

 $_Umrvz_{m}$ (sodium oxybate) for extended-release oral suspension (

FOR ADULTS AND CHILDREN 7 YEARS OF AGE AND OLDER WITH NARCOLEPSY



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[™] (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 <u>www.LUMRYZREMS.com</u> or by calling 1-877-453-1029.

With narcolepsy, you may be facing disruptions around the clock

Symptoms of narcolepsy are often missed and misunderstood



Before starting treatment, even if I slept a full 8, sometimes 10, hours, I would still fall asleep the next day during class and have to take naps." —*Tyler F., living with narcolepsy*

Tyler was compensated by Avadel Pharmaceuticals for his time. Individual results may vary.

Narcolepsy is a chronic sleep disorder. It affects the brain's ability to control your sleep-wake cycles disrupting both your days and nights.

Two common symptoms of narcolepsy are excessive daytime sleepiness (EDS) and cataplexy.



- A persistent feeling of sleepiness that disrupts your day
- Usually the first symptom people notice
- Can occur at random, or during less active situations such as when watching TV



Cataplexy:

- Sudden attacks of muscle weakness often triggered by strong emotions
- Can be mild and feel like knees buckling, or as severe as full-body paralysis
- Usually lasts for a few seconds or minutes

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.

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.

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

Narcolepsy may sometimes feel like an "invisible condition" it can take 8-15 years from when symptoms first start to an accurate diagnosis.

However, you are not alone. Narcolepsy affects over **168,000** adults and children in the US.

Managing your narcolepsy symptoms may be challenging.

Current treatment options may cause or even require interruptions in sleep.



Daytime treatments approved to treat narcolepsy may cause insomnia.



Other oxybate options require waking up in the middle of the night to take a second dose.

There are options for treating narcolepsy. Talk with your healthcare provider about which is the best medication for you.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Are you taking a twice-nightly oxybate like XYREM® (sodium oxybate) or XYWAV® (calcium, magnesium, potassium, and sodium oxybates) to treat your narcolepsy symptoms?

- Adhering to a treatment regimen can be challenging. Managing a consistent twice-nightly dosing schedule can be an added challenge for both you and your loved ones
- It is important to talk to your treatment team about how you're feeling and any challenges you are experiencing
- If you are taking a twice-nightly oxybate to treat your narcolepsy symptoms, take the quiz on the other side of this page and discuss the results with your healthcare provider

Read the following statements and check the boxes that apply to your experience with twice-nightly oxybates

Sometimes I need someone else to help me wake up to take the second dose

Every night I have to spend time preparing and planning the second dose of my twice-nightly oxybate treatment

When I wake up late to take my second dose, it impacts my morning schedule

When I skip my second dose, either by accident or on purpose, I feel an impact the next day

My sleep is interrupted by my narcolepsy treatment

How often do you skip or wake up late to take the second dose of your current treatment? (*Circle one*)

- 0 times per week
- 1-2 times per week
- 3-5 times per week
- More than 6 times per week

Discuss the answers above with your healthcare provider and ask about other options for treating narcolepsy.

INTRODUCING



Once-at-bedtime LUMRYZ is designed differently



LUMRYZ is an FDA-approved once-atbedtime oxybate treatment to help improve symptoms of cataplexy or EDS in adults and children 7 years of age and older.



Designed to work during your sleepNo second dose waiting on your nightstand to take in the middle of the night



Demonstrated effectivenessLUMRYZ delivered daytime symptom improvement in a clinical trial



Premeasured packets • Contain the prescribed dose each time



Discreet and convenient travel • Pack the number of dose packets you will need for your trip

Ask your healthcare provider if once-at-bedtime LUMRYZ could be right for you.

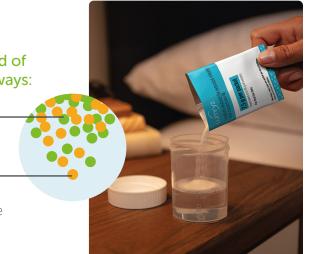
IMPORTANT SAFETY INFORMATION (cont'd)

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.

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LUMRYZ contains a blend of granules that work in 2 ways:

- Immediate-release granules start working as you fall asleep
- granules start working later in place of waking for a second dose



Each dosage strength comes in a different-color packet.

The active ingredient in LUMRYZ is sodium oxybate.

Sodium oxybate is strongly recommended by the American Academy of Sleep Medicine (AASM) to treat narcolepsy. This is based on evidence that it reduces cataplexy and EDS.

How might a single dose at night impact your day?

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.

(sodium oxybate) for extended-release oral suspension (1)

Once-at-bedtime LUMRYZ is proven to help improve daytime symptoms of narcolepsy*

A once-at-bedtime treatment means there is no interrupting your sleep to take a second dose

Participants in a clinical trial of LUMRYZ experienced[†]:

REDUCED EDS

1.5x more wakefulness during the day

LESS CATAPLEXY

57% fewer cataplexy attacks

OVERALL IMPROVEMENT

73% were rated much or very much improved by clinicians

In the clinical trial for LUMRYZ, some participants saw **significant symptom improvements as early as week 3**, while others saw symptom improvements at week 13 after titrating to a higher 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.

¹As seen in participants taking the 9-g dose of LUMRYZ and compared to baseline results at the start of the trial.



Since starting once-at-bedtime LUMRYZ, I feel less sleepy and more awake. I can spend time on my art without falling asleep and getting paint all over my clothes—so I feel more in the moment."

-Wendy B., living with narcolepsy and treating with LUMRYZ

Wendy was compensated by Avadel Pharmaceuticals for her time. Individual results may vary.

IMPORTANT SAFETY INFORMATION (cont'd)

• 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.

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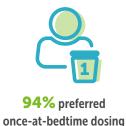
In a study^{*†} collecting the treatment experiences and preferences of participants who **switched from a twice-nightly oxybate to LUMRYZ:**



69% reported missing their second dose of twice-nightly oxybate either by accident or on purpose



80% said they felt worse symptoms the day after not taking the second dose



93% would recommend LUMRYZ to family or friends with narcolepsy

Results are descriptive and should not be considered clinical evidence.

*At the start of the study, 129 participants shared their experiences taking a twice-nightly oxybate in the last 3 months before switching to LUMRYZ. 98 participants shared their preferred dosing schedule after 3 months on a stable dose of LUMRYZ, and 68 completed a questionnaire at the end of the study to share their perspectives. These are personal preferences and should not be considered clinical evidence.

This was the secondary objective of the study. The primary objective was to evaluate the long-term safety of LUMRYZ, which found no new safety concerns to report.

IMPORTANT SAFETY INFORMATION (cont'd)

• **Sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you or your child start sleepwalking.

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.



The most common side effects reported by participants in the clinical trial were:

Nausea • Dizziness • Bedwetting • Headache • Vomiting

There were no clinically meaningful changes in blood pressure or heart rate.

In pediatric patients, the most common side effects 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**.

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

Remember to share all of your narcolepsy symptoms, goals, and treatment experiences with your healthcare team to find the best treatment fit for you.

LUMRYZ may not be appropriate for some people with narcolepsy. Your healthcare provider can help determine if LUMRYZ is a good fit for you.

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.

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The FDA found once-at-bedtime dosing to be a major contribution to patient care:

"LUMRYZ once-at-bedtime dosing provides an opportunity to **reduce sleep disruptions and fragmented sleep** in a way that is not possible with twice-nightly dosing."

"This is important because the goal of treating sleep disorders is to **restore a normal sleep pattern and healthier overall sleep**."

-FDA Clinical Superiority Findings, October 2024*

*Based on a determination of Orphan Drug Exclusivity by the FDA Office of Orphan Products Development between LUMRYZ and XYREM or XYWAV. There are no head-to-head data for LUMRYZ and XYREM or XYWAV.



For adults: Once you and your healthcare provider have decided LUMRYZ is right for you, they will consider the best way for you to start treatment.[†]

Switching to LUMRYZ

If you ARE currently taking a sodium oxybate: Your healthcare provider can switch you to LUMRYZ at the closest dose—equal to the amount of medicine you're taking now.

Starting with LUMRYZ

If you ARE NOT currently taking a sodium oxybate: Your healthcare provider will start you on the lowest dose of LUMRYZ and increase your dose gradually over time until you reach the dose that's right for you.

[†]For pediatric dosing, please see the full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

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.



Make LUMRYZ part of your bedtime routine

Katie shares why LUMRYZ is right for her

Take 1 premeasured packet, once at bedtime, for the prescribed dose.

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



Learn how to PREPARE, SHAKE, and TAKE LUMRYZ Scan the QR code or visit LUMRYZ.com to watch a step-by-step guide on how to take LUMRYZ.





PREPARE at your bedside by pouring water, then adding 1 premeasured packet into the provided mixing cup. **Do not** use hot water.

SHAKE for at least 60 seconds (1 minute).



lie in bed as you may fall asleep guickly.*

Make sure to take all the medicine in the mixing cup. After, add more water to the mixing cup and shake well again for 10 seconds, then take what remains of the mixture.



Because of this extended-release formulation. LUMRYZ does not fully dissolve in water and will have a gritty texture even after being shaken thoroughly in the mixing cup.

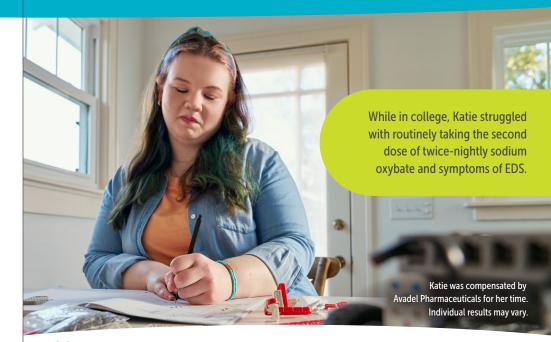
*Avoid getting out of your bed after taking LUMRYZ. Some people fall asleep within 5 minutes of taking LUMRYZ and most will fall asleep within 15 minutes. The time it takes you to fall asleep might be different from night to night.

These instructions are not complete. Please see Instructions for Use for complete administration directions.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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Once-at-bedtime LUMRYZ for me means I go to sleep, and the only thing I have to think of is what I'm going to be doing the next day. I'm not exhausted. I'm awake enough to do things like make myself breakfast."

-Katie L., living with narcolepsy and treating with LUMRYZ



See how LUMRYZ helped treat EDS and cataplexy for these individuals.

Scan the QR code or visit lumryz.com/real-lumryz-stories.



IMPORTANT SAFETY INFORMATION (cont'd)

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RYZUP Support Services is your partner in care

Getting started on LUMRYZ



We provide personalized support to help you access, start, and stay on track with your LUMRYZ treatment plan.

Nurse and Pharmacy support is available to you:



Your personal RYZUP Nurse Care Navigator (NCN) is dedicated to helping you start LUMRYZ and will be with you throughout your treatment journey.



Your NCN will help you navigate the insurance process and help connect you with financial assistance you might qualify for. LUMRYZ is covered for more than 90% of commercially insured patients on all national plans.



Once you are ready to start LUMRYZ, your NCN can help you coordinate with your specialty pharmacy, can share information about your new treatment, and can help you prepare for check-ins with your healthcare team.



Financial assistance programs are available.

Co-pay Assistance

Your co-pay could be as little as \$0 if you have commercial insurance.*

Temporary Access Program (TAP)

If there is a delay in insurance coverage, you may be eligible for up to 120 days of free LUMRYZ.[†]

Patient Assistance Program (PAP)

Treatment is available free of charge to eligible patients who are uninsured or underinsured.[‡]

*This offer is valid only for patients who have commercial insurance. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Additional terms and conditions apply. <u>Download</u> the full terms and conditions of the co-pay program.

[†]Applies only to eligible, commercially insured patients.

[‡]PAP application required. Patient must meet certain financial and other criteria.

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LUMRYZ is only available after enrollment in the LUMRYZ Risk Evaluation and Mitigation Strategy (REMS) and RYZUP Support Services. Your healthcare provider and specialty pharmacy will also be certified in the LUMRYZ REMS.

Before you can begin LUMRYZ, your healthcare provider's office will start the process to enroll you in:



To complete enrollment, you will need to sign 2 forms:

- Patient Authorization Form
- LUMRYZ REMS Patient Enrollment Form

You may be asked to sign these forms in the healthcare provider's office. If not, you may receive two (2) separate emails with instructions for how to complete and e-sign.

Expect a call from your NCN soon after completing the required enrollment steps.



Learn what to expect after being prescribed LUMRYZ

Scan the QR code to download a quick guide about RYZUP Support Services.



IMPORTANT SAFETY INFORMATION

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EXPERIENCE A NIGHT AND DAY DIFFERENCE

LUMRYZ is the first and only FDA-approved oxybate for adults and children 7 years of age and older designed to help improve symptoms of cataplexy or EDS with a once-at-bedtime dose.



PREMEASURED PACKETS For dosing and discreet travel



ONCE AT BEDTIME For your daytime symptoms



PERSONALIZED SUPPORT

For every step of the way

Download a discussion guide to help you talk to your healthcare provider about LUMRYZ Scan the QR code or visit <u>LUMRYZ.com/resources</u>.

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