

XYREM REMS PROGRAM PRESCRIPTION FORM

XYREM[®] (sodium oxybate) oral solution 0.5 g/mL



Form available online at www.XYREMS.com, must be printed, signed, and either:

Fax to XYREM REMS Program: 1-866-470-1744 (toll free)

OR mail to XYREM REMS Program, PO Box 66589, St. Louis, MO 63166-6589.

For more information, call the XYREM REMS Program at 1-866-997-3688 (toll free).

Please Print (*denotes required field; †denotes required field for pediatric patients on initial fill and restarts)

Prescriber Information

*First Name: _____ M.I.: _____ *Last Name: _____

*Street Address: _____ *Phone: _____

*City: _____ *State: _____ *Zip Code: _____ *Fax: _____

*DEA No.: _____ *NPI No.: _____

Office Contact: _____ Office Contact Phone: _____ *State License No.: _____

Patient Information

*First Name: _____ M.I.: _____ *Last Name: _____ *Primary Phone: _____

*Date of Birth (MM/DD/YYYY): _____ † Weight (if under age 18): _____ kg *Gender: M F Cell Phone: _____

*Address: _____ Work Phone: _____

*City: _____ *State: _____ *Zip Code: _____ E-Mail: _____

*MEDICATIONS: (list all known current prescription and non-prescription medications and dosages or submit as a separate page)

COMORBIDITIES: (list known comorbidities or submit as a separate page)

Total Quantity

1 2 3 month(s) supply (circle one)

Refills:

0 1 2 3 4 5 (circle one)

Dispensing Instructions

Directions: Take first dose p.o., diluted in ¼ cup of water, at bedtime. Take second dose p.o., diluted in ¼ cup of water 2.5 to 4 hours later.

Note: Prepare both doses at the same time prior to bedtime. The XYREM shipment does not include water for dilution.

Initial prescription fill cannot exceed 1 month of therapy. Refills cannot exceed 3 months supply.

Please complete **EITHER** the titrated dosing **OR** fixed dosing section.

Please see the Prescriber Brochure and the full Prescribing Information for additional dosing instructions.

Titrated XYREM Dosing: Titrate to Effect

Starting Dose: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose for _____ days

1st Titration: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose for _____ days

2nd Titration: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose for _____ days

3rd Titration: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose for _____ days

First dose is ordinarily taken at bedtime; second dose is taken 2.5 to 4 hours later.

For patients who sleep more than 8 hours per night, the first dose of Xyrem may be given at bedtime or after an initial period of sleep.

****For patients who weigh less than 20 kg, lower starting dosage, maximum weekly dosage increases and total maximum nightly dosage should be considered.**

Note: Unequal dosages may be required for some patients to achieve optimal treatment.

Fixed XYREM Dosing

Dose: First dose: _____ g + Second dose (2.5 to 4 hours later): _____ g = _____ g Total Nightly Dose

Special Dosing Instructions

Prescriber Verification—My signature below signifies that: I understand the statements and agree to the REMS requirements, which are found on the back of this form; XYREM is medically appropriate for this patient; and I have informed the patient and/or caregiver that the XYREM REMS Program will send him or her a copy of the XYREM Medication Guide with each prescription fill and the appropriate educational material (XYREM REMS Program Patient Quick Start Guide for adult patients and XYREM REMS Program Brochure for Pediatric Patients and their Caregivers for pediatric patients) with the first prescription fill.

*Prescriber Signature: _____ *Date: _____

Supervising Physician Signature: _____ Date: _____
(If required by state law)

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Prescriber: Signature verification is required on the **FRONT** page of this XYREM REMS Program Prescription Form as acknowledgment that you have an understanding of and/or agree to the following:

I understand that XYREM is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

I understand that:

- XYREM is a 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 XYREM
- Concurrent use of XYREM 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
 - If use of these CNS depressants in combination with XYREM is required, dose reduction or discontinuation of one or more CNS depressants (including XYREM) should be considered
 - If short-term use of an opioid (e.g., post- or perioperative) is required, interruption of treatment with XYREM should be considered
- 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 XYREM use
- XYREM is a Schedule III controlled substance with potential for abuse and misuse
- Safe use and handling by patients is important in order to prevent abuse/misuse and accidental exposure to family/friends, including children
- XYREM is to be prescribed only to patients enrolled in the XYREM REMS Program

I have read and understand the Prescribing Information and XYREM REMS Program Prescriber Brochure.

I have screened this 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

I have counseled this patient and/or caregiver on:

- The serious risks associated with XYREM
- Contraindications (alcohol and sedative hypnotics)
- Risk of concomitant use of XYREM with alcohol, other CNS depressants, or other potentially interacting agents
- Preparation and dosing instructions for XYREM
- Risk of abuse and misuse associated with use of XYREM
- Risk of operating hazardous machinery, including automobiles or airplanes, for the first 6 hours after taking a dose of XYREM
- Preparation and dosing instructions for XYREM
- Safe use, handling, and storage of XYREM