

Instructions for Use



Lumryz. (sodium oxybate) for extended-release oral suspension @ 1 packet per dose

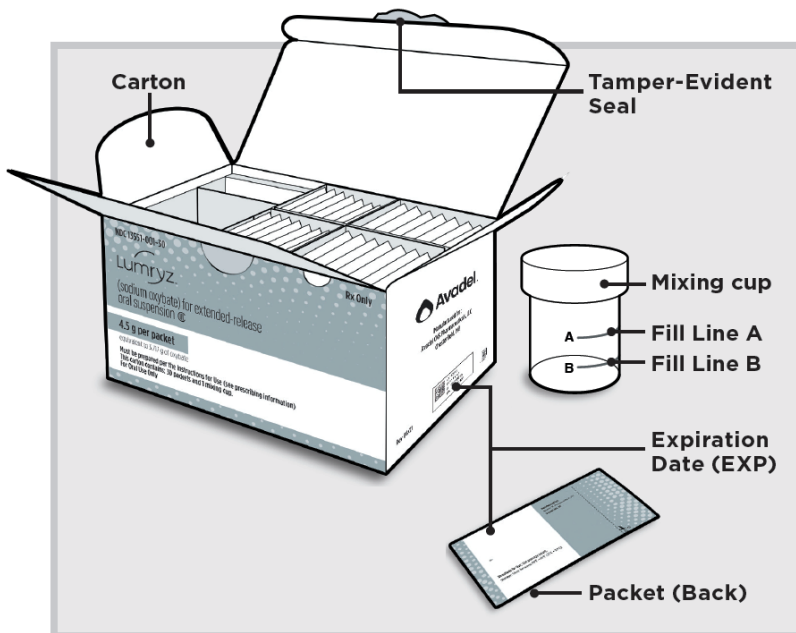
This Instructions for Use contains information on how to take LUMRYZ. Read this Instructions for Use before taking LUMRYZ and each time you get a refill. There may be new information.

This information does not take the place of talking to your doctor about your medical condition or your treatment. **If you have questions, please talk with your doctor.**

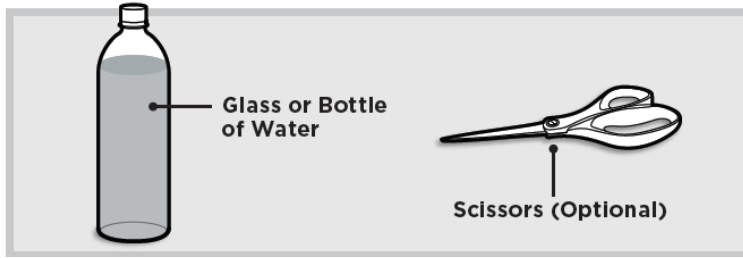
Important information when taking LUMRYZ

- Take 1 packet of LUMRYZ each day at bedtime.
- Avoid getting out of your bed after taking LUMRYZ. Some people fall asleep within 5 minutes of taking LUMRYZ and most will fall asleep within 15 minutes. The time it takes you to fall asleep might be different from night to night.
- Medicines that cause sleepiness should not be used while taking LUMRYZ.
- **Do not** use LUMRYZ with alcohol.
- **Do not** drive or operate heavy machinery within 6 hours of taking LUMRYZ.
- Mix and take LUMRYZ within 30 minutes. If not taken within 30 minutes of mixing, throw it away (dispose of it) and prepare a new dose.

LUMRYZ carton and contents



Additional supplies needed



How should I store LUMRYZ?

- Store LUMRYZ and all medicines out of the reach of children.
- Store LUMRYZ at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store LUMRYZ in a clean and dry place.

Before using LUMRYZ

- Before using a new LUMRYZ carton, check the tamper-evident seal on the carton lid to make sure it is not missing or broken.
- **Do not** use if the tamper-evident seal is missing or broken.
- Check the expiration date (EXP) on the LUMRYZ carton.
- **Do not** use LUMRYZ after the expiration date (EXP) on the label has passed.
- Open the LUMRYZ carton by tearing the tamper-evident seal with your hands or by using a pair of scissors.

Before each use

- Clean the mixing cup by rinsing it with water and letting it dry before each use.
- **Do not** use a measuring device other than the mixing cup that comes in your LUMRYZ carton to measure and take a dose of LUMRYZ.
- Check the expiration date (EXP) on the packet label. **Do not** use the LUMRYZ packet after the expiration date (EXP) has passed.

Important: Make sure to prepare LUMRYZ at bedside.



Gather the following supplies and place them on a flat surface at your bedside:

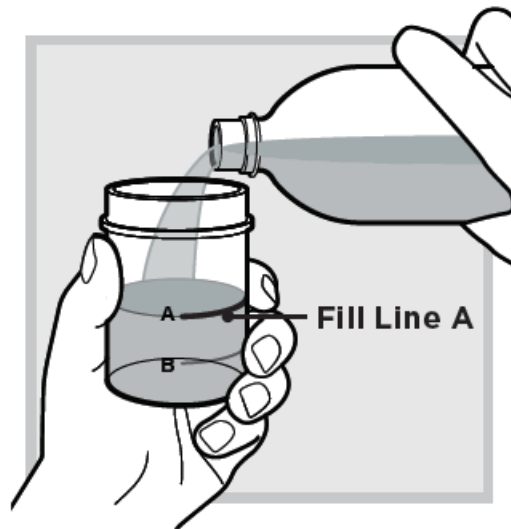
- 1 bottle or glass of water (1/3 cup). Do not use hot water.
- 1 LUMRYZ packet
- 1 clean mixing cup. - The cap is not child resistant.
- 1 pair of scissors (optional)

Mix the LUMRYZ solution at your bedside

1.) At your bedside, open the mixing cup by twisting the cap to the left (counter-clockwise) to remove it.

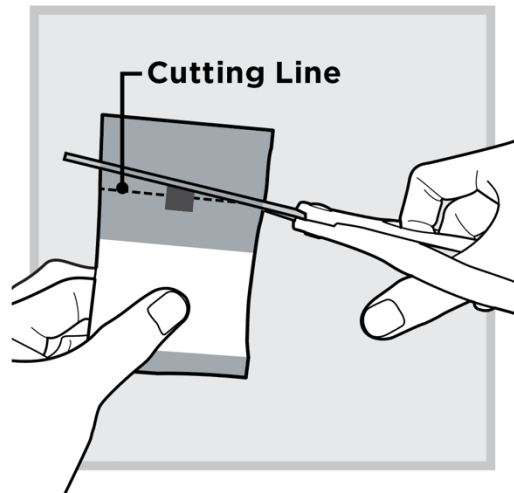


2.) Fill the mixing cup with water up to **Fill Line A** (top line) and set the mixing cup down on a flat surface.



3.) Open 1 packet:

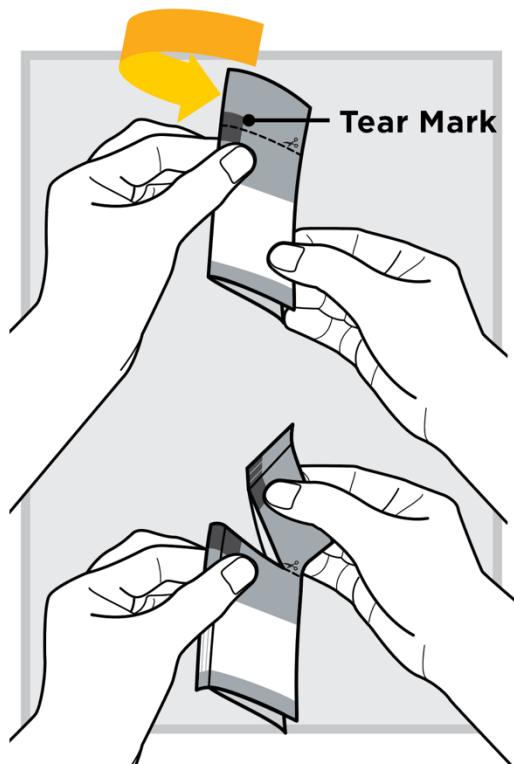
Use scissors to cut open the packet along the **Cutting Line**, located on the back of the packet.



-or-

Fold the packet in half at the gray **Tear Mark** located on the back of the packet.

Tear the packet open with your hands.

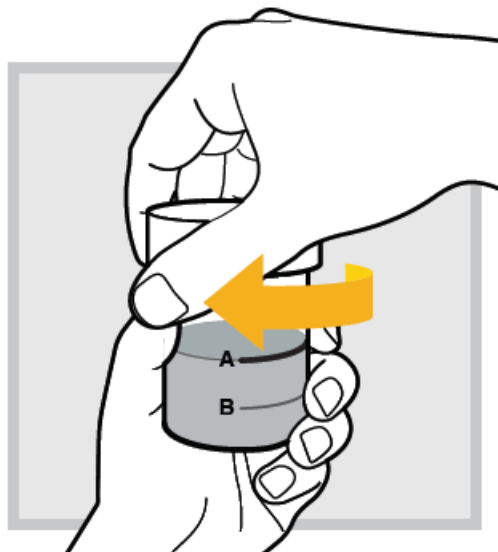


4.) Pour the entire content from the packet into the water-filled mixing cup.

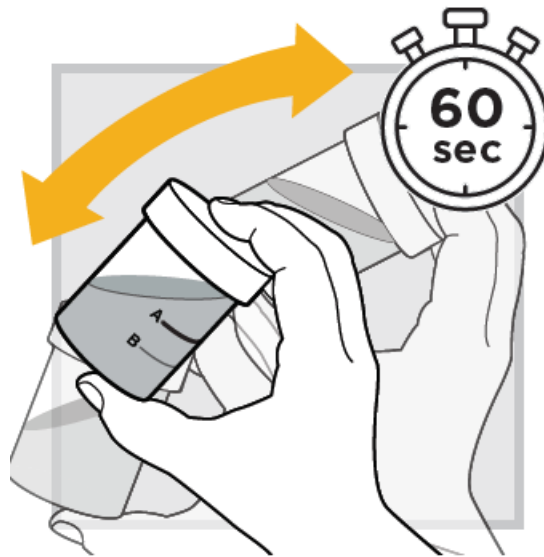
Make sure there is no powder left in the packet.



5.) Close the mixing cup by twisting the cap to the right (clockwise) until firmly closed.

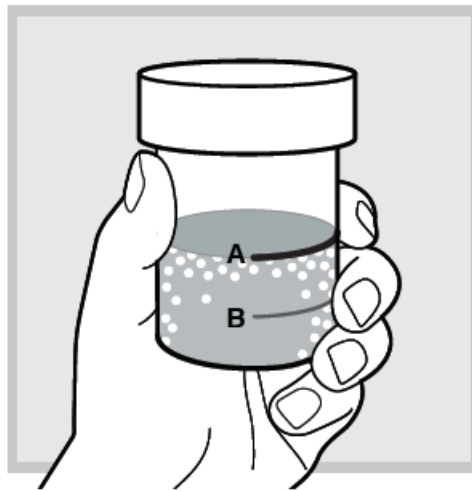


6.) Mix the water and powder solution by shaking the closed mixing cup well for at least **60 seconds (1 minute)**.



7.) Make sure the solution is mixed thoroughly.

The mixed solution will appear slightly milky with some lumps.



The mixing cup cap is not child resistant. If the mixed solution is not drunk immediately, then do not remove the cap, and keep out of reach of children.

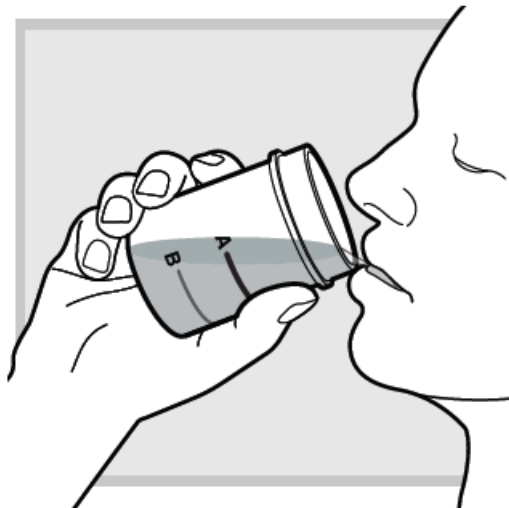
Take the LUMRYZ solution at your bedside

8.) Open the mixing cup by twisting the cap to the left (counter-clockwise) and remove it.



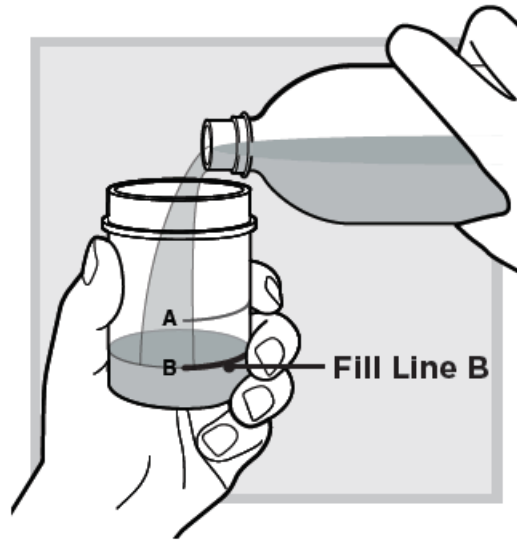
9.) While sitting in bed drink the mixed solution within **30 minutes** of mixing.

Make sure to drink all the mixed solution in the mixing cup.

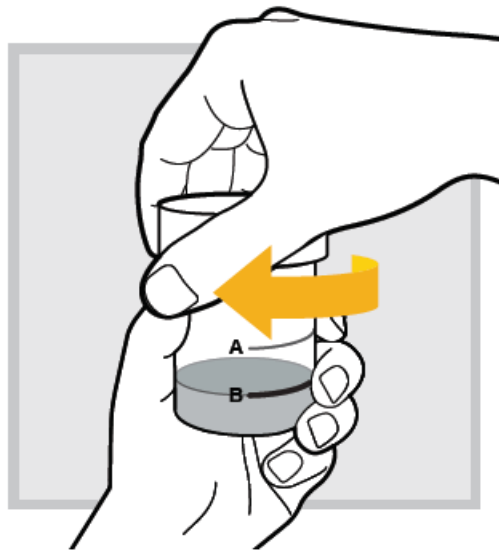


10.) Immediately refill your mixing cup with water up to **Fill Line B** (lower line) to mix in any medicine left in the mixing cup.

Do not open another packet of LUMRYZ. Take only 1 packet each day at bedtime.



11.) Close the mixing cup by twisting the cap to the right (clockwise) until firmly closed.



12.) Shake well again for **10 seconds**.



13.) Open the mixing cup by twisting the cap to the left (counter-clockwise) and remove it.



14.) Drink the mixed solution immediately after mixing.

Make sure to drink all the mixed solution in the mixing cup.



15.) Leave the empty mixing cup at your bedside and immediately lie down to go to sleep.

Avoid getting out of your bed after taking your dose.

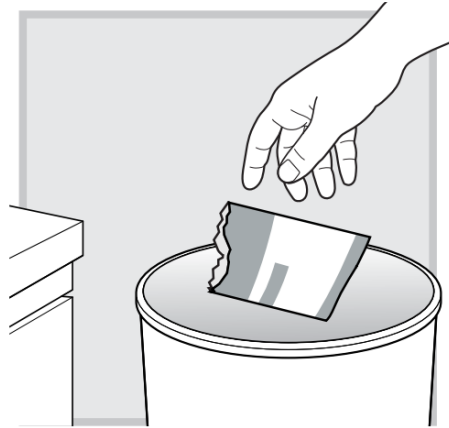


Continue to Step 16 

How do I throw away (dispose of) LUMRYZ?

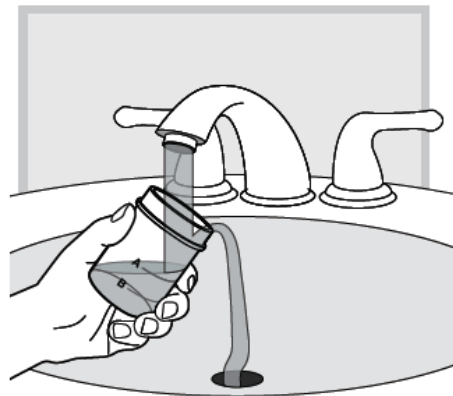
16.) The next day, place the empty LUMRYZ packet in the trash.

If any LUMRYZ remains in the packet, rinse it down the sink prior to disposal.



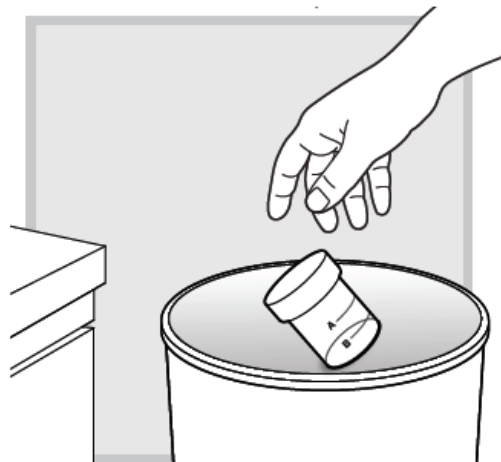
17.) Empty any unused LUMRYZ down the sink drain the next day.

Clean the mixing cup by rinsing it with water and letting it dry before each use.



After you finish all of the packets in your LUMRYZ carton

After you have finished your last packet in the carton, throw away the rinsed mixing cup in the trash.



If you have additional questions about LUMRYZ, talk with your doctor.

You can also contact:

Avadel CNS Pharmaceuticals, LLC
Chesterfield, MO 63005 USA

For more information on LUMRYZ,
visit www.lumryz.com or call
888-8VADEL (888-828-2335).

 Lumryz™ (sodium oxybate) for extended-release
oral suspension © **1 packet per dose**



Manufactured for:
Avadel CNS Pharmaceuticals, LLC
Chesterfield, MO 63005 USA



© Avadel 2023. All rights reserved. AVADEL, the AVADEL logo, LUMRYZ, and the LUMRYZ logo are trademarks of an Avadel company.

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

Approved: 05-2023