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
Contact Us

Sodium Oxybate REMS Program

Phone
U.S. Phone 855 705 2424
Outside the U.S. Phone +1 855 705 2424

Fax
800 353 0987

Mailing Address
Sodium Oxybate REMS Program
P.O. Box XXXXX
City, ST XXXXX XXXX

If you require any additional assistance or information, please call the Sodium Oxybate REMS Program at 855-705-2424
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
Last Name
Email Address
Certification ID (opt)
Username
Password
Confirm Password

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

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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.

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

Prescribers enrolled in the Sodium Oxybate REMS Program agree to:

1. Participate in a Patient Information Program and the Sodium Oxybate REMS Program as described on the Prescriber Information Sheet.

2. Evaluate each patient prior to initiating therapy with sodium oxybate on the same risk and safety use, and handling of sodium oxybate using the Sodium Oxybate REMS Program Quick Start Guide.

3. Evaluate each patient prior to initiating therapy with sodium oxybate on the same risk and safety use, and handling of sodium oxybate using the Sodium Oxybate REMS Program Quick Start Guide.

4. Evaluate each patient prior to initiating therapy with sodium oxybate on the same risk and safety use, and handling of sodium oxybate using the Sodium Oxybate REMS Program Quick Start Guide.

5. Evaluate each patient prior to initiating therapy with sodium oxybate on the same risk and safety use, and handling of sodium oxybate using the Sodium Oxybate REMS Program Quick Start Guide.

6. Evaluate each patient prior to initiating therapy with sodium oxybate on the same risk and safety use, and handling of sodium oxybate using the Sodium Oxybate REMS Program Quick Start Guide.

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:
   - The approved indications for sodium oxybate.
   - The potential for abuse and misuse of sodium oxybate.
   - The risks and benefits of sodium oxybate.
   - The potential for adverse effects of sodium oxybate.

2. Having reviewed the patient for the following:
   - The potential for abuse and misuse of sodium oxybate.
   - The risks and benefits of sodium oxybate.
   - The potential for adverse effects of sodium oxybate.
   - The potential for drug interactions with sodium oxybate.

3. Having counseled the patient on:
   - The potential for abuse and misuse of sodium oxybate.
   - The risks and benefits of sodium oxybate.
   - The potential for adverse effects of sodium oxybate.
   - The potential for drug interactions with sodium oxybate.

4. This sodium oxybate is medically appropriate for the patient.

5. Having had a complete examination and nonprescription medications, and a physical examination form.

If you require any additional assistance or information, please call the Sodium Oxybate REMS Program at 1-855-755-3106.
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

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

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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

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

- Download All
  - Medication Guide
  - Sodium Oxybate REMS Program Patient Quick Start Guide
  - Sodium Oxybate REMS Program Pharmacy Enrollment Form

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