XYWAV and XYREM REMS

XYWAV and XYREM REMS PRESCRIBER ENROLLMENT FORM

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

Complete and submit form online at www.XYWAVXYREMREMS.com, OR scan and e-mail to ESSDSPrescribers@express-scripts.com, OR fax to XYWAV and XYREM REMS at 1-866-470-1744 (toll free), OR mail to XYWAV and XYREM REMS, PO Box 66589, St. Louis, MO 63166-6589.

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

Note: Completion of this form and enrollment in the REMS allows you to prescribe both XYWAV and XYREM.

Step 1: Prescriber Attestations

I have:

- Reviewed the Prescribing Information
- Reviewed the Prescriber Brochure

I understand:

- XYWAV is indicated for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy
- XYWAV is indicated for the treatment of idiopathic hypersomnia (IH) in adults
- XYREM is indicated for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy
- XYWAV and XYREM are Schedule III CNS depressants and can cause obtundation and clinically significant respiratory depression at recommended doses
- The use of XYWAV or XYREM in combination with alcohol or sedative hypnotics is contraindicated
- Concurrent use of XYWAV or 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
- 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 or XYREM use

Before Treatment Initiation (first dose), I must:

- Assess the patient's health status to determine if XYWAV or XYREM is medically appropriate by screening for history of alcohol or substance abuse, sleep-related breathing disorders, compromised respiratory function, depression, suicidality, concomitant use of sedative hypnotics and other CNS depressants or potentially interacting agents. Document and submit my findings to the XYWAV and XYREM REMS using the product-specific **Prescription Form**
- Counsel the patient on the serious risks associated with XYWAV or XYREM safe use, handling, and storage using the product-specific **Patient Quick Start Guide** and **Brochure for Pediatric Patients and their Caregivers**
- Enroll the patient by completing and submitting the **Patient Enrollment Form** to the XYWAV and XYREM REMS
- Order the prescription using the product-specific **Prescription Form** and submit it to the XYWAV and XYREM REMS

Before Treatment Re-Initiation, I must:

- **For patients disenrolled for suspicion of abuse, misuse, or diversion:** Communicate with the pharmacy regarding all relevant patient history and re-enroll the patient if the pharmacist and I agree
- **For patients with a lapse in treatment of 6 months or longer:** Order the prescription using the product-specific Prescription Form and submit it to the XYWAV and XYREM REMS

During Treatment, Within the first 3 months of starting treatment, and recommended every 3 months thereafter, I must:

- Assess the patient for concomitant use of sedative hypnotics and other CNS depressants, or potentially interacting agents; serious adverse events, and signs of abuse and misuse, including an increase in dose or frequency of dosing, reports of lost, stolen, or spilled medication, and drug-seeking behavior

At all times, I must:

- 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 Jazz Pharmaceuticals
- Assess the patient's potential for abuse, misuse, and diversion. Report all instances of behavior that give rise to a reasonable suspicion of abuse, misuse, or diversion, including all requests for early refills, and all reports of lost, stolen, destroyed, or spilled drug to the REMS.
- Report all requests to disenroll a patient for suspected abuse, misuse, or diversion to the XYWAV and XYREM REMS

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.: _____ *NPI no.: _____

Facility/Practice Name: _____

*Street Address: _____

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

*Phone: _____ *Fax: _____ E-mail: _____

Office Contact: _____ Office Contact Phone: _____

Additional Office Location 1

Facility/Practice Name: _____

*Street Address: _____

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

*Phone: _____ *Fax: _____ E-mail: _____

Office Contact: _____ Office Contact Phone: _____

Additional Office Location 2

Facility/Practice Name: _____

*Street Address: _____

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

*Phone: _____ *Fax: _____ E-mail: _____

Office Contact: _____ Office Contact Phone: _____

Additional office locations and contacts can be entered online at XYWAVXYREMREMS.com.

Step 3: **Prescriber signature is required below for enrollment in the XYWAV and XYREM REMS**

By signing below, I acknowledge the above attestations, and I understand that my personally identifiable information provided above will be shared with Jazz Pharmaceuticals, Inc., its agents, contractors, and affiliates and entered into a prescriber database for the XYWAV and XYREM REMS. I agree that I may be contacted in the future by mail, e-mail, fax, and/or telephone concerning XYWAV, XYREM, and the XYWAV and XYREM REMS.

*Prescriber Signature: _____ *Date: _____

Report SERIOUS ADVERSE EVENTS by contacting Jazz Pharmaceuticals at 1-800-520-5568 or AEReporting@jazzpharma.com.