SODIUM OXYBATE (SOX) REMS PHARMACY ENROLLMENT FORM

sodium oxybate oral solution 0.5 g/mL

Please complete all required fields below and fax to the Sodium Oxybate REMS at 1-877-641-0108.

Pharmacies must be specially certified in the Sodium Oxybate REMS to dispense sodium oxybate. Sodium oxybate will not be stocked in retail pharmacy outlets. To become certified, every pharmacy must designate an Authorized Representative to:

1. **Complete certification using this Pharmacy Enrollment Form**
   - Fax the completed form to the Sodium Oxybate REMS
2. **Review the Certified Pharmacy Training Module A and Certified Pharmacy Training Module B**
   - Complete the **Module A Knowledge Assessment** and the **Module B Knowledge Assessment**
   - Fax completed knowledge assessments to the Sodium Oxybate REMS
3. **Provide relevant training to the pharmacy staff and pharmacists in each pharmacy**
   - Maintain a record of the training
   - Submit documentation of training to the Sodium Oxybate REMS
4. **Establish processes and procedures to communicate patient information with the Sodium Oxybate REMS**

IN ORDER FOR THE ENROLLMENT PROCESS TO BE COMPLETE, AUTHORIZED REPRESENTATIVES MUST AGREE TO THE FOLLOWING:

As the Authorized Representative, I must:

- Review **Certified Pharmacy Training Module A** and **Certified Pharmacy Training Module B**.
- Successfully complete the **Module A Knowledge Assessment** and **Module B Knowledge Assessment** and submit both to the Sodium Oxybate REMS
- Complete and submit the **Pharmacy Enrollment Form**
- Train all relevant staff involved in dispensing using **Certified Pharmacy Training Module A**
- Have all relevant staff involved in dispensing successfully complete the **Module A Knowledge Assessment** and submit to the Sodium Oxybate REMS
- Train all pharmacists involved in dispensing using the **Certified Pharmacy Training Module A** and **Certified Pharmacy Training Module B**
- Have all pharmacists involved in dispensing successfully complete the **Module A Knowledge Assessment** and **Module B Knowledge Assessment** and submit to the Sodium Oxybate REMS
- Establish processes and procedures to assess the patient's concomitant use of sedative hypnotics, and other CNS depressants, or other potentially interacting agents that are either unknown to the prescriber or pose a high risk of serious interaction
- Establish processes and procedures to verify the following: the patient and prescriber are enrolled, the patient has no other sodium oxybate prescriptions
- Establish processes and procedures to verify and document the following by contacting all other REMS for oxybate products: the patient has no other active prescriptions that overlap with the current prescription for sodium oxybate by obtaining oxybate prescription information of last dispense date, days' supply, and prescriber's name; and the patient and prescriber have not been disenrolled from any other REMS for oxybate products for suspected abuse, misuse, or diversion
- Establish processes and procedures to verify all prescription information including patient name and two additional identifiers, prescriber name and information, dose, titration information (if applicable), number of refills, dosing directions, total quantity (days' supply), and concomitant medications
- Establish processes and procedures to assess the patient's potential for abuse, misuse, and diversion by reviewing the alerts and **Risk Management Report** histories in the REMS

- Establish processes and procedures to provide 24-7 toll-free access to a Sodium Oxybate REMS trained pharmacist; to dispense no more than a one-month supply for the initial shipment and no more than a three-month supply for subsequent shipments; and to ship, track, and verify receipt of sodium oxybate to the patient or patient-authorized adult designee using an overnight service
- Establish processes and procedures to report each prescription filled for sodium oxybate to all other REMS for oxybate products and document to the REMS
- Establish processes and procedures to reconcile sodium oxybate inventory using the pharmacy's inventory management system
- Establish processes and procedures to provide dispensing data and shipment and receipt dates to the REMS

Before dispensing, the pharmacy must:

- For new patients and existing patients who restart sodium oxybate treatment after not receiving product for 6 months or longer: Counsel the patient using the **Patient Counseling Checklist**. Document and submit to the REMS
- For patients who report a change in their medication use or medical history: Document and submit to the Sodium Oxybate REMS using the **Patient Counseling Checklist**
- Assess the patient's concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents that are either are unknown to the prescriber or pose a high risk of serious interaction through the processes and procedures established as a requirement of the REMS
- Verify in this REMS that the patient has no other active sodium oxybate prescriptions that overlap with the current prescription for sodium oxybate through the processes and procedures established as a requirement of the REMS. Document and submit to the REMS
- Verify the following by contacting all other REMS for oxybate products through the processes and procedures established as a requirement of the REMS: the patient has no other active prescriptions for oxybate products that overlap with the current prescription for sodium oxybate by obtaining oxybate prescription information of last dispense date, days' supply, and prescriber's name; and the patient and prescriber have not been disenrolled from any other REMS for oxybate products for suspected abuse, misuse, or diversion. Document and submit to the REMS
- Assess the patient's and their prescriber's potential for abuse, misuse, and diversion by reviewing the alerts and **Risk Management Report** history in the REMS. Document the confirmation to the REMS
- Obtain authorization by contacting the REMS to verify the pharmacy is certified, the prescriber is certified, the patient is enrolled, the **Patient Counseling Checklist** is completed as required, the alerts and **Risk Management Report** history for the patient and their prescriber are reviewed by the pharmacist and the patient has no active, overlapping prescriptions for oxybate products
- For patients previously disenrolled for suspicion of abuse, misuse, or diversion: communicate all relevant patient history to the prescriber and determine whether to re-enroll the patient if the prescriber and pharmacist agree
- Verify the patient's prescription information including patient name and two additional identifiers, prescriber name and information, dose, titration information (if applicable), number of refills, dosing directions, total quantity (days' supply), and concomitant medications through the processes and procedures established as a requirement of the REMS
- For patients who request an early refill or if abuse, misuse, and diversion is suspected: Discuss the request or concern with the prescriber
- Dispense no more than a one-month (30-day) supply for the initial shipment
- Dispense no more than a three-month (90-day) supply for subsequent shipments

After dispensing, within 1 business day:

- Report each prescription filled for sodium oxybate to all REMS for oxybate products through the processes and procedures established as a requirement of the REMS. Document and submit to the REMS

Before shipping, the pharmacy must:

- Verify the patient's shipping address and that the patient or patient-authorized adult designee will be available to receive the shipment through the processes and procedures established as a requirement of the REMS
- Ship sodium oxybate directly to each patient or a patient-authorized adult designee through the processes and procedures established as a requirement of the REMS
- Provide new patients with the **Patient Quick Start Guide** with the first shipment

After shipping, the pharmacy must:

- Track and verify receipt of each shipment of sodium oxybate through the processes and procedures established as a requirement of the REMS
- Document and submit the dispensing data, and shipment and receipt dates to the REMS

To maintain certification to dispense, the pharmacy must:

- Have a new Authorized Representative review **Certified Pharmacy Training Module A** and **Certified Pharmacy Training Module B**
- Have a new Authorized Representative successfully complete the **Module A Knowledge Assessment** and **Module B Knowledge Assessment** and submit both to the REMS
- Have a new Authorized Representatives enroll in the REMS by completing the **Pharmacy Enrollment Form** and submitting it to the REMS

To maintain certification to dispense, every year, the pharmacy must:

- Train all relevant staff involved in dispensing sodium oxybate using the **Certified Pharmacy Training Module A**
- Have all relevant staff involved in dispensing sodium oxybate, successfully complete the **Module A Knowledge Assessment** and submit it to the REMS
- Train all pharmacists involved in dispensing sodium oxybate using the **Certified Pharmacy Training Module A** and **Certified Pharmacy Training Module B**
- Have all pharmacists involved in dispensing successfully complete the **Module A Knowledge Assessment**, and the **Module B Knowledge Assessment** and submit both knowledge assessments to the REMS

At all times the pharmacy must:

- Provide 24/7 toll-free access to a Sodium Oxybate REMS trained pharmacist
- Ship sodium oxybate directly to the patient or a patient-authorized adult designee using an overnight service
- Document and report all potential adverse events reported from all sources including CNS depression, respiratory depression, loss of consciousness, coma, and death to the REMS
- Report lost, stolen, destroyed, or spilled drug to the Sodium Oxybate REMS using the **Risk Management Report**
- Report each prescription filled for sodium oxybate to all other REMS for oxybate products through the processes and procedures established as a requirement of the REMS. Document and submit to the REMS
- Monitor all instances of patient and prescriber behavior that give rise to a reasonable suspicion of abuse, misuse, and diversion, including all requests for early refills, and all reports of lost, stolen, destroyed, or spilled drug. Report to the REMS 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**
- Not distribute, transfer, loan, or sell sodium oxybate
- Not stock sodium oxybate in retail pharmacies
- Maintain records of staff training and completion of knowledge assessments
- Maintain records of inventory reconciliation using the pharmacy's inventory management system
- Maintain records of all processes and procedures including compliance with those processes and procedures
- Comply with audits carried out by the Sodium Oxybate Applicants or a third party acting on behalf of the Sodium Oxybate Applicants to ensure that all processes and procedures are in place and are being followed

Pharmacy Information (All fields required)			
Pharmacy Name:			
Address:	City:	State:	Zip Code:
Phone:	Fax:		
NPI:	DEA:		

Authorized Representative Information (All fields required)		
First Name:	Last Name:	
Phone:	Fax:	Email:
Job Title / Role:	Credentials:	
Preferred Method of Contact: ☐ Email ☐ Fax		
By signing below, I acknowledge that I will comply with the Authorized Representative responsibilities outlined on this form.		
Authorized Representative Signature:		**Date:**

Please fax all pages of this form to the Sodium Oxybate REMS at 1-877-641-0108. You will receive a confirmation via your preferred method of contact provided on this form.