

LUMRYZ is proven to treat the daytime symptoms of cataplexy or EDS, while its once-at-bedtime dosing means no waking up for a second dose.

IMPORTANT SAFETY INFORMATION

WARNING: Taking LUMRYZTM (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 www.LUMRYZREMS.com or by calling 1-877-453-1029.

INDICATIONS

LUMRYZ (sodium oxybate) for extended-release oral suspension is a prescription medicine used to treat the following symptoms in adults with narcolepsy:

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

Please see Important Safety Information throughout, and full Prescribing Information, including BOXED Warning, and Medication Guide available at LUMRYZ.com.



With narcolepsy, you may be facing disruptions around the clock

Managing your narcolepsy symptoms may be challenging



Narcolepsy is a neurological disorder that impairs your ability to regulate sleep cycles, affecting both your days and nights.

Two common symptoms of narcolepsy are EDS and cataplexy.



EDS, or the persistent feeling of drowsiness during the day, is typically the first symptom of narcolepsy people notice.



Some people also experience cataplexy—sudden periods of muscle weakness that can be triggered by strong emotions.

These disruptions create a burden for people with narcolepsy.

IMPORTANT SAFETY INFORMATION (cont'd)

It is not known if LUMRYZ (sodium oxybate) for extended-release oral suspension (CIII) is safe and effective in people less than 18 years of age.

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

 $\label{thm:condition} \textit{Keep LUMRYZ in a safe place to prevent abuse and misuse}. \textit{Selling or giving away LUMRYZ may harm}$

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Sleep is important to overall health. Not getting proper sleep can:

Impact your mental health • Increase your risk of health problems • Make it harder to fight off sickness

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



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



Daytime treatments approved to treat narcolepsy may cause insomnia.

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

IMPORTANT SAFETY INFORMATION (cont'd)

others and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Anyone who takes LUMRYZ (sodium oxybate) for extended-release oral suspension (CIII) 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.

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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.
 Having to wake in the middle of the night to take a second dose of your twice-nightly oxybate 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 and relate to any of the challenges on the following page, discuss your treatment options with your doctor

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

I have to rely on others in my household to wake

me for the second, middle-of-the-night dose
Every night, I have to spend time preparing and planning the second dose of my twice-nightly oxybate treatment
When I miss or mistime the second dose of my twice-nightly oxybate treatment, intentionally or accidentally, I feel the impact the following day
My sleep is interrupted by my narcolepsy treatment

How often do you miss the second dose of your twice-nightly oxybate treatment? (Circle one)

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

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



improve symptoms of cataplexy or EDS with a once-at-bedtime dose.



Potential for less interrupted sleep

• No second dose waiting on your nightstand to take in the middle of the night



Demonstrated effectiveness

• LUMRYZ 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 doctor if once-at-bedtime LUMRYZ could be right for you.

IMPORTANT SAFETY INFORMATION (cont'd)

Falling asleep guickly, 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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Once-at-bedtime LUMRYZ is designed differently

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

- Immediate-release granules start working as you fall asleep
- Controlled-release 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:

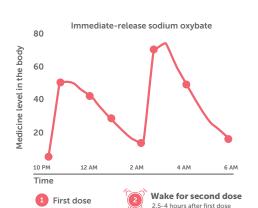
• Breathing problems, including slower breathing, trouble breathing, and/or short periods of not breathing while sleeping (eg, sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they take LUMRYZ.

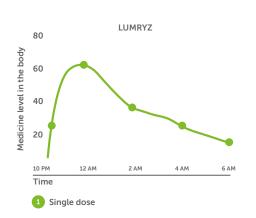


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A single, once-at-bedtime treatment means no interrupting your sleep to take another dose.





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 have or had depression or have tried to harm yourself. Call your doctor right away if you have symptoms of mental health problems or a change in weight or appetite.

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Once-at-bedtime LUMRYZ is proven to improve daytime symptoms of cataplexy or EDS*

People who received LUMRYZ experienced:



REDUCED EDS
Stayed awake 1.5x longer



REDUCED
CATAPLEXY ATTACKS

57% fewer cataplexy attacks



IMPROVED SYMPTOMS

73% were rated by clinicians to be much or very much improved



IMPROVEMENT IN WEEKS

Significant improvements as soon as 3 weeks into the trial[†]

With daytime symptom treatment and no middle-of-the-night dosing, LUMRYZ can help make a night and day difference.

*These results, measured at weeks 3, 8, and 13, show daytime symptom improvement of participants on the 6-g, 7.5-g, and 9-g dose of LUMRYZ in a clinical trial.

†As seen in participants taking a 6-g dose of LUMRYZ.

IMPORTANT SAFETY INFORMATION (cont'd)

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

Tell your doctor if you are on a salt-restricted diet or if you have high blood pressure, heart failure, or kidney problems.

LUMRYZ contains a lot of sodium (salt) and may not be right for you.



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Side effects of LUMRYZ

LUMRYZ once-at-bedtime dosing was found to be a major contribution to patient care

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

Nausea • Dizziness • Bedwetting • Headache • Vomiting



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.



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

When talking with your doctor, it's important to discuss all of your narcolepsy symptoms, goals, and treatment experiences so that you can work together to find the best treatment fit for you.

LUMRYZ may not be appropriate for some people with narcolepsy. Your doctor 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. LUMRYZ can

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The FDA has determined LUMRYZ to be clinically superior* to both XYREM® (sodium oxybate) and XYWAV® (calcium, magnesium, potassium, and sodium oxybates):



"LUMRYZ once-at-bedtime dosing does not disrupt or fragment sleep."

• "XYREM and XYWAV require waking up to take a second dose during the night"

"LUMRYZ is more convenient, easier, and less burdensome vs having to wake up for a second dose on a nightly basis. This is important as narcolepsy may require lifelong treatment."

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

OOPD, Office of Orphan Products Development.

Switching to LUMRYZ

If you ARE currently taking a sodium oxybate: Your doctor can switch you to LUMRYZ at the closest dose—equal to what you're taking now.

Starting on LUMRYZ

If you ARE NOT currently taking a sodium oxybate: Your doctor 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.

Once you and your doctor have decided LUMRYZ is right for you, your doctor will consider the best way for you to start treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

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.



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Make LUMRYZ part of your bedtime routine

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

LUMRYZ should be taken at least 2 hours after eating and be the last thing you do before bed:



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).



TAKE your medicine and **lie in bed** as you may fall asleep quickly.*



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 <u>Instructions for Use</u> for complete administration directions.

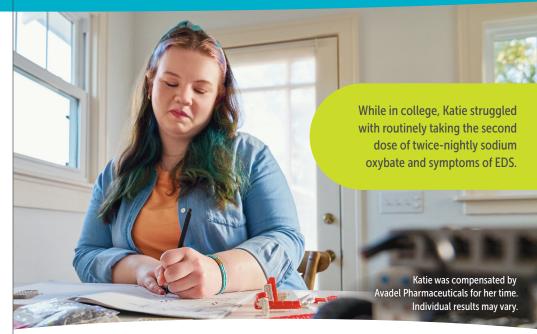
IMPORTANT SAFETY INFORMATION (cont'd)

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

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Katie shares why LUMRYZ is right for her



"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 the daytime symptoms of narcolepsy for these individuals.

Scan the QR code or visit LUMRYZ.com/Real-LUMRYZ-Stories.

IMPORTANT SAFETY INFORMATION (cont'd)

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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 understand coverage and help connect you with any financial assistance you might qualify for.



When you're ready to start taking LUMRYZ, your NCN will call you to review how to take the medication and answer questions you may have. They will also coordinate with your specialty pharmacy to make sure you receive reminders when your LUMRYZ prescription needs to be refilled.

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

For those that are eligible, RYZUP also offers programs if there is a delay in insurance coverage[†] or if you 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. For full terms and conditions of the co-pay program, visit <u>LUMRYZ.com/RYZUP</u>.

[†]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 doctor and REMS-certified specialty pharmacy will also be certified in the LUMRYZ REMS

Before you can begin LUMRYZ, your doctor's office will start the process to enroll you into:



RYZUP Support Services



LUMRYZ REMS

To complete enrollment, you will need to sign 2 forms in order to access LUMRYZ:

- RYZUP Patient Authorization Form
- LUMRYZ REMS Patient Enrollment Form

You may be asked to sign these forms in the doctor's office or receive them by email for you to e-sign. *Note: You may receive each document in a separate email.*

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



Want to learn more about RYZUP Support Services?

Visit <u>LUMRYZ.com/RYZUP</u> or scan the QR code.

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Codium oxybate) for extended-release oral suspension ®

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INDICATIONS

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

It is not known if LUMRYZ is safe and effective in people less than 18 years of age.

Do not take LUMRYZ if you take 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 have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

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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.

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 have or had depression or have tried to harm yourself. Call your doctor right away if you have symptoms of mental health problems or a change in weight or appetite.
- Sleepwalking. Sleepwalking can cause injuries. Call your doctor if you start sleepwalking.

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

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EXPERIENCE A NIGHT AND DAY DIFFERENCE

LUMRYZ is the first and only FDA-approved sodium oxybate treatment designed to help improve symptoms of cataplexy and EDS with a once-at-bedtime dose.



PREMEASURED PACKETSFor dosing and discreet travel



ONCE AT BEDTIMENo middle-of-the-night alarm clock



PERSONALIZED SUPPORTFor every step of the way



Watch a step-by-step guide on how to take LUMRYZ. Scan the QR code or visit I UMRY7 com.

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