

SODIUM OXYBATE REMS PROGRAM RISK MANAGEMENT REPORT

Sodium oxybate oral solution 500 mg/mL

Sodium Oxybate
REMS Program

Instructions

Risk Management Reports (RMRs) are filled out by pharmacies that are certified in the Sodium Oxybate REMS Program to document and report events that give rise to a reasonable suspicion of abuse, misuse, diversion, or any behavior or information that may indicate the drug is not being used according to the prescriber's instructions. For immediate reporting, RMRs can be completed by the pharmacist online at www.SodiumOxybateREMSProgram.com. Alternatively, a pharmacist can complete a print version and fax to the Sodium Oxybate REMS Program at 800-353-0987.

The RMR history of a patient allows for the review of prior events of suspected abuse, misuse, or diversion and gives the pharmacist a more complete picture of the patient's history. The availability of individual patient RMRs enables the pharmacist to track and monitor for trends suggesting abuse, misuse, or diversion in individual patients. A trend or pattern of behavior in a patient's RMR history can be an indicator of abuse, misuse, or diversion and identifies patients who may require additional scrutiny when another event, such as an early refill request, occurs. In these cases, the RMR history informs actions of the pharmacist.

Examples of events that would require completion of an RMR under the Sodium Oxybate REMS Program include, but are not limited to, the following:

- Patient requests for early refills.
- Patient's loss/misuse of the product.
- Patient claim that he or she did not receive the product but the delivery service shows receipt of delivery, or that the shipment was lost, stolen, or delivered to an incorrect address and was not returned.
- Tampering with or counterfeiting or contamination of the product.
- Inquiries and/or arrests by law and regulatory enforcement agencies associated with the misuse or diversion of the product, or crimes related to the product.
- Prescribers whose DEA and/or state license numbers cannot be validated and the prescriber is submitting a *Sodium Oxybate REMS Program Prescriber Enrollment Form, Prescription Form, or Patient Enrollment Form*.

To complete a RMR:

- Contact the Sodium Oxybate REMS Program to assign a unique Control Number to each report in the Sodium Oxybate REMS Program.
- Complete investigation of the event, which may include contacting the patient, prescriber, law enforcement agency, or other parties.
- Attach any additional documentation required to support the investigation, including but not limited to the following: DEA 106 Form, police or fire report, or report from the shipping service.
- Complete review, follow-up, and sign-off of the RMR.
 - When the event involves suspected abuse, misuse, or diversion, the prescriber will be contacted and an alert may be placed in the prescriber database or patient database of the Sodium Oxybate REMS Program to ensure prescriber and pharmacist awareness.
 - The Sodium Oxybate REMS Program will monitor any associated patient or prescriber activity during the course of the investigation and for a period after the investigation, where appropriate.
 - The certified pharmacies will complete and submit the RMR to the Sodium Oxybate REMS Program. The Sodium Oxybate REMS Program will work with the sponsors to determine the need to notify local, state, or federal authorities.
- Send the RMR to the Sodium Oxybate REMS Program within one business day.
- If the RMR includes a potential adverse event, the potential adverse event is reported to the FDA through the Sodium Oxybate sponsors. If the RMR includes a product complaint, the event is also reported to the FDA through the Sodium Oxybate sponsors.

Sodium Oxybate REMS Program Risk Management Report

Date:	Control Number:	Type of Reporter:	<input type="checkbox"/> Patient	<input type="checkbox"/> Prescribing Physician	<input type="checkbox"/> Pharmacist	<input type="checkbox"/> Other
Name of Reporter (if not a patient):			Name and Address of Pharmacy:			
Nature of Report (e.g., early refill request, lost or stolen bottle, package not received, other):						
Identification Number (patient and/or prescriber ID associated with RMR):					Date Enrolled in Program:	
Have the alerts and RMR history been reviewed with the patient?			<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date(s) of RMR Event (Start/End):	
RMR Event (please provide detail):						
Early Refill Requested? <input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, reason for early refill request (e.g., dose increase, spilled medication, lost/stolen product):						
Prescriber Contacted?		<input type="checkbox"/> Yes	If yes, what was the outcome of the conversation?			
		<input type="checkbox"/> No	If no, what is the reason?			
Was early refill approved?			<input type="checkbox"/> Yes	<input type="checkbox"/> No	Early refill status reason:	
Potential adverse event associated with report?			<input type="checkbox"/> Yes	<input type="checkbox"/> No	If yes, AE number:	
Summary of investigation: <input type="checkbox"/> Yes <input type="checkbox"/> No						
Attachments (check all that apply): <input type="checkbox"/> DEA 106 Form <input type="checkbox"/> Police/Fire Report <input type="checkbox"/> Shipping Service Report <input type="checkbox"/> Other (specify):						
Should patient be monitored (alert placed)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
Are you requesting disenrollment for suspected abuse, misuse, or diversion?		For the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No		For the prescriber? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Yes <input type="checkbox"/> No		Patient Name: _____		Prescriber Name: _____		
Pharmacist in Charge Name:		Signature:		Date:		