

INSTRUCTIONS FOR USE

Lumryz[®] (sodium oxybate) for extended-release
oral suspension **1 packet per dose**



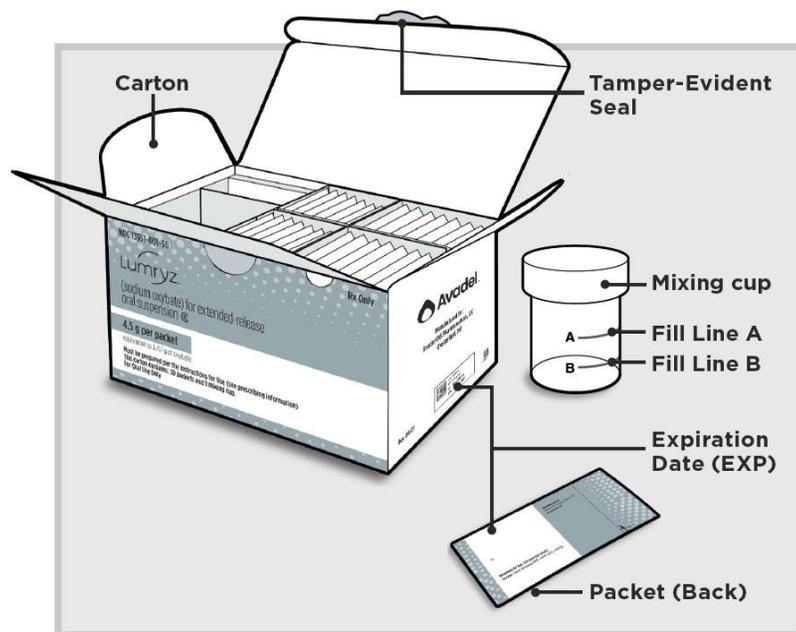
This Instructions for Use contains information on how to take LUMRYZ. Read this Instructions for Use before you (or your child) take LUMRYZ and each time you (or your child) get a refill. There may be new information.

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

Important information when taking LUMRYZ

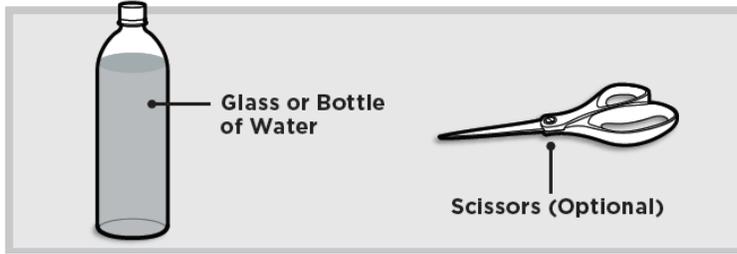
- Take (or give) 1 packet of LUMRYZ each day at bedtime.
- You will need to mix LUMRYZ with water before you take or give your child the dose.
- You (or your child) should avoid getting out of bed after taking LUMRYZ. Some people fall asleep within 5 minutes of taking LUMRYZ and most will fall asleep within 15 minutes. The time it takes 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. Those activities should not be done until you know how LUMRYZ affects you.
- Mix and take (or give) LUMRYZ within 30 minutes. If not taken or given within 30 minutes of mixing, throw it away (dispose of it) and prepare a new dose.

LUMRYZ carton and contents



LUMRYZ comes in different package sizes. The LUMRYZ package you receive may look different from the picture shown above.

Additional supplies needed



How should I store LUMRYZ?

- Store LUMRYZ at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store LUMRYZ in the original packet prior to mixing with water.
- LUMRYZ suspension should be taken within 30 minutes of preparation.
- When you have finished using the LUMRYZ packet, throw it away (dispose of it) in the trash. If any LUMRYZ remains in the packet, rinse it down the sink before throwing away.
- Store LUMRYZ and all medicines out of the reach of children and pets.

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 (or your child's) bedside:

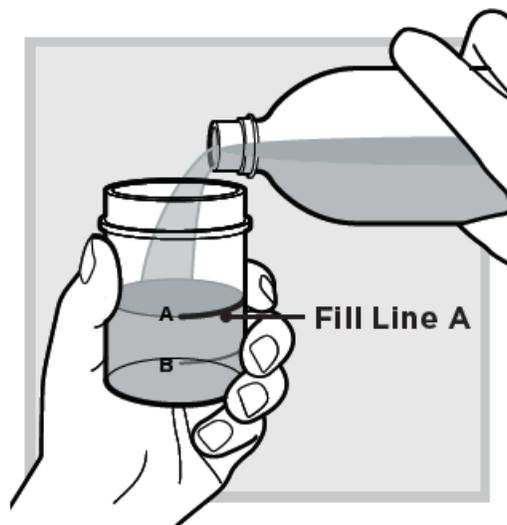
- 1 bottle or glass of water (1/3 cup). Do not use hot water.
- 1 LUMRYZ packet
- 1 clean mixing cup. The cap is not child resistant.
- 1 pair of scissors (optional)

Mix the LUMRYZ solution at your (or your child's) bedside

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

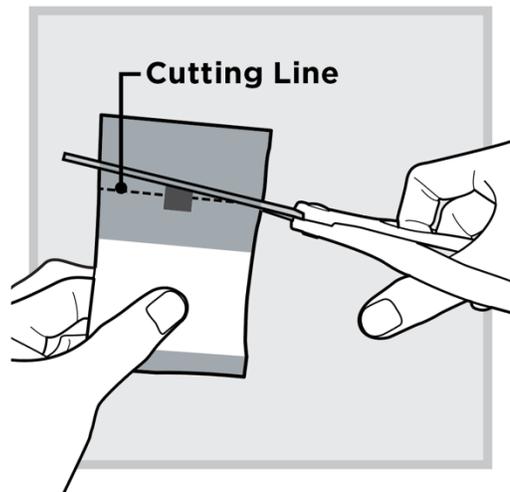


2.) Fill the mixing cup with water up to **Fill Line A** (top line) and set the mixing cup down on a flat surface.



3.) Open 1 packet:

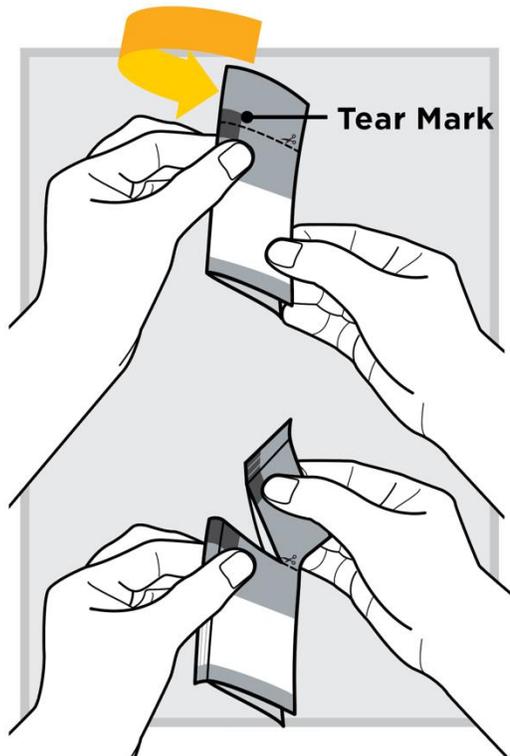
Use scissors to cut open the packet along the **Cutting Line**, located on the back of the packet.



-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.

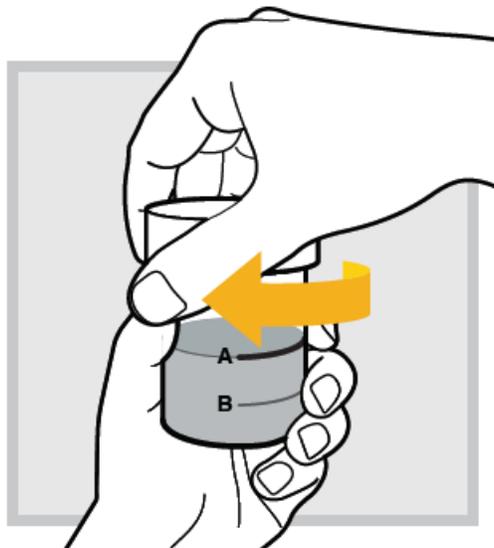


4.) Pour the entire content from the packet into the water-filled mixing cup.

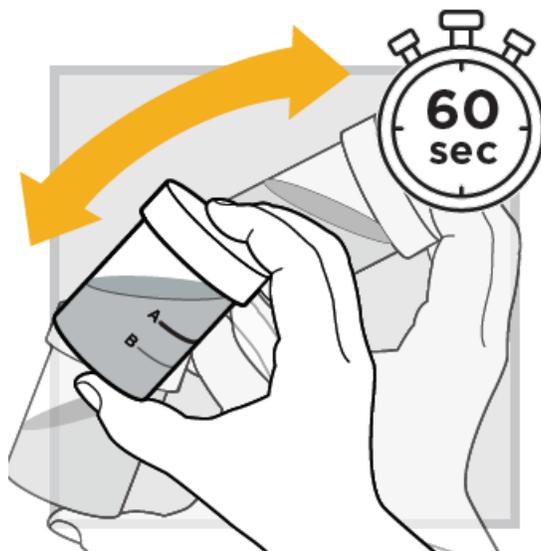
Make sure there is no powder left in the packet.



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

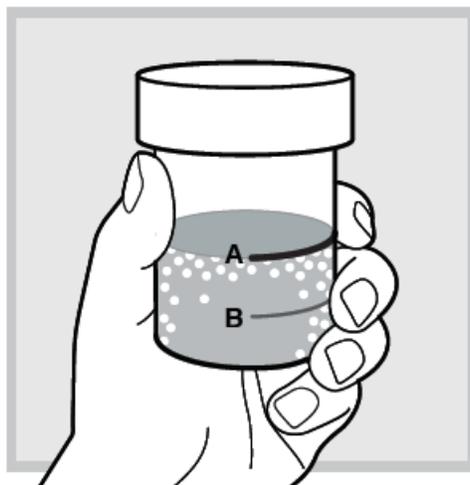


6.) Mix the water and powder solution by shaking the closed mixing cup well for at least **60 seconds (1 minute)**.



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.

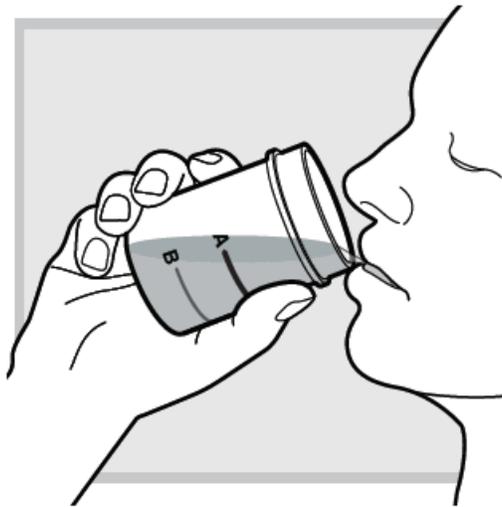
Take the LUMRYZ solution at your (or your child's) bedside

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

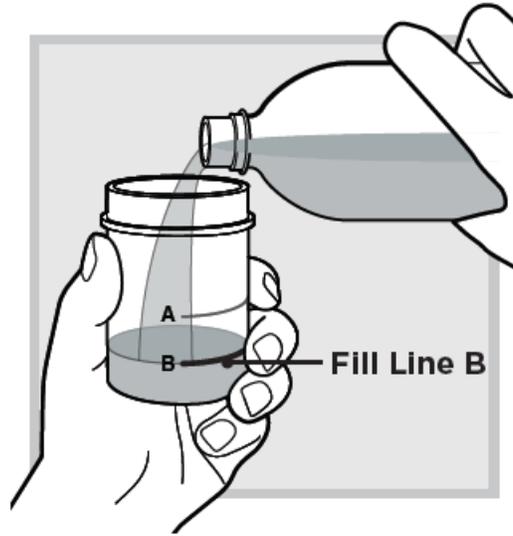


9.) While sitting in bed drink (or have your child drink) the mixed solution within **30 minutes** of mixing.

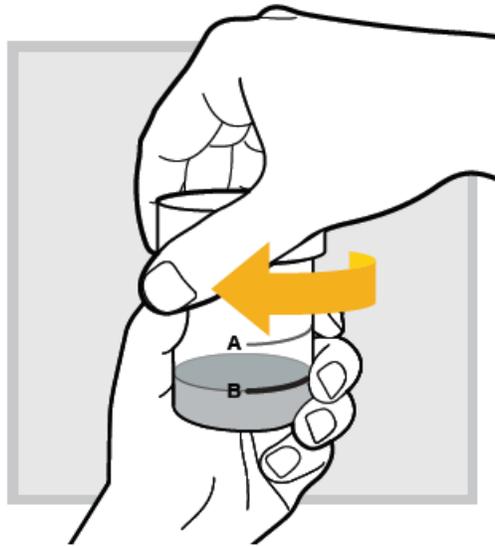
Make sure you (or your child) drink all the mixed solution in the mixing cup.



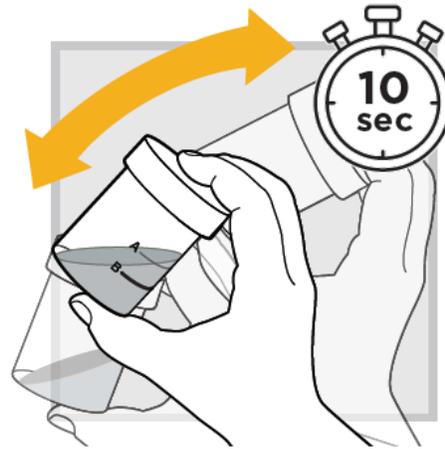
10.) Immediately refill the mixing cup with water up to **Fill Line B** (lower line) to mix in any medicine left in the mixing cup. **Do not open another packet of LUMRYZ. Take (or give) only 1 packet each day at bedtime.**



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.

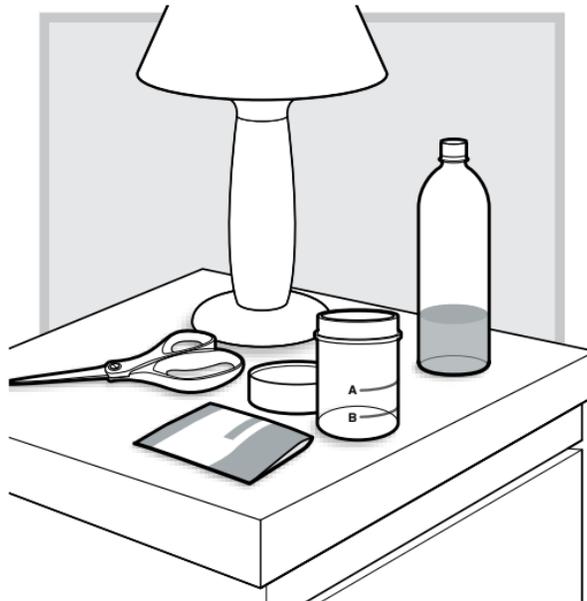


14.) Drink (or have your child drink) the mixed solution immediately after mixing.
Make sure you (or your child) drink all the mixed solution in the mixing cup.



15.) Leave the empty mixing cup at your (or your child's) bedside and immediately lie down (or have your child lie down) to go to sleep.

Avoid getting out of your bed (or having your child get out of bed) after taking LUMRYZ.

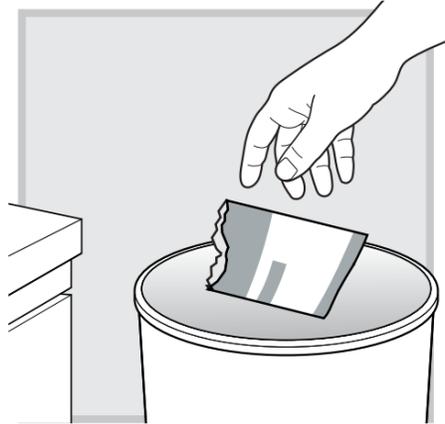


Continue to Step 16

How do I throw away (dispose of) LUMRYZ?

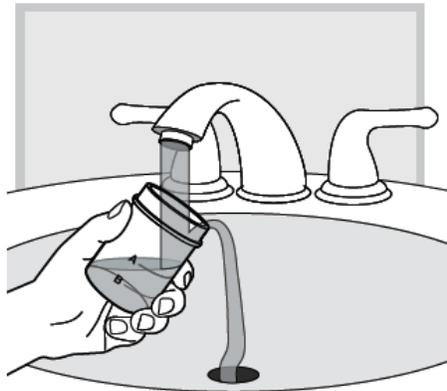
16.) The next day, place the empty LUMRYZ packet in the trash.

If any LUMRYZ remains in the packet, rinse it down the sink before (prior to) throwing away (disposal).



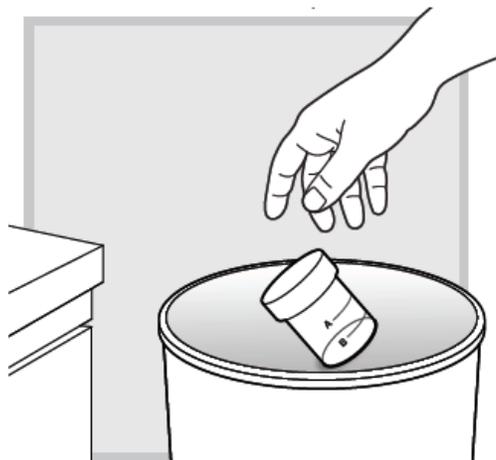
17.) Empty any unused LUMRYZ down the sink drain the next day.

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



After you (or your child) finish all of the packets in the LUMRYZ carton

After you have (or your child has) finished your (or your child's) 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
888-8AVADEL (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



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

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