# XYWAV and XYREM REMS

### XYWAV and XYREM REMS PRESCRIBER ENROLLMENT FORM

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

Complete and submit form online at www.XYWAVXYREMREMS.com, <u>OR</u> scan and e-mail to ESSDSPrescribers@express-scripts.com, <u>OR</u> fax to XYWAV and XYREM REMS at 1-866-470-1744 (toll free), <u>OR</u> 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: ALL BOXES BELOW MUST BE CHECKED (1) IN ORDER FOR THE ENROLLMENT PROCESS TO BE COMPLETE AND BEFORE YOU CAN ENROLL PATIENTS AND PRESCRIBE XYWAV or XYREM

I understand that:

- 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 (EDS) in patients 7 years of age and older with
  narcolepsy
- □ I have read the Prescribing Information (PI) and the XYWAV and XYREM REMS Prescriber Brochure and understand that:
  - 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

I agree to:

- Enroll each patient in the XYWAV and XYREM REMS
- 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 and/or caregiver prior to initiating therapy on the serious risks and safe use, handling, and storage of XYWAV or XYREM
- Evaluate patients within the first 3 months of starting XYWAV or XYREM. It is recommended that patients be re-evaluated every 3 months thereafter while taking XYWAV or XYREM
- Report all potential serious adverse events, including CNS depression, respiratory depression, loss of consciousness, coma, and death, and any cases of suspected abuse, misuse, or diversion to Jazz Pharmaceuticals

#### Step 2: To help expedite the enrollment process, please PRINT clearly (\*denotes required field)

	Prescriber	r 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: Additional office locations and contacts			

### 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.





