See Figure C.** Place the open bottle upright on a flat surface.

**Figure C**



**First time use of bottle only:**

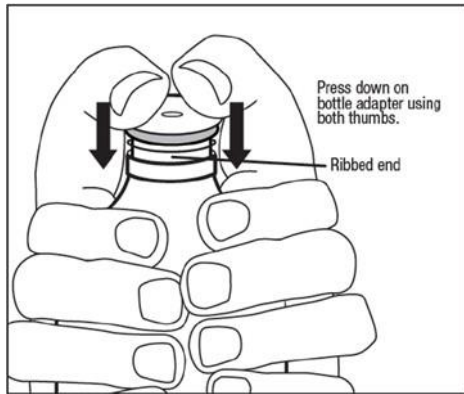
**Unwrap the bottle adapter.**

Place the ribbed end of the bottle adapter in the bottle top.

Wrap both hands around the bottle. Press down on the bottle adapter using both thumbs. Push the ribbed end of the bottle adapter firmly into the neck of the bottle until the adapter top is even with the bottle top. **See Figure D.**

**Do not** remove the bottle adapter from the bottle after it is inserted. Write the date that you first open the bottle on the bottle label.

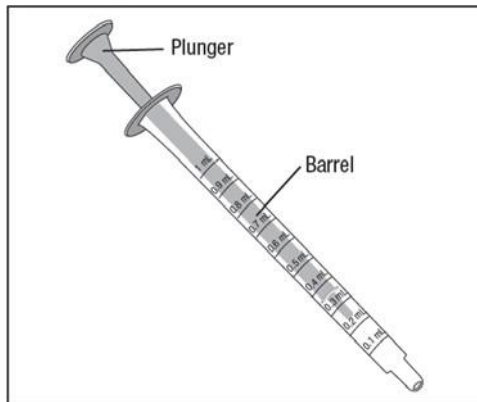
**Figure D**



**Step 4. Unwrap the oral dispenser if it is the first time you are using the oral dispenser.**

Check your dose in milliliters (mL) as prescribed by your healthcare provider. Find this number on the barrel of the oral dispenser. **See Figure E.**

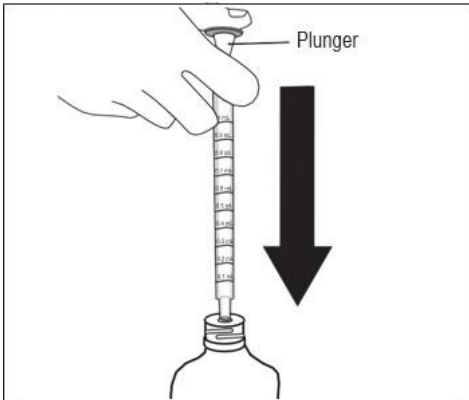
**Figure E**



The oral dispenser only holds 1 mL of medicine at a time. If your dose is more than 1 mL, you will need to repeat Steps 5 through 8 using the same oral dispenser until your entire dose has been drawn from the bottle.

**Step 5.** Push the plunger of the oral dispenser all the way down. Insert the oral dispenser into the bottle adapter.  
**See Figure F.**

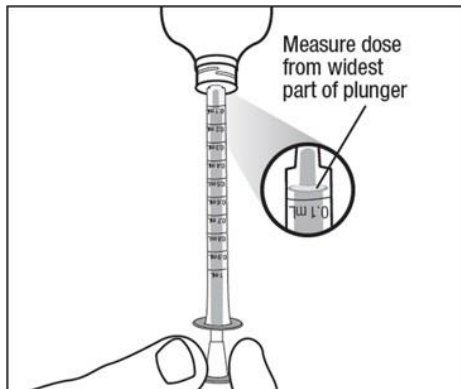
**Figure F**



**Step 6.** With the oral dispenser in the bottle adapter, carefully turn the bottle upside down. Slowly pull back on the plunger until the widest part of the plunger is at the line marking on the oral dispenser of the number of mL needed for your dose. **See Figure G. Do not** use the narrow tip on the end of the plunger to measure the dose.

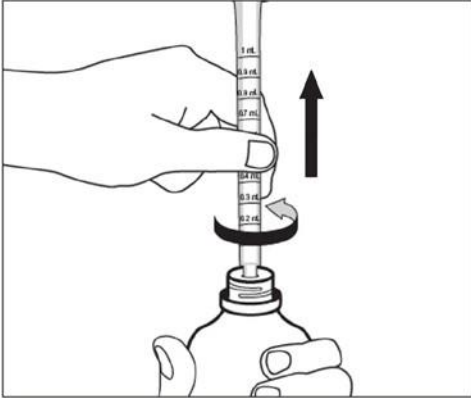
If you see air bubbles in the oral suspension, fully push in the plunger so the oral suspension flows back into the bottle. Then withdraw the dose of oral suspension that you need.

**Figure G**



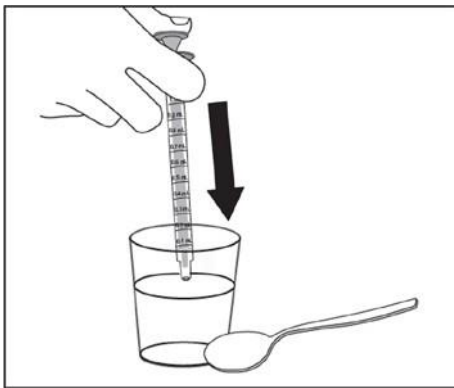
**Step 7.** Leave the oral dispenser in the bottle adapter and turn the bottle to an upright position. Place the bottle onto a flat surface. Remove the oral dispenser from the bottle adapter by gently twisting the oral dispenser while pulling it straight up. **See Figure H.**

**Figure H**



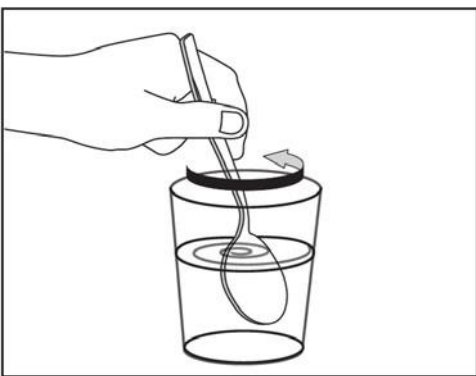
**Step 8. Slowly** push all the way down on the plunger of the oral dispenser to add the PYQUVI oral suspension dose to a household cup filled with 3 to 4 ounces of juice or milk. **See Figure I.**

**Figure I**



**Step 9. Stir** the PYQUVI oral suspension and juice or milk with a spoon to mix well. **See Figure J.**

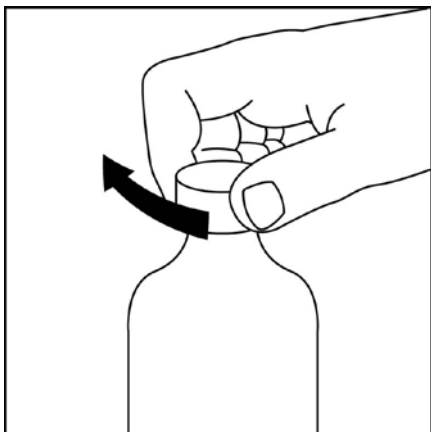
**Figure J**



**Step 10.** Immediately drink the juice or milk that is mixed with PYQUVI oral suspension.

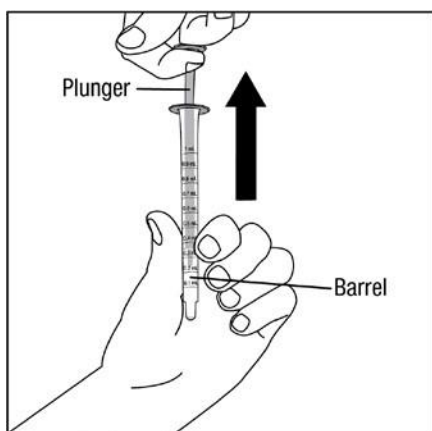
**Step 11.** Replace the cap tightly on the bottle by turning the cap in a clockwise direction (to the right). **See Figure K.**

**Figure K**



**Step 12.** Wash the oral dispenser after each use. The oral dispenser should be taken apart by pulling back on the plunger and removing it from the barrel of the oral dispenser. **See Figure L.**

**Figure L**



**Step 13.** After the barrel and plunger are dry, put the oral dispenser back together by pushing the plunger back into the barrel.

**How should I store PYQUVI oral suspension?**

- Store the bottle upright at room temperature between 68°F to 77°F (20°C to 25°C).
- Throw away (discard) any unused PYQUVI oral suspension after 1 month of first opening the bottle.

**What are the ingredients in PYQUVI oral suspension?**

**Active ingredient:** deflazacort

**Inactive ingredients:** Benzyl Alcohol, Carboxymethylcellulose Sodium, Colloidal silicon dioxide, Glacial Acetic Acid, Noncrystallizing Sorbitol Solution, Magnesium Aluminum Silicate, Polysorbate 80, Purified water.

Manufactured by:

Aucta Pharmaceuticals, Inc.

Piscataway, NJ 08854

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

LB5122-01

Issued: 02/2025