LUMRYZ™ REMS | Prescriber Enrollment Form

Lumryz
(sodium oxybate) for extended-release oral suspension

Complete and submit this form online at www.LUMRYZREMS.com, OR fax to 1-877-206-3198 (toll free).

For more information, please call the LUMRYZ REMS at 1-877-453-1029.

TO BECOME A CERTIFIED PRESCRIBER IN THE LUMRYZ REMS AND PRESCRIBE LUMRYZ:

1. Review the LUMRYZ Prescribing Information.
2. Review the **Prescriber Brochure.**
3. Complete steps 1, 2 and 3 below and submit this **Prescriber Enrollment Form** to the LUMRYZ REMS.

STEP 1: PRESCRIBER ATTESTATIONS

I have:
- Reviewed the Prescribing Information.
- Reviewed the **Prescriber Brochure**.

I understand:
- 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 anti-epileptic 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**.
- 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, and signs of abuse and misuse, including an increase in dose or frequency of dosing, reports of lost, stolen, or spilled medication, and drug-seeking behavior.

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

At all times, I must:
1. 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.
2. 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**.
3. Report requests to disenroll a patient for suspected abuse, misuse, or diversion to the REMS using the **Risk Management Report**.

STEP 2: TO HELP EXPEDITE THE ENROLLMENT PROCESS, PLEASE COMPLETE ALL REQUIRED FIELDS (PLEASE PRINT)

PRESCRIBER INFORMATION (*denotes required field)

*First Name:	M.I.:	*Last Name:	*DEA No.:

Facility/Practice Name: Abington Neurological Associates	*State License No.:	*NPI No.:

*Professional Designation: ☐ MD ☐ DO ☐ PA ☐ NP ☐ Other_____

*Medical Specialty: ☐ Sleep Medicine ☐ Neurology ☐ Pulmonology ☐ Psychiatry ☐ Internal Medicine ☐ Other_____

*Address Line 1: 1151 Old York Road

Address Line 2: Suite 200

*City: Abington	*State: PA	*Zip Code: 19001

*Phone: 215-957-9250	*Fax: 215-957-9254	*Email: abingtonneuro@abingtonneurology.com

*Preferred Method of Contact: ☐ Email ☐ Fax

OFFICE CONTACT INFORMATION (If you should need to add more than three office contacts, please call the LUMRYZ REMS at 1-877-453-1029.)

Office Contact First Name:	Office Contact Last Name:	Office Contact Phone:	Office Contact Email:

STEP 3: PRESCRIBER SIGNATURE IS REQUIRED BELOW FOR ENROLLMENT IN THE LUMRYZ REMS

By signing below, I acknowledge the above attestations, and I understand my personally identifiable information provided above will be shared with Avadel CNS Pharmaceuticals, LLC, its agents, contractors, and affiliates and entered into a prescriber database for the LUMRYZ REMS. I agree that I may be contacted in the future by mail, email, fax, and/or telephone concerning LUMRYZ, the LUMRYZ REMS, and other LUMRYZ programs and services.

_____ *Prescriber Signature

_____ *Date

Report adverse events to Avadel CNS Pharmaceuticals, LLC at productsafety@avadel.com or 1-888-828-2335.