

## INSTRUCTIONS FOR USE

ERLEADA® (er lee'dah)

(apalutamide)

tablets

This Instructions for Use contains information on how to prepare and take or give a dose of ERLEADA tablets if you cannot swallow ERLEADA tablets whole or if you have a feeding tube. Read this Instructions for Use before you prepare and take or give the first dose of ERLEADA, and each time you get a refill. Ask your healthcare provider or pharmacist if you have any questions.

### Important information you need to know before preparing a dose of ERLEADA:

- ERLEADA comes in 2 different strengths, 60 mg tablets and 240 mg tablets. Please find the instructions below that refer to your prescribed ERLEADA strength for how to prepare and take or give ERLEADA tablets.

### Preparing and taking ERLEADA if you cannot swallow tablets whole:

#### Preparing and taking ERLEADA 60 mg tablets by placing the tablets in non-carbonated water then mixing with orange juice, applesauce, or more non-carbonated water:

- Step 1.** Place your entire prescribed dose of 60 mg tablets in a cup. **Do not crush or split the tablets.**
- Step 2.** Add about 4 teaspoons (20 mL) of non-carbonated water to make sure that the tablets are completely covered in water.
- Step 3.** Wait 2 minutes until the tablets are broken up and spread out, then stir the mixture.
- Step 4.** Add 2 tablespoons (30 mL) of orange juice, applesauce, or non-carbonated water to the cup and stir the mixture.
- Step 5.** Swallow the mixture right away.
- Step 6.** Rinse the cup with enough non-carbonated water to make sure that you take your full dose of ERLEADA and drink it right away.

**Do not** store ERLEADA that is mixed with non-carbonated water, orange juice, or applesauce for later use.

#### Preparing and taking ERLEADA 240 mg tablet by placing the tablet in non-carbonated water then mixing with orange juice, applesauce, or more non-carbonated water:

- Step 1.** Place the whole 240 mg tablet in a cup. **Do not crush or split the tablet.**
- Step 2.** Add about 2 teaspoons (10 mL) of non-carbonated water to make sure that the tablet is completely covered in water.
- Step 3.** Wait 2 minutes until the tablet is broken up and spread out, then stir the mixture.
- Step 4.** Add 2 tablespoons (30 mL) of orange juice, applesauce, or non-carbonated water to the cup and stir the mixture.
- Step 5.** Swallow the mixture right away.
- Step 6.** Rinse the cup with enough non-carbonated water to make sure that you take your full dose of ERLEADA and drink it right away.

**Do not** store ERLEADA that is mixed with non-carbonated water, orange juice, or applesauce for later use.

### Preparing and giving ERLEADA through a feeding tube:

#### Preparing and giving ERLEADA 60 mg tablets through a feeding tube 8 French or larger:

- Step 1.** Remove the plunger out of the syringe (use at least a 50 mL syringe).
- Step 2.** Add your entire prescribed dose of 60 mg tablets into the syringe body (barrel) and place the plunger back in the syringe. **Do not crush or split the tablets.**
- Step 3.** Withdraw 20 mL of non-carbonated water into the syringe.
- Step 4.** Wait 10 minutes and then shake the syringe very well (vigorously) to break the tablets apart completely.
- Step 5.** Attach the syringe to the feeding tube and give the mixture right away.
- Step 6.** Withdraw non-carbonated water into the same syringe and flush through the feeding tube. Repeat **Step 6** until no pieces of tablets are left in the syringe or feeding tube.

#### Preparing and giving ERLEADA 240 mg tablet through a feeding tube 8 French or larger:

- Step 1.** Remove the plunger out of the syringe (use at least a 20 mL syringe).
- Step 2.** Add one 240 mg tablet into the syringe body (barrel) and place the plunger back in the syringe. **Do not crush or split the tablet.**
- Step 3.** Withdraw 10 mL of non-carbonated water into the syringe.
- Step 4.** Wait 10 minutes and then shake the syringe very well (vigorously) to break the tablet apart completely.
- Step 5.** Attach the syringe to the feeding tube and give the mixture right away.
- Step 6.** Withdraw non-carbonated water into the same syringe and flush through the feeding tube. Repeat **Step 6** until no pieces of tablet are left in the syringe or feeding tube.

**How should I store ERLEADA?**

- Store ERLEADA at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- ERLEADA comes in a child-resistant bottle.
- Store ERLEADA in the original package to protect from light and moisture.
- The bottle of ERLEADA contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not throw away (discard) the desiccant.

**Keep ERLEADA and all medicines out of the reach of children.**

**Manufactured for:** Janssen Products, LP, Horsham, PA 19044, USA

For patent information: [www.janssenpatents.com](http://www.janssenpatents.com)

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For more information, call Janssen Products, LP at 1-800-526-7736 (1-800-JANSSEN) or go to [www.erleada.com](http://www.erleada.com).

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

Revised: 07/2024