

**Medication Guide**  
**LUMRYZ™ (LOOM rize)**  
**(sodium oxybate)**

**for extended-release oral suspension, CIII**

Read this Medication Guide carefully before you start taking LUMRYZ and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

**What is the most important information I should know about LUMRYZ?**

- LUMRYZ is a central nervous system (CNS) depressant. Taking LUMRYZ with other 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)
  - death

Ask your doctor if you are not sure if you are taking a medicine listed above.

- LUMRYZ is a federal controlled substance (CIII). The active ingredient of LUMRYZ is a form of gamma-hydroxybutyrate (GHB) that is also a federal controlled substance (CI). Abuse of illegal GHB, either alone or with other CNS depressants may cause serious medical problems, including:
  - seizure
  - trouble breathing (respiratory depression)
  - changes in alertness (drowsiness)
  - coma
  - death

Call your doctor right away if you have any of these serious side effects.

- 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 6 hours after taking LUMRYZ. Those activities should not be done until you know how LUMRYZ affects you.
- 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.
- Because of the risk of CNS depression, abuse, and misuse, LUMRYZ is available only by prescription and filled through certified pharmacies in the LUMRYZ REMS. You must be enrolled in the LUMRYZ REMS to receive LUMRYZ. For more information on how to receive LUMRYZ, visit [www.LUMRYZREMS.com](http://www.LUMRYZREMS.com). Before you receive LUMRYZ, your doctor or pharmacist will make sure that you understand how to use LUMRYZ safely and effectively. If you have any questions about LUMRYZ, ask your doctor or call the LUMRYZ REMS at 1-877-453-1029.

**What is LUMRYZ?**

LUMRYZ is a prescription medicine used in people 7 years of age or older to treat the following symptoms of narcolepsy:

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

It is not known if LUMRYZ is safe and effective in children under 7 years of age.

**Do not take LUMRYZ if you or your child:**

- take other sleep medicines or sedatives (medicines that cause sleepiness)
- drink alcohol
- have a rare problem called succinic semialdehyde dehydrogenase deficiency

**Before taking LUMRYZ, tell your doctor about all medical conditions, including if you or your child:**

- have a history of drug abuse.
- have short periods of not breathing while sleeping (sleep apnea).
- have trouble breathing or have lung problems. You or your child may have a higher chance of having serious breathing problems when taking LUMRYZ.
- have or had depression or have tried to harm yourself. You or your child should be watched carefully for new symptoms of depression.
- have or had behavior or other psychiatric problems such as:
  - anxiety
  - seeing or hearing things that are not real (hallucinations)
  - feeling more suspicious (paranoia)

- being out of touch with reality (psychosis)
- acting aggressive
- agitation
- have liver problems.
- are on a salt-restricted diet. LUMRYZ contains a lot of sodium (salt) and may not be right for you or your child.
- have high blood pressure.
- have heart failure.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if LUMRYZ can harm your unborn baby.
- are breastfeeding or plan to breastfeed. LUMRYZ passes into breast milk. You and your doctor should decide if you or your child will take LUMRYZ or breastfeed.

**Tell your doctor about all the medicines you or your child take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially, tell your doctor if you or your child take other medicines to help you or your child sleep (sedatives) or that may make you or your child sleepy, such as some medicines to treat pain, anxiety, depression, or seizures. Know the medicines you or your child takes. Keep a list of them to show your doctor and pharmacist when you or your child get a new medicine.

#### **How should I take or give LUMRYZ?**

- Read the **Instructions for Use** for detailed instructions on how to take or give LUMRYZ.
- Take or give LUMRYZ exactly as your doctor tells you to take or give it.
- LUMRYZ is taken by mouth 1 time at bedtime.
- Wait at least 2 hours after eating before taking or giving LUMRYZ.
- After mixing LUMRYZ, take or give it within 30 minutes. Do not mix LUMRYZ with hot water.
- Take or give LUMRYZ at bedtime while you or your child is in bed and lie down immediately. You or your child should remain in bed after taking LUMRYZ.
- LUMRYZ can cause physical dependence and craving for the medicine when it is not taken as directed.
- Never change the LUMRYZ dose without talking to your or your child's doctor.
- LUMRYZ can cause sleep very quickly without feeling drowsy. Some people fall asleep within 5 minutes and most fall asleep within 15 minutes. The time it takes to fall asleep might be different from night to night.
- 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.
- If you or your child take too much LUMRYZ, call your doctor or go to the nearest hospital emergency room right away.

#### **What are the possible side effects of LUMRYZ?**

**LUMRYZ can cause serious side effects, including:**

- See **“What is the most important information I should know about LUMRYZ?”**
- **breathing problems, including:**
  - slower breathing.
  - trouble breathing.
  - short periods of not breathing while sleeping (sleep apnea).

People who already have breathing or lung problems have a higher chance of having breathing problems when they use 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
  - difficulty concentrating

**Call your doctor right away if you or your child has symptoms of mental health problems, or a change in weight or appetite.**

- **sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you start or your child starts sleepwalking. Your doctor should check you or your child.

**The most common side effects of LUMRYZ in adults include:**

- nausea
- dizziness
- bedwetting

- headache
- vomiting

**The most common side effects of LUMRYZ in children 7 years of age and older include:**

- nausea
- bedwetting
- vomiting
- headache
- decreased weight
- decreased appetite
- dizziness
- sleepwalking

Side effects may increase when taking higher doses of LUMRYZ.

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 may report side effects to FDA at 1-800-FDA-1088.

#### **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.

**Keep LUMRYZ and all medicines out of the reach of children and pets.**

#### **General information about the safe and effective use of LUMRYZ.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LUMRYZ for a condition for which it was not prescribed. Do not give LUMRYZ to other people, even if they have the same symptoms. It may harm them.

You can ask your pharmacist or doctor for information about LUMRYZ that is written for health professionals.

#### **What are the ingredients in LUMRYZ?**

**Active ingredients:** sodium oxybate

**Inactive ingredients:** carrageenan, hydrogenated vegetable oil, hydroxyethyl cellulose, magnesium stearate, malic acid, methacrylic acid copolymer, microcrystalline cellulose, povidone, xanthan gum.

**Distributed By:**

Avadel CNS Pharmaceuticals, LLC Chesterfield, MO 63005

For more information, go to [www.LUMRYZREMS.com](http://www.LUMRYZREMS.com) or call the LUMRYZ REMS at 1-877-453-1029.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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