

## Risk Evaluation and Mitigation Strategy (REMS)

The goal of the XYREM REMS Program is to mitigate the risk of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of XYREM by:

### 1. Informing prescribers, pharmacists, and patients of:

- i. The risk of significant CNS and respiratory depression associated with XYREM
- ii. The contraindication of use of XYREM with sedative hypnotics and alcohol
- iii. The potential for abuse, misuse, and overdose associated with XYREM
- iv. The safe use, handling, and storage of XYREM

### 2. Ensuring that pharmacy controls exist prior to filling prescriptions for XYREM that:

- i. Screen for concomitant use of sedative hypnotics, and other potentially interacting agents
- ii. Monitor for inappropriate prescribing, misuse, abuse, and diversion of XYREM
- iii. Notify prescribers when patients are receiving concomitant contraindicated medications or there are signs of potential abuse, misuse, or diversion

### MATERIALS FOR HEALTHCARE PROFESSIONALS

- XYREM Prescribing Information
- XYREM REMS Program Prescriber Enrollment Form
- XYREM REMS Program Patient Enrollment Form
- XYREM REMS Program Prescription Form
- XYREM REMS Program Patient Counseling Checklist
- XYREM REMS Program Prescriber Brochure
- XYREM REMS Program Pharmacy Training Program

### MATERIALS FOR PATIENTS

- Medication Guide
- XYREM REMS Program Patient Quick Start Guide

## XYREM REMS Program Overview

- All prescribers must enroll in the XYREM REMS Program and comply with requirements for prescribing XYREM
- All patients must be enrolled in the XYREM REMS Program to receive XYREM
- All patients are required to be counseled on the serious risks and safe use of XYREM
- XYREM will be dispensed only by the specially certified central pharmacy

## XYREM is approved for:

- Treatment of cataplexy in patients with narcolepsy
- Treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy

If you require any additional assistance or information, please call the XYREM REMS Program at 1-866-XYREM88® (1-866-997-3688)



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# Prescriber Roles & Responsibilities

To become certified, each prescriber must complete a one-time enrollment by completing the XYREM REMS Program Prescriber Enrollment Form and submitting it to the XYREM REMS Program via facsimile, E-mail, or mail.

### Prescribers enrolled in the XYREM REMS Program agree to:

1. Review the Prescribing Information (PI) and the XYREM REMS Program Prescriber Brochure.
2. Screen each 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
3. Counsel each patient prior to initiating therapy with XYREM on the serious risks and safe use and handling of XYREM using the XYREM REMS Program Quick Start Guide.
4. Enroll each patient in the XYREM REMS Program by completing the XYREM REMS Program Patient Enrollment Form and submitting the form to the XYREM REMS Program.
5. Evaluate each patient within the first 3 months of starting XYREM therapy, including an evaluation of the following. It is recommended that patients be re-evaluated every 3 months thereafter while taking XYREM.
  - a. Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
  - b. Serious adverse events
  - c. Signs of abuse and misuse, including:
    - i. an increase in dose or frequency of dosing
    - ii. reports of lost, stolen, or spilled medication
    - iii. drug-seeking behavior
6. 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.

### Each time a new prescription is written the prescriber will complete the XYREM REMS Program Prescription Form and submit it to the XYREM REMS Program. By completing and signing this form, the prescriber acknowledges:

1. Having an understanding of:
  - a. The approved indications for XYREM:
    - i. Treatment of cataplexy in narcolepsy
    - ii. Treatment of excessive daytime sleepiness in narcolepsy
  - b. The serious risks associated with XYREM
  - c. The Prescribing Information and XYREM REMS Program Prescriber Brochure
2. Having screened the patient for the following:
  - a. History of alcohol or substance abuse
  - b. History of sleep-related breathing disorders
  - c. History of compromised respiratory function
  - d. Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
  - e. History of depression or suicidality
3. Having counseled the patient on:
  - a. The serious risks associated with XYREM
  - b. Contraindications (alcohol and sedative hypnotics) and implications of concomitant use of XYREM with other potentially interacting agents
  - c. Preparation and dosing instructions for XYREM
  - d. Risk of abuse and misuse associated with XYREM
  - e. Risk of operating hazardous machinery including automobiles or airplanes for the first 6 hours after taking a dose of XYREM
  - f. Safe use, handling, and storage of XYREM
4. That XYREM is medically appropriate for the patient
5. Having listed all known prescription and nonprescription medications and doses on the XYREM REMS Program Prescription Form