LUMRYZ™ REMS | LUMRYZ Prescription Form

LUMRYZ (sodium oxybate) for extended-release oral suspension

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.

Note: This form may not satisfy all legal requirements for prescribing LUMRYZ in your state.
Please submit all prescriptions in accordance with applicable state laws or as required by institutional policy. 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):	*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: _____

LUMRYZ PRESCRIPTION

_____ LUMRYZ 4.5 g 7 dose packets QTY: _____ box(es) of 7	_____ LUMRYZ 4.5 g 30 dose packets QTY: _____ box(es) of 30 _____ refills
_____ LUMRYZ 6 g 7 dose packets QTY: _____ box(es) of 7	_____ LUMRYZ 6 g 30 dose packets QTY: _____ box(es) of 30 _____ refills
_____ LUMRYZ 7.5 g 7 dose packets QTY: _____ box(es) of 7	_____ LUMRYZ 7.5 g 30 dose packets QTY: _____ box(es) of 30 _____ refills
_____ LUMRYZ 9 g 7 dose packets QTY: _____ box(es) of 7	_____ LUMRYZ 9 g 30 dose packets QTY: _____ box(es) of 30 _____ refills
*Only one strength shipped to patient at a time	*Only one strength shipped to patient at a time

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 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 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 that the LUMRYZ REMS will send him/her a *Patient Brochure* 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

Phone: 1-877-453-1029 | www.LUMRYZREMS.com | Fax: 1-877-206-3198

Avadel™

Lumryz
(sodium oxybate) for extended-release oral suspension

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 adults with narcolepsy.
  - Excessive daytime sleepiness (EDS) in adults 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.

I have read and understand the Prescribing Information and *Prescriber Brochure*.

I have screened this patient for:

- History of alcohol or substance abuse, sleep-related breathing disorders, compromised respiratory function, depression or suicidality, concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents.

I have counseled this patient on:

- The serious risks and safe use, handling, and storage of LUMRYZ using the *Patient Brochure*.

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 LUMRYZ 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 other 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.

I must:

- Report potential serious adverse events, including CNS depression, respiratory depression, loss of consciousness, coma, death, and any cases of suspected abuse, misuse, or diversion to Avadel CNS Pharmaceuticals, LLC.
- Report requests to disenroll a patient to a certified pharmacy.

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 the other REMS for oxybate products for suspected abuse, misuse, or diversion.
- Report this prescription filled for LUMRYZ to the LUMRYZ REMS and the other REMS for oxybate products.

Avadel