Lumryz
(sodium oxybate) for extended-release oral suspension Ⓒ

LUMRYZ™ REMS | LUMRYZ Prescription Form

LUMRYZ (sodium oxybate) for extended-release oral suspension

Fax completed form to one of the certified pharmacies. A list of certified pharmacies is available to certified prescribers at www.LUMRYZREMS.com or by calling the LUMRYZ REMS at 1-877-453-1029. For more information, please call the LUMRYZ REMS at 1-877-453-1029.

Please Print (*denotes required field)

PRESCRIBER INFORMATION

*First Name:	M.I.:	*Last Name:
*NPI No.:	*DEA No.:	*State License No.:
*Street Address:		*Phone:
*City:	*State: ☐ *Zip Code:	*Fax:
Office Contact Name:		Office Contact Phone:

PATIENT INFORMATION

*First Name:	M.I.:	*Last Name:	*Primary Phone:
*Date of Birth (MM/DD/YYYY):	Weight (*required for pediatric patients): _____ kg	*Gender: ☐ Male ☐ Female ☐ Other	Cell Phone:
*Address:			Work Phone:
*City:	*State: ☐ *Zip Code:		Email:

***Medications:** (list all known current prescription and non-prescription medications and dosages or submit as a separate page)
☐ Check box if separate page(s) attached. Total number of additional pages: _____

Comorbidities: (list all known comorbidities or submit as a separate page)
☐ Check box if separate page(s) attached. Total number of additional pages: _____

*Indication for Use (Select One): ☐ G47.411 Narcolepsy with cataplexy ☐ G47.419 Narcolepsy without cataplexy ☐ Other (please specify) _____
LUMRYZ's approved indications are for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years and older with narcolepsy.

LUMRYZ (sodium oxybate) for extended-release oral suspension
The available strengths of LUMRYZ are 4.5 g, 6 g, 7.5 g and 9 g in box quantities of 7 or 30 packets or a Starter Pack containing 28 packets (7 packets of 4.5 g, 14 packets of 6 g and 7 packets of 7.5 g).

Please complete one of the below prescription options (either Starter Pack, Titrated Dose, or Maintenance Dose):

Medication	Package Type & Strength	Quantity	# of Refills
_____ *Please specify medication name above*	☐ Starter Pack NDC: 13551-005-01 Starter Pack includes 4.5 g (Week 1), 6 g (Week 2 and Week 3) and 7.5 g packets (Week 4)	_____ Starter Pack box of seven (7) 4.5 g, fourteen (14) 6 g, seven (7) 7.5 g packets	N/A
	☐ Titrated Dose Week 1 _____ g Week 2 _____ g Week 3 _____ g Week 4 _____ g	_____ box(es) of seven (7) _____ box(es) of seven (7) _____ box(es) of seven (7) _____ box(es) of seven (7)	N/A
	☐ Maintenance Dose _____ g	_____ box(es) of thirty (30)	_____

Dispensing Instructions: ***Initial prescription fill cannot exceed 1 month of therapy; refills cannot exceed 3 months' supply of therapy.***

Directions: ☐ Take contents of one packet mixed with water in provided mixing cup once per night orally at bedtime.
Note: Prepare the dose of LUMRYZ at bedtime according to label instructions. The LUMRYZ shipment does not include water for mixing.

Special Instructions:

PRESCRIBER PRESCRIPTION VERIFICATION: I understand and agree that, as the prescriber, I will comply with my state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me, as the prescriber. Prescriber attests this is his/her legal signature. NO STAMPS.

_____ *Prescriber Signature _____ *Date

PRESCRIBER REMS VERIFICATION: My signature below signifies that: I understand the statements and agree to the LUMRYZ REMS requirements which are found on page 2 of this form; LUMRYZ is medically appropriate for this patient; and, I have informed the patient and/or caregiver for pediatric patients that the LUMRYZ REMS will send the patient a **Patient Brochure** for adult patients or a **Pediatric Patients and their Caregivers Brochure** for pediatric patients with his or her first prescription fill.

_____ *Prescriber Signature _____ *Date

Printed Supervising Physician Name (if required by state law):

_____ Supervising Physician Signature _____ Date

PHARMACY VERIFICATION: My signature below signifies that: I understand the statements and agree to the LUMRYZ REMS requirements which are found on page 2 of this form.

_____ *Pharmacist Signature _____ *Date

Prescriber and Pharmacist: Signature verification is required on the first page of this **Prescription Form** as acknowledgment that you have an understanding of and/or agree to the following:

PRESCRIBER ATTESTATIONS

I understand that:

- LUMRYZ is approved for the treatment of
  - Cataplexy in patients 7 years of age and older with narcolepsy.
  - Excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
- LUMRYZ is a Schedule III central nervous system (CNS) depressant and can cause obtundation and clinically significant respiratory depression at recommended doses.
- LUMRYZ is contraindicated in combination with alcohol and sedative hypnotics.
- Concurrent use of LUMRYZ with certain other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating antiepileptic drugs, general anesthetics, muscle relaxants, and/or illicit CNS depressants, may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death.
- Patients who have sleep apnea or compromised respiratory function (e.g., asthma, COPD, etc.) may be at higher risk of developing respiratory depression, loss of consciousness, coma, and death with LUMRYZ use.

Before treatment initiation (first dose), I must:

- Assess the patient's health status to determine if LUMRYZ is medically appropriate by screening for history of alcohol and drug abuse, sleep-related breathing disorders, compromised respiratory function, depression, suicidality, concomitant use of sedative hypnotics and other CNS depressants or potentially interacting agents. Document and submit to a certified pharmacy using the **Prescription Form**.
- Counsel the patient on the serious risks and safe use, handling, and storage of LUMRYZ using the **Patient Brochure** for adult patients or the **Pediatric Patients and their Caregivers Brochure** for pediatric patients.
- Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS.
- Order the prescription using the **Prescription Form** and submit it to a certified pharmacy.

Before treatment re-initiation, I must:

- **For patients disenrolled for suspicion of abuse, misuse, or diversion:** Communicate with the pharmacy regarding all relevant patient history and re-enroll the patient if the pharmacist and I agree.
- **For patients with a lapse in treatment of 6 months or longer:** Order the prescription using the **Prescription Form** and submit it to a certified pharmacy.

Within the first 3 months of starting treatment, I must:

- Assess the patient for:
  - Concomitant use of sedative hypnotics, other CNS depressants, or potentially interacting agents
  - Serious adverse events
  - Signs of abuse and misuse, including an increase in dose or frequency of dosing, reports of lost, stolen, or spilled medication, and/or drug-seeking behavior

It is recommended that patients be re-assessed every 3 months while taking LUMRYZ.

At all times, I must:

- Report all potential serious adverse events, including CNS depression, respiratory depression, loss of consciousness, coma, and death; and any cases of suspected abuse, misuse, or diversion to Avadel CNS Pharmaceuticals, LLC.
- Assess the patient's potential for abuse, misuse, and diversion. Document and submit all instances of behavior that give rise to a reasonable suspicion of abuse, misuse, or diversion, including all requests for early refills, and all reports of lost, stolen, destroyed, or spilled drug using the **Risk Management Report**.
- Report requests to disenroll a patient for suspected abuse, misuse, or diversion to the REMS using the **Risk Management Report**.

PHARMACIST ATTESTATIONS

As the pharmacist, I must

- Verify that the patient has no other active, overlapping prescriptions for an oxybate product that overlap with the current LUMRYZ prescription.
- Verify the patient and prescriber have not been disenrolled in any other REMS for oxybate products for suspected abuse, misuse, or diversion.
- Report this prescription filled for LUMRYZ to the LUMRYZ REMS and all other REMS for oxybate products.