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

Starting LUMRYZ with confidence

ONCE AT BEDTIME

An overview for starting LUMRYZ, the first and only single-dose sodium oxybate for adults and children 7 years of age and older with narcolepsy.

 $LUMYZ_{m}$ (sodium oxybate) for extended-release oral suspension \mathbb{C}



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 <u>1-877-453-1029</u>.

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

Once-at-bedtime LUMRYZ is designed differently

Make LUMRYZ part of your bedtime routine

LUMRYZ contains a unique 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.



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

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>.

Your first delivery of LUMRYZ will include everything you need to get started.



LUMRYZ carton and contents:

- A mixing cup
- Individual dose packets (7 or 30 count)
- Instructions for Use
- Prescribing Information and Medication Guide



Gather the following supplies and place by 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 to open the packet (optional)

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

Premeasured packets contain the prescribed dose each time.

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.

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



Know what to expect when taking LUMRYZ

Scan or go to LUMRYZ.com to watch a step-by-step guide on how to take LUMRYZ.



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

Make these steps a habit at bedtime

These instructions are not complete. Please see <u>Instructions for Use</u> for complete administration directions at <u>LUMRYZ.com</u>.



Prepare at your bedside by pouring **water**, **then adding 1 premeasured packet** into the provided mixing cup.

• Make sure you fill the mixing cup to line A with water. **Do not** use hot water



Shake for at least 60 seconds (1 minute). • Make sure the solution is mixed thoroughly

The mixture will appear slightly milky with some granules that stick together even when fully mixed.



Take your medicine.

- While sitting in bed, drink all 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

Due to the extended-release formulation, the mixture will taste salty, and the texture will be gritty when you take your full dose.

Now you're ready to sleep! 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.**

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.

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



Safety

The most common side effects in the clinical trial were nausea, dizziness, bedwetting, headache, and vomiting. The most common side effects in children include nausea, bedwetting, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking.

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.

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>.

Starting your treatment with LUMRYZ

RYZUP Support Services is your partner in care

We understand you may have guestions when starting treatment.

Here are some things that may help you stay on track with treatment:



Everyone responds to treatment differently

• 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*



It may be helpful to keep a journal to track how you are feeling



It may take time for the body to adjust to a new medicine

- The most common side effects reported in the clinical trial were nausea, dizziness, bedwetting. headache, and vomiting
- In pediatric patients, the most common side effects include nausea, bedwetting, vomiting, headache, weight decreased, decreased appetite, dizziness, and sleepwalking
- In the clinical trial for LUMRYZ, participants typically experienced side effects when starting a new dose, then those side effects generally declined over time while staying on the same dose



It's important to share your treatment experience with your healthcare provider

- Your healthcare provider may make adjustments to your dose based on how you are responding to treatment
- Talk with your healthcare provider about any side effects you're experiencing on LUMRYZ

Your experience matters

Check-ins with your healthcare team allow you to share how you are feeling during the first few weeks after starting LUMRYZ.

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

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.

Please see Important Safety Information throughout, and full Prescribing Information, including **BOXED Warning, and Medication Guide.**



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



You should expect a call from your Nurse Care Navigator (NCN) soon after your healthcare provider enrolls you in RYZUP Support Services and the LUMRYZ REMS to discuss any questions you may have about your treatment.

Your NCN can answer questions about how to take LUMRYZ, and provide details about refills, product delivery, or changes in your insurance coverage.



Coordinate delivery

Your NCN will coordinate with your specialty pharmacy to make sure you receive reminders when your LUMRYZ prescription needs to be refilled.



Your NCN is available with support throughout your treatment journey, including help preparing for check-ins with your healthcare provider.

It's normal to have questions

Reach out to your NCN if you aren't sure who to talk to about financial assistance programs or changes in your insurance coverage.

REMS, Risk Evaluation and Mitigation Strategy.



Just prescribed LUMRYZ? Scan the QR code to learn more about RYZUP Support Services with the Patient Information Guide.

Please see Important Safety Information throughout, and full Prescribing Information, including BOXED Warning, and **Medication Guide.**



ONCE AT BEDTIME FOR YOUR DAYTIME

LUMRYZ is used to treat cataplexy or excessive daytime sleepiness (EDS) in adults and children 7 years of age and older with narcolepsy.



(sodium oxybate) for extended-release oral suspension @

Daytime symptom treatment of cataplexy or EDS without waking up for a second dose.



Scan or go to <u>LUMRYZ.com</u> for more information, including a step-by-step guide on how to take LUMRYZ.

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.

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 <u>www.fda.gov/medwatch</u>, or call <u>1-800-FDA-1088</u>.

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



The Avadel logo, LUMRYZ™, RYZUP™, the droplet brand mark, and other Avadel brands are trademarks of an Avadel company. © 2024 Avadel. All rights reserved. PM-US-LUM-0505 11/2024