

**SODIUM OXYBATE REMS PROGRAM
PRESCRIBER ENROLLMENT FORM**
Sodium oxybate oral solution 500 mg/mL

Sodium Oxybate
REMS Program

Complete this form through www.SodiumOxybateREMSProgram.com.
OR fax the completed form to the Sodium Oxybate REMS Program at 800-353-0987 (toll free),
OR mail to: Sodium Oxybate REMS Program, PO Box XXXXX, City, ST XXXXX-XXXX.
For further information, please call the Sodium Oxybate REMS Program at 855-705-2424.

STEP 1: ALL BOXES BELOW MUST BE CHECKED IN ORDER FOR THE ENROLLMENT PROCESS TO BE COMPLETE AND BEFORE YOU CAN ENROLL PATIENTS AND PRESCRIBE SODIUM OXYBATE

- I understand that sodium oxybate is approved for the treatment of:
- Cataplexy in narcolepsy
 - Excessive daytime sleepiness (EDS) in narcolepsy
- I have read the Prescribing Information (PI) and the *Sodium Oxybate REMS Program Prescriber Brochure* and understand that:
- Sodium oxybate is a Schedule III CNS depressant and can cause obtundation and clinically significant respiratory depression at recommended doses
 - Alcohol and sedative hypnotics are contraindicated in patients who are using sodium oxybate
 - Concurrent use of sodium oxybate with other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating anti-epileptics, general anesthetics, muscle relaxants, and/or illicit CNS depressants, may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death
 - Patients who have sleep apnea or compromised respiratory function (e.g., asthma, COPD, etc.) may be at higher risk of developing respiratory depression, loss of consciousness, coma, and death with sodium oxybate use

I agree to:

- Enroll each patient in the Sodium Oxybate REMS Program
- Screen each patient for history of alcohol or substance abuse, sleep-related breathing disorders, compromised respiratory function, depression, suicidality, and concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
- Counsel each patient prior to initiating therapy on the serious risks and safe use, handling, and storage of sodium oxybate
- Evaluate patients within the first 3 months of starting sodium oxybate. It is recommended that patients be re-evaluated every 3 months thereafter while taking sodium oxybate
- Report all potential adverse events, including 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

STEP 2: TO HELP EXPEDITE THE ENROLLMENT PROCESS, PLEASE PRINT CLEARLY (*denotes required field)

| Prescriber Information | | | |
|--|---------------------|-----------------------|---|
| *FIRST NAME: | M.I.: | *LAST NAME: | PROF. DESIGNATION: (MD, DO, PA, NP): |
| *DEA No.: | *STATE LICENSE No.: | | |
| FACILITY/PRACTICE NAME: | | | NPI No.: |
| *STREET ADDRESS: | | | |
| *CITY: | *STATE: | *ZIP CODE: | |
| *PHONE: | *FAX: | EMAIL: | |
| *PREFERRED METHOD OF CONTACT : <input type="checkbox"/> EMAIL <input type="checkbox"/> FAX | | | |
| OFFICE CONTACT: | | OFFICE CONTACT PHONE: | |

STEP 3: PRESCRIBER SIGNATURE IS REQUIRED BELOW FOR ENROLLMENT IN THE SODIUM OXYBATE REMS PROGRAM

By signing below, I acknowledge the above attestations, and I understand that my personally identifiable information provided above will be shared with the Sodium Oxybate REMS Program, its agents, contractors, and affiliates and entered into a prescriber database for the Sodium Oxybate REMS Program. I agree that I may be contacted in the future by mail, email, fax, and/or telephone concerning sodium oxybate, the Sodium Oxybate REMS Program, and other sodium oxybate programs and services.

*Prescriber Signature: _____ *Date: _____

Report adverse events by contacting the Sodium Oxybate REMS Program at 855-705-2424.