

(sodium oxybate) for extended-release oral suspension @

# YOUR BEDSIDE LUMRYZ GUIDE

Starting a new treatment can be a big step. You can use this guide as you make LUMRYZ a part of your bedtime routine.



Wendy B., living with narcolepsy and treating with LUMRYZ

### **INDICATIONS**

LUMRYZ (sodium oxybate) for extended-release oral suspension is a prescription medicine used to treat the following symptoms in patients 7 years of age and older with narcolepsy:

- sudden onset of weak or paralyzed muscles (cataplexy)
- excessive daytime sleepiness (EDS)

### **IMPORTANT SAFETY INFORMATION**

WARNING: Taking LUMRYZ<sup>TM</sup> (sodium oxybate) with other central nervous system (CNS) depressants such as medicines used to make you fall asleep, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol, or street drugs, may cause serious medical problems, including trouble breathing (respiratory depression), low blood pressure (hypotension), changes in alertness (drowsiness), fainting (syncope), and death.

The active ingredient of LUMRYZ (sodium oxybate) is a form of gamma hydroxybutyrate (GHB), a controlled substance. Abuse or misuse of illegal GHB alone or with other CNS depressants (drugs that cause changes in alertness or consciousness) have caused serious side effects. These effects include seizures, trouble breathing (respiratory depression), changes in alertness (drowsiness), coma, and death. Call your doctor right away if you have any of these serious side effects.

Because of these risks, LUMRYZ is available only by prescription and filled through certified pharmacies in the LUMRYZ REMS program. You must be enrolled in the LUMRYZ REMS to receive LUMRYZ. Further information is available at <a href="https://www.LUMRYZREMS.com">www.LUMRYZREMS.com</a> or by calling 1-877-453-1029.

# Everyone responds to treatment differently

# Remember to listen to your body

### It may take time to notice a difference in your daytime symptoms.



In the clinical trial, some participants saw improvement in their symptoms by week 3 on a 6-g dose, while others saw improvement at week 13 after increasing the dose.\*

\*The LUMRYZ double-blind, placebo-controlled clinical trial included participants with narcolepsy treated with LUMRYZ (n=107). The results measured at week 3 (n=88), week 8 (n=77), and week 13 (n=69) showed daytime symptom improvement of participants on the 6-g, 7.5-g, and 9-g doses of LUMRYZ, respectively. Individual results may vary.



Over time, you and your healthcare provider will work together to **find a dose that is effective and tolerable for you**—a process called titration. In a clinical trial, it took 3 to 13 weeks for participants to see symptom improvement.

# It may help to keep track of how you're feeling.



As you take LUMRYZ, you'll want to consider how you feel in the morning and throughout the day. It can be helpful to track how symptoms of excessive daytime sleepiness (EDS) and/or cataplexy may change.



Explore more about the titration process by scanning the QR code or visiting MyLUMRYZ.com.

### IMPORTANT SAFETY INFORMATION (cont'd)

Do not take LUMRYZ if you take or your child takes other sleep medicines or sedatives (medicines that cause sleepiness), drink alcohol, or have a rare problem called succinic semialdehyde dehydrogenase deficiency.

Please see Important Safety Information throughout, and full <u>Prescribing Information</u>, including BOXED Warning, and <u>Medication Guide</u>.

You and your healthcare provider will work together to adjust your dose based on how you respond to treatment.



The most common side effects of LUMRYZ in adults include nausea, dizziness, bedwetting, headache, and vomiting.



The most common side effects of immediate-release sodium oxybate in children include nausea, bedwetting, vomiting, headache, weight decreased, decreased appetite, dizziness, and sleepwalking.



In the clinical trial, side effects typically occurred when participants started a new dose. Generally, the side effects then **declined over time while staying on the same dose**.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

Keep LUMRYZ in a safe place to prevent abuse and misuse. Selling or giving away LUMRYZ may harm others and is against the law. Tell your doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Anyone who takes LUMRYZ should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery, or flying an airplane, for at least six (6) hours after taking LUMRYZ. Those activities should not be done until you know how LUMRYZ affects you.

Falling asleep quickly, including while standing or while getting up from the bed, has led to falls with injuries that have required some people to be hospitalized.



# The unique formulation of LUMRYZ makes it a once-at-bedtime oxybate

# This formulation also leads to a unique taste and texture

LUMRYZ is designed to release medicine into your body while you sleep.

This requires a unique blend of 2 types of granules (immediate-release and controlled-release).





LUMRYZ is delivered with premeasured packets and a mixing cup.

Each dosage strength comes in a different-color packet.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

LUMRYZ can cause serious side effects, including the following:

- **Breathing problems, including** slower breathing, trouble breathing, and/or short periods of not breathing while sleeping (eg, sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they take LUMRYZ.
- Mental health problems, including confusion, seeing or hearing things that are not real (hallucinations), unusual or disturbing thoughts (abnormal thinking), feeling anxious or upset, depression, thoughts of killing yourself or trying to kill yourself, increased tiredness, feelings of guilt or worthlessness, and difficulty concentrating. Tell your doctor if you or your child have or had depression or have tried to harm yourself. Call your doctor right away if you or your child have symptoms of mental health problems or a change in weight or appetite.
- **Sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you or your child start sleepwalking.

Please see Important Safety Information throughout, and full <u>Prescribing Information</u>, including BOXED Warning, and <u>Medication Guide</u>.

Some things you may notice as you prepare, shake, and take\* your LUMRYZ dose:



Mixing

Your dose will not fully dissolve in water, even after shaking thoroughly in the mixing cup.



Taste

Your dose has a salty taste.



**Texture** 

Because your dose will not fully dissolve, the **texture** may appear gritty and slightly milky with some granules that stick together even when fully mixed.



Residue

Make sure to take your full dose. There may still be residue around the cup after you do.

\*These instructions are not complete. Please see <u>Instructions for Use</u> for complete administration directions.



To help keep track of your sleep with LUMRYZ, scan the QR code or visit MyLUMRYZ.com.



Traveling?

Just pack the number of dose packets you need. Your premeasured packets contain your prescribed dose each time.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

Tell your doctor if you or your child are on a salt-restricted diet or have high blood pressure, heart failure, or kidney problems. LUMRYZ contains a lot of sodium (salt) and may not be right for you.



# How LUMRYZ fits into your bedtime routine

# Now you're ready to sleep

LUMRYZ should be taken at least 2 hours after eating and be the last thing you do before going to bed. This helps the medicine absorb into the bloodstream.

Please see Instructions for Use for complete administration directions.

### **PREPARE** the medicine at your bedside by:

- Filling the mixing cup to line A with water. **Do not** use hot water
- Pouring the entire contents of 1 premeasured packet into the mixing cup



### SHAKE for at least 60 seconds (1 minute)

- Make sure the solution is mixed thoroughly
- The mixture will appear slightly milky with some lumps



### TAKE your medicine

- While sitting in bed, drink all of the contents of the cup within **30 minutes** after mixing
- Make sure to take your full dose: After drinking, immediately fill the mixing cup to Line B with water, shake for 10 seconds, and drink the rest



• Place the empty packet in the mixing cup. Then twist the cap back on to keep away from children and pets. 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

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# Lie down and tuck yourself in, as you may fall asleep quickly after taking LUMRYZ.

As with other oxybates, do not drive for at least 6 hours after taking your once-at-bedtime dose.





To watch a step-by-step guide on how to take LUMRYZ, scan the QR code or visit MyLUMRYZ.com.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

The most common side effects of LUMRYZ in adults include nausea, dizziness, bedwetting, headache, and vomiting. Your side effects may increase when you take higher doses of LUMRYZ. The most common side effects in children include nausea, bedwetting, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking.

LUMRYZ can cause physical dependence and craving for the medicine when it is not taken as directed. These are not all the possible side effects of LUMRYZ.

For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call <a href="https://example.com/1-800-FDA-1088">1-800-FDA-1088</a>.



# You are not alone on your LUMRYZ treatment journey

# Who do I call for ...?

RYZUP™ Support Services will be here for you throughout your treatment experience.



### Your RYZUP Support Services Nurse Care **Navigator (NCN)**

Your NCN will help you access, start, and stay on track with your LUMRYZ treatment plan.



Available to help you **prepare for** check-ins with your healthcare team



Will help you **navigate** the insurance process and any changes to your insurance



Can initiate a **3-way** phone call with your specialty pharmacy to start the conversation about arranging your next shipment



**You can reach your NCN** at 1-844-485-7636 from 8:00 AM to 8:00 PM Eastern Time, Monday through Friday.

## Use this guide to review who to reach out to for help with a specific topic.

### **Healthcare Provider**

Your go-to for medical information and questions about your LUMRYZ treatment plan.

- Reviewing your **symptoms**
- Treatment experiences and/or side effects
- Managing the **titration process** (making adjustments to your dose or discontinuing if necessary)
- Adjusting the length of time between refills (eq. 90 days)
- Other **medical** questions or concerns

#### Your NCN

Your support partner for LUMRYZ and insurance questions.

- Educational resources about LUMRYZ
- Discussing what information may be helpful to **share with your healthcare team** before check-ins
- Support if there are **changes to your insurance** or financial situation
- Processing any patient services **renewals or authorizations** that may be needed throughout the year
- Help with navigating medication **refills**

### **Specialty Pharmacy**

Your contact for arranging shipments and a resource for answering product-related questions.

- Product-related questions about LUMRYZ
- Arranging **shipments** of your prescription
- Reviewing the **refill** process
- Questions about the LUMRYZ Risk Evaluation and **Mitigation Strategy (REMS)**

To ensure support is on hand, add your treatment contacts to your phone. These include your NCN, healthcare provider, and specialty pharmacy.

Accredo: 1-800-424-2618 **CVS Specialty Pharmacy:** 1-800-834-2806

**Optum Frontier Therapies:** 1-877-851-0010 AssistRX: 1-913-396-7696

If you don't know your specialty pharmacy, your NCN can help.

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# We have created an online library to help you throughout your treatment journey with LUMRYZ



For resources, FAQs, and more helpful information while taking LUMRYZ scan the QR code or go to MyLUMRYZ.com.

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