

Sodium Oxybate
REMS Program

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Risk Evaluation and Mitigation Strategy (REMS)

The goal of the Sodium Oxybate REMS Program is to mitigate the risk of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of sodium oxybate by:

1. Informing prescribers, pharmacists, and patients of:
 - i. The risk of significant Central Nervous System (CNS) and respiratory depression associated with sodium oxybate
 - ii. The contraindication of use of sodium oxybate with sedative hypnotics and alcohol
 - iii. The potential for abuse, misuse, and overdose associated with sodium oxybate
 - iv. The safe use, handling, and storage of sodium oxybate
2. Ensuring that pharmacy controls exist prior to filling prescriptions for sodium oxybate that:
 - i. Screen for concomitant use of sedative hypnotics, and other potentially interacting agents
 - ii. Monitor for inappropriate prescribing, misuse, abuse, and diversion of sodium oxybate
 - iii. Notify prescribers when patients are receiving concomitant contraindicated medications or there are signs of potential abuse, misuse, or diversion

Sodium Oxybate REMS Program Overview

- All prescribers and pharmacies must enroll in the Sodium Oxybate REMS Program and comply with requirements for prescribing and dispensing sodium oxybate
- All patients must be enrolled in the Sodium Oxybate REMS Program to receive sodium oxybate
- All patients are required to be counseled on the serious risks and safe use of sodium oxybate
- Sodium oxybate will be dispensed only by pharmacies that are specially certified through the Sodium Oxybate REMS Program

Sodium oxybate is approved for:

- Treatment of cataplexy in patients with narcolepsy
- Treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy

If you require any additional assistance or information, please call the Sodium Oxybate REMS Program at 855-705-2424

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Contact Us

Sodium Oxybate REMS Program

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Sodium Oxybate REMS Program

P.O. Box XXXXX

City, ST XXXXX XXXX

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Create an Account

Pharmacists and prescribers can create a web account in the Sodium Oxybate REMS Program by completing the fields below. The Username you specify must be unique within this website. All fields below are required unless otherwise indicated.

First Name	<input type="text"/>
Last Name	<input type="text"/>
Email Address	<input type="text"/>
Certification ID (opt)	<input type="text"/>
	<i>(If you certified via fax, please enter your Certification ID)</i>
Username	<input type="text"/>
	<input type="button" value="Suggest Username"/> <input type="button" value="Check Username Availability"/>
	<input type="checkbox"/> Use Email Address as Username
Password	<input type="password"/>
Confirm Password	<input type="password"/>
	<input type="button" value="Cancel"/> <input type="button" value="Submit"/>

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Frequently Asked Questions

– Is it still possible to enroll offline?

Yes, you can still enroll offline. Enrollment forms are located under the [Resources](#) tab.

– Do I need to complete the online version of the Prescriber Enrollment Form if I am already enrolled in the Sodium Oxybate REMS Program?

No. If you are already enrolled in the Sodium Oxybate REMS Program or have completed the prescriber enrollment process offline and faxed it, you do not need to complete the online version of the prescriber enrollment form.

You can still use the online enrollment form to enroll your patients.

– How long does it take to process my enrollment so I can enroll patients?

Generally, the Sodium Oxybate REMS Program will process your enrollment within 2 to 3 business days.

– How will I be notified that my patient is enrolled?

Once you complete the patient enrollment form, both you and the patient have signed the form, and the form has been submitted, the Sodium Oxybate REMS Program will process the enrollment form within 2 to 3 business days.

Once the enrollment has been processed you will receive a notification from the Sodium Oxybate REMS Program.

– Will my or my patient's information be shared with any third parties?

Your or your patient's information will only be shared with other sodium oxybate REMS programs, its agents, contractors, and affiliates.

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Prescriber Roles & Responsibilities

To become certified, each prescriber must complete a one-time enrollment by completing the Sodium Oxybate REMS Program Prescriber Enrollment Form and submitting it to the Sodium Oxybate REMS Program online or offline via fax or mail.

Enroll Now

Prescribers enrolled in the Sodium Oxybate REMS Program agree to:

1. Review the Prescribing Information (PI) and the Sodium Oxybate REMS Program Prescriber Brochure.
2. Screen each patient for:
 - History of alcohol or substance abuse
 - History of sleep-related breathing disorders
 - History of compromised respiratory function
 - Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
 - History of depression or suicidality
3. Counsel each patient prior to initiating therapy with sodium oxybate on the serious risks and safe use and handling of sodium oxybate using the Sodium Oxybate REMS Program Quick Start Guide.
4. Enroll each patient in the Sodium Oxybate REMS Program by completing the Sodium Oxybate REMS Program Patient Enrollment Form and submitting the form to the Sodium Oxybate REMS Program.
5. Evaluate each patient within the first three (3) months of starting sodium oxybate therapy, including an evaluation of the following. It is recommended that patients be re-evaluated every three (3) months thereafter while taking sodium oxybate.
 - a. Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
 - b. Serious adverse events
 - c. Signs of abuse and misuse, including:
 - i. An increase in dose or frequency of dosing
 - ii. Reports of lost, stolen, or spilled medication
 - iii. Drug-seeking behavior
6. Report all potential serious adverse events, including CNS depression, respiratory depression, loss of consciousness, coma, death, and any cases of suspected abuse, misuse, or diversion to the Sodium Oxybate REMS Program.

The prescriber will complete the *Sodium Oxybate REMS Program Prescription Form* for each new prescription and submit the form to one of the certified pharmacies, based on the patient's zip code, as indicated by the online certified pharmacy lookup on www.SodiumOxybateREMSProgram.com. By completing and signing this form, the prescriber acknowledges:

1. Having an understanding of:
 - a. The approved indications for sodium oxybate:
 - i. Treatment of cataplexy in narcolepsy
 - ii. Treatment of excessive daytime sleepiness in narcolepsy
 - b. The serious risks associated with sodium oxybate
 - c. The Prescribing Information and Sodium Oxybate REMS Program Prescriber Brochure
2. Having screened the patient for the following:
 - a. History of alcohol or substance abuse
 - b. History of sleep-related breathing disorders
 - c. History of compromised respiratory function
 - d. Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
 - e. History of depression or suicidality
3. Having counseled the patient on:
 - a. The serious risks associated with sodium oxybate
 - b. Contraindications (alcohol and sedative hypnotics) and implications of concomitant use of sodium oxybate with other potentially interacting agents
 - c. Preparation and dosing instructions for sodium oxybate
 - d. Risk of abuse and misuse associated with sodium oxybate
 - e. Risk of operating hazardous machinery including automobiles or airplanes for the first six (6) hours after taking a dose of sodium oxybate
 - f. Safe use, handling, and storage of sodium oxybate
4. That sodium oxybate is medically appropriate for the patient
5. Having listed all known prescription and non-prescription medications and doses on the Sodium Oxybate REMS Program Prescription Form

Materials for Prescriber

- [IMPORTANT UPDATE FOR PRESCRIBERS ON Sodium Oxybate \(XOXYBATE\) REMS PROGRAM](#)
- [Sodium Oxybate Prescribing Information](#)
- [Sodium Oxybate REMS Program Prescriber Enrollment Form](#)
- [Sodium Oxybate REMS Program Patient Enrollment Form](#)
- [Sodium Oxybate REMS Program Prescriber Brochure](#)
- [Sodium Oxybate REMS Program Quick Start Guide](#)
- [Sodium Oxybate REMS Program Prescription Form](#)

Pharmacy

Certification in the Sodium Oxybate REMS Program requires pharmacies to agree to:

1. Designate an authorized representative to complete and submit the Sodium Oxybate REMS Pharmacy Enrollment Form on behalf of the pharmacy
2. Ensure that the authorized representative oversees implementation and compliance with the Sodium Oxybate REMS Program by the following:
 - i. Ensure that all pharmacy staff involved in the Sodium Oxybate REMS Program complete the *Sodium Oxybate REMS Program Certified Pharmacy Training Program* Module A
 - ii. Ensure that all pharmacists who dispense sodium oxybate complete the *Sodium Oxybate REMS Program Certified Pharmacy Training Program* Modules A and B
3. Dispense sodium oxybate only to patients enrolled in the Sodium Oxybate REMS Program pursuant to a valid prescription written by a prescriber specially certified in the Sodium Oxybate REMS Program
4. Dispense only after obtaining a Pre Dispense Authorization (PDA) for each sodium oxybate prescription
5. Recertify in the Sodium Oxybate REMS Program if the pharmacy designates a new authorized representative
6. Provide 24/7 toll free access to a pharmacist at a Sodium Oxybate REMS Program specially certified pharmacy
7. Ship sodium oxybate directly to each patient or a patient authorized adult designee, and track and verify receipt of each shipment of sodium oxybate
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. Report all potential adverse events reported by all sources, including any CNS depression, respiratory depression, loss of consciousness, coma, and death, and any cases of suspected abuse, misuse, or diversion to the Sodium Oxybate REMS Program for documentation

Enroll Now

Materials for Pharmacy

[Medication Guide](#)



[Sodium Oxybate REMS Program Pharmacy Enrollment Form](#)

If you require any additional assistance or information, please call the Sodium Oxybate REMS Program at 855-705-2424

Patient

Patients prescribed sodium oxybate must enroll in the Sodium Oxybate REMS Program. If you were previously registered in the XYREM REMS, your certified prescriber will need to enroll you in the Sodium Oxybate REMS Program.

Materials for Patients

[Medication Guide](#)

 [Sodium Oxybate REMS Program Patient Quick Start Guide](#)

 [Sodium Oxybate REMS Program Patient Enrollment Form](#)

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Resources

Resources for Prescribers

 [Download All](#)

 [Sodium Oxybate Prescribing Information](#)

 [Sodium Oxybate REMS Program Prescriber Enrollment Form](#)

 [Sodium Oxybate REMS Program Patient Enrollment Form](#)

 [Sodium Oxybate REMS Program Prescriber Brochure](#)

Resources for Patients

 [Download All](#)

[Medication Guide](#)

 [Sodium Oxybate REMS Program Patient Quick Start Guide](#)

Resources for Pharmacies

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 [Sodium Oxybate REMS Program Patient Quick Start Guide](#)

 [Sodium Oxybate REMS Program Pharmacy Enrollment Form](#)

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