

SODIUM OXYBATE REMS PROGRAM PHARMACY ENROLLMENT FORM

Sodium oxybate oral solution 500 mg/mL

Sodium Oxybate
REMS Program

For immediate enrollment, please go to www.SodiumOxybateREMSprogram.com.

To submit this form via fax, please complete all required fields below and fax to 800-353-0987. You will receive a confirmation via the contact preference you list below.

Pharmacies must be specially certified in the Sodium Oxybate REMS Program 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 *Sodium Oxybate REMS Pharmacy Enrollment Form* and submit the completed form to the Sodium Oxybate REMS Program.
2. Provide relevant training to the pharmacy staff and pharmacists in each pharmacy and maintain a record of the training.
3. Ensure the pharmacy enables its Pharmacy Management System (PMS) to support electronic communication with the Sodium Oxybate REMS Program system using established telecommunication standards.

Authorized Representative Responsibilities

By signing this form, I attest that my pharmacy has put processes and procedures in place to:

1. Dispense sodium oxybate only to patients enrolled in the Sodium Oxybate REMS Program pursuant to a valid prescription written by a prescriber certified in the Sodium Oxybate REMS Program.
2. Ensure that all pharmacy staff involved in the Sodium Oxybate REMS Program complete the *Sodium Oxybate REMS Program Certified Pharmacy Training Program* and maintain a record of the training.
3. Ensure that all pharmacists that dispense sodium oxybate complete the pharmacist training in the *Sodium Oxybate REMS Program Certified Pharmacy Training Program* and maintain a record of the training.
4. Obtain a Pre-Dispense Authorization (PDA) for each sodium oxybate prescription by entering all prescriptions in the pharmacy management system, including cash payments.
5. Provide 24-7 toll-free access to a pharmacist at a Sodium Oxybate REMS Program specially certified pharmacy.
6. Recertify in the Sodium Oxybate REMS Program if the pharmacy designates a new authorized representative.
7. Ship sodium oxybate directly to each patient or a patient-authorized adult designee using an overnight service, track and verify receipt of each shipment of sodium oxybate, and provide shipment and receipt dates to the Sodium Oxybate REMS program for documentation.
8. Limit the first shipment for each patient to a one-month supply of sodium oxybate, and subsequent shipments to no more than a three-month supply of sodium oxybate.
9. Include a sodium oxybate Medication Guide with each shipment and provide a copy of the *Sodium Oxybate REMS Program Patient Quick Start Guide* to each new patient.
10. Document and report all potential serious adverse events reported by all sources, including any CNS depression, respiratory depression, loss of consciousness, coma, and death, and any instances of patient or prescriber behavior that give rise to a reasonable suspicion of abuse, misuse, or diversion to the Sodium Oxybate REMS Program.
11. Report all potential adverse events related to suspected abuse, misuse, or diversion, by completing and submitting the *Sodium Oxybate REMS Program Risk Management Report (RMR)* to the Sodium Oxybate REMS Program.
12. Maintain documentation that all processes and procedures are in place and are being followed for the Sodium Oxybate REMS Program and provide upon request to the Sodium Oxybate Sponsors, FDA, or a third party acting on behalf of the Sodium Oxybate Sponsors or FDA.
13. Comply with audits by the Sodium Oxybate Sponsors, FDA, or a third party acting on behalf of the Sodium Oxybate Sponsors or FDA to ensure that all processes and procedures are in place and are being followed for the Sodium Oxybate REMS Program.
14. Prohibit the sale, loan, or transfer of any sodium oxybate inventory to any other pharmacy institution, distributor, or prescriber.

Prior to dispensing sodium oxybate, my pharmacy will:

15. Complete the *Sodium Oxybate REMS Program Patient Counseling Checklist* and its requirements each time sodium oxybate is dispensed and submit the completed checklist to the Sodium Oxybate REMS Program.
16. Validate each sodium oxybate prescription by:
 - a. Verifying that the prescriber is certified, the patient is enrolled and the patient has no other active sodium oxybate prescription by entering all prescriptions in the pharmacy management system, including cash payments by obtaining a PDA via electronic telecommunication verification.
 - b. Confirming all prescription information, including patient name and two additional identifiers, prescriber name and information, dose, titration information (if applicable), number of refills, dosing directions, totally quantity (days' supply), and concomitant medications.
 - c. Contacting the Xyrem REMS Program by phone to verify that the patient has no other active prescriptions for sodium oxybate, the patient/prescriber has not been disenrolled in the Xyrem REMS program for suspected abuse, misuse, or diversion, and to report all prescriptions filled for sodium oxybate.
 - d. Documenting that the call to the Xyrem REMS Program was completed using the *Sodium Oxybate REMS Program Prescription Form*.
17. Review the relevant patient information obtained from the Sodium Oxybate REMS Program website (www.SodiumOxybateREMSProgram.com) and the *Sodium Oxybate REMS Program Prescription Form*, including:
 - a. Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents that either are unknown to the prescriber or pose a high risk of serious interaction with sodium oxybate.
 - b. Alerts and *Sodium Oxybate REMS Program RMR* regarding potential abuse, misuse, or diversion.

Pharmacy Information (All fields required)

Pharmacy Name:

Address:

City:

State:

Zip Code:

NCPDP:

NPI:

DEA:

Authorized Representative Information (All fields required)

First Name:

Last Name:

Phone:

Fax:

Email:

Preferred Contact Method: Phone Fax Email

By signing below, I acknowledge that I will comply with the Authorized Representative Responsibilities outlined on this form.

Authorized Representative Signature:

Date:

Next Steps

1. After completing and signing this form, please fax to 800-353-0987.
2. Once this form is processed, you will receive instructions on submitting test transaction to the Sodium Oxybate REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Sodium Oxybate REMS Program.
3. After successful completion of the test transactions, you will receive a pharmacy certification confirmation. Upon receipt, your pharmacy is certified and your pharmacy staff is now eligible to complete their training.