

XYWAV PRESCRIPTION FORM

XYWAV® (calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL



Form available online at www.XYWAVXYREMREMS.com. Either submit online, OR print, sign, and:

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

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

For more information, call the XYWAV and XYREM REMS 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

*Indication for Use (required for initial prescription and any change in diagnosis)
Select one: ☐ Cataplexy or EDS in Narcolepsy OR ☐ Idiopathic Hypersomnia OR ☐ Other

*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 (select one) Refills: 0 1 2 3 4 5 (select one)

Dispensing Instructions

Directions For 1 Time a Night Dosing (IH Patients): Take the dose p.o., diluted in ¼ cup of water, at bedtime

Directions For 2 Times a Night Dosing (For Narcolepsy and IH): 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 XYWAV 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 Prescribing Information for additional dosing instructions.

Titration XYWAV Dosing: Titrate to Effect

2 times a night dosing (For Narcolepsy and IH)	OR 1 time a night dosing (IH patients)	Number of Days (at each titration step)
Starting Dose: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose	Starting Dose: Dose: _____ g	Dose for _____ days
1st Titration: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose	1st Titration: Dose: _____ g	Dose for _____ days
2nd Titration: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose	2nd Titration: Dose: _____ g	Dose for _____ days
3rd Titration: First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose	3rd Titration: Dose: _____ g	Dose for _____ days

Doses may be divided equally or unequally and the first dose taken at bedtime and the second dose taken 2.5 to 4 hours later.

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

**If XYWAV is used in patients 7 years of age and older who weigh less than 20 kg, a lower starting dosage, lower maximum weekly dosage increases, and lower total maximum nightly dosage should be considered.

Fixed XYWAV Dosing

2 times a night dosing (For Narcolepsy and IH)	OR 1 time a night dosing (IH patients)
First dose: _____ g + Second dose: _____ g = _____ g Total Nightly Dose	Dose: _____ g

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; XYWAV is medically appropriate for this patient; and I have informed the patient and/or caregiver that the XYWAV and XYREM REMS will send him or her the appropriate educational material (XYWAV Patient Quick Start Guide for adult patients and XYWAV Brochure for Pediatric Patients and their Caregivers for pediatric patients) with the first prescription fill.

*Prescriber Signature: _____

*Date: _____

XYWAV and XYREM REMS

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

I understand that XYWAV 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 XYWAV is indicated for the treatment of idiopathic hypersomnia in adults.

I understand that:

- XYWAV 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 XYWAV
- Concurrent use of XYWAV 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 XYWAV is required, dose reduction or discontinuation of one or more CNS depressants (including XYWAV) should be considered
 - If short-term use of an opioid (e.g., post- or perioperative) is required, interruption of treatment with XYWAV 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 XYWAV use
- XYWAV 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
- XYWAV is to be prescribed only to patients enrolled in the XYWAV and XYREM REMS

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