Dear Prescriber,

Welcome to the XYREM REMS Program, which was developed in collaboration with the Food and Drug Administration (FDA) as a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of the drug outweigh its risks.

This brochure provides valuable information about the XYREM REMS Program that includes important prescribing information, educational and counseling requirements, and materials necessary for program enrollment and prescribing XYREM® (sodium oxybate) oral solution, including:

- **XYREM REMS Program Prescriber Enrollment Form**—a one-time enrollment is required for all prescribers of XYREM.
- **XYREM REMS Program Patient Enrollment Form**—a one-time patient enrollment in the XYREM REMS Program is required for each new patient for whom XYREM will be prescribed.
- **XYREM REMS Program Prescription Form**—required for prescribing XYREM. This form must be used for new prescriptions and may also be used for refills and renewals of XYREM prescriptions.
- **XYREM REMS Program Patient Quick Start Guide**—answers important questions for patients about how to get XYREM, how to use XYREM properly, and how to store it safely. It also gives important information about the risks associated with XYREM.

The XYREM REMS Program Prescriber Enrollment Form, XYREM REMS Program Patient Enrollment Form, and XYREM REMS Program Prescription Form must be completed in full and sent to the XYREM REMS Program. For your convenience, the XYREM REMS Program Prescriber Enrollment Form and the XYREM REMS Program Patient Enrollment Form are available online at [www.XYREMREMS.com](http://www.XYREMREMS.com) and all three forms can be requested by calling the XYREM REMS Program toll-free at 1-866-997-3688. The central Certified Pharmacy with the XYREM REMS Program is responsible for processing all prescriptions for XYREM. Continue reading this brochure to learn more about the XYREM REMS Program and your responsibilities as a prescriber of XYREM.

Please review the Prescribing Information for XYREM.

XYREM may be dispensed only to patients enrolled in the XYREM REMS Program.

**XYREM is Approved for:**
- Treatment of cataplexy in narcolepsy
- Treatment of excessive daytime sleepiness (EDS) in narcolepsy

If you require any additional assistance or information, please call the XYREM REMS Program at 1-866-XYREM88® (1-866-997-3688) or visit [www.XYREMREMS.com](http://www.XYREMREMS.com)

Sincerely,

Jazz Pharmaceuticals
IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
- XYREM is contraindicated in patients being treated with sedative hypnotics.
- Patients should not drink alcohol when using XYREM.
- XYREM is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency.

WARNINGS AND PRECAUTIONS

CNS Depressant
- XYREM is a CNS depressant. Concurrent use of XYREM with other CNS depressants, including but not limited to opioid analgesics; benzodiazepines; sedating antidepressants, antipsychotics, or 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 may be at a higher risk of developing respiratory depression, loss of consciousness, coma, and death with XYREM use.

Healthcare providers should caution patients about operating hazardous machinery for the first 6 hours after taking a dose of XYREM.

Abuse and Misuse
- XYREM is a Schedule III controlled substance.
- The active ingredient of XYREM, sodium oxybate, is the sodium salt of gamma-hydroxybutyrate (GHB), a Schedule I controlled substance. Abuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse events, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Illicit GHB has also been associated with drug-facilitated sexual assault.
- The rapid onset of sedation, coupled with the amnestic features of XYREM, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (e.g., assault victim).
- You should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse of XYREM (e.g., increase in size or frequency of dosing; reports of lost, stolen, or spilled medication; drug-seeking behavior; feigned cataplexy).

XYREM REMS Program
- XYREM is to be prescribed only to patients enrolled in the XYREM REMS Program. XYREM is available only through a restricted distribution program called the XYREM REMS Program. Required components of the XYREM REMS Program are:
  - Healthcare providers who prescribe XYREM must be specially certified. To be certified, prescribers must complete the XYREM REMS Program Enrollment Forms and comply with the REMS requirements.
  - XYREM will be dispensed only by the central pharmacy that is specially certified.
  - XYREM will be shipped only to enrolled patients with documentation of safe use conditions. To be enrolled, patients must sign the XYREM REMS Program Patient Enrollment Form and acknowledge that they have been counseled on the serious risks and safe use of XYREM.

Further information is available at www.XYREMREMS.com or 1-866-XYREM88® (1-866-997-3688)
Depression, Suicidality, and Other Behavioral/Neuropsychiatric Adverse Events

- The emergence of depression in patients treated with XYREM was seen in clinical trials and requires careful and immediate attention. Patients with a previous history of a depressive illness and/or suicide attempt should be monitored especially carefully for the emergence of depressive symptoms while taking XYREM. XYREM can cause the emergence of neuropsychiatric adverse events (psychosis, paranoia, hallucination, and agitation), loss of consciousness, and sleepwalking. Patients should be instructed to call their healthcare provider if they experience any of these events.
- Anxiety can also occur in patients treated with XYREM.

Use in Patients Sensitive to High Sodium Intake

- XYREM has a high sodium content.
- Daily sodium intake should be considered in patients on salt-restricted diets or with heart failure, hypertension, or compromised renal function.

Most Common Adverse Events

- In three controlled clinical trials, the most common adverse reactions (incidence ≥5% and twice the rate seen with placebo) in XYREM-treated patients were nausea (20%), dizziness (15%), vomiting (11%), somnolence (8%), enuresis (7%), and tremor (5%).

- Of the 398 XYREM-treated patients with narcolepsy, 10.3% of patients discontinued because of adverse reactions compared with 2.8% of patients receiving placebo. The most common adverse reaction leading to discontinuation was nausea (2.8%). The majority of adverse reactions leading to discontinuation began during the first few weeks of treatment.

- Please see Prescribing Information for XYREM.
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Prescribing Information and a Medication Guide are also included.
The procedure for writing and dispensing prescriptions for XYREM is outlined below.

**PRESCRIBERS OF XYREM**

Prescribing XYREM requires a one-time enrollment.

- **If you are prescribing XYREM for the first time**, complete the XYREM REMS Program Prescriber Enrollment Form, found either in this XYREM REMS Program Prescribers Brochure or online at [www.XYREMEMS.com](http://www.XYREMEMS.com). Please fax it to 1-866-470-1744 (toll-free), scan and send via e-mail to XYREMPrescribers@express-scripts.com, or mail to XYREM REMS Program, PO Box 66589, St. Louis, MO 63166-6589.

- **On the XYREM REMS Program Prescriber Enrollment Form**, please confirm that:
  - You understand that XYREM is approved for:
    - Treatment of cataplexy in patients with narcolepsy
    - Treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy
  - You have read and understand the Prescribing Information and this XYREM REMS Program Prescribers Brochure
  - You agree to 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
  - You agree to counsel your patients on:
    - The serious risks associated with XYREM
    - Contraindications (alcohol and sedative hypnotics)
    - Risks of concomitant use of XYREM with alcohol and/or other CNS depressants
    - 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
    - Risk of abuse and misuse associated with use of XYREM
    - Safe use, handling, and storage of XYREM
  - You will enroll each patient in the XYREM REMS Program by completing the one-time XYREM REMS Program Patient Enrollment Form and submitting the form to the XYREM REMS Program
  - You will evaluate each patient within the first 3 months of starting XYREM, including an evaluation of the following. It is recommended that patients be re-evaluated every 3 months thereafter while on XYREM therapy:
    - Patient’s concomitant medications
    - Serious adverse events
    - Signs of abuse and misuse such as an increase in dose or frequency of dosing; reports of lost, stolen, or spilled medication; and/or drug seeking behavior
  - You will 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
PATIENT ENROLLMENT

- All patients must be enrolled one time in the XYREM REMS Program, using the XYREM REMS Program Patient Enrollment Form.

- On the XYREM REMS Program Patient Enrollment Form:
  - Verify that you have provided counseling to each patient about the serious risks associated with the use of XYREM and the safe use conditions as described in the XYREM REMS Program Patient Quick Start Guide.
  - Obtain mandatory patient signature acknowledging that he/she has been counseled on the serious risks and safe use conditions of XYREM and has had the opportunity to ask you any questions he/she may have about XYREM.
  - Complete the accompanying Supplemental Patient Authorization Form by obtaining mandatory patient signature granting you the authority to release personal information to Jazz Pharmaceuticals and its business partners and agents, including the pharmacy that will fill the prescription (Supplemental Patient Authorization Form is not part of the XYREM REMS Program).
  - Fax the completed XYREM REMS Program Patient Enrollment Form including Supplemental Patient Authorization Form to the XYREM REMS Program at 1-866-470-1744 (toll free) or mail to XYREM REMS Program, PO Box 66589, St. Louis, MO 63166-6589.

PRESCRIBING REQUIREMENTS

- Write prescriptions for both new and existing patients using the XYREM REMS Program Prescription Form. If the patient has a lapse in therapy for 6 months or more, a new prescription will be required.
  - Fill out the form completely and clearly to ensure timely fulfillment of your patient’s prescription.
  - Verify that you have screened your 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
  - Verify that you have counseled the patient regarding:
    - The serious risks associated with XYREM
    - Contraindications (alcohol and sedative hypnotics)
    - The risks of concomitant use of alcohol or other CNS depressants, including sedating antidepressants, antipsychotics, or anti-epileptics; opioids; benzodiazepines; muscle relaxants; and general anesthetics
    - The risks 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
    - The risk of abuse and misuse associated with XYREM
    - Safe use, handling, and storage of XYREM (refer to pages 13 & 14 of this brochure for Patient Counseling Information)
  - Provide a list of all current prescription and non-prescription medications and dosages that the patient is currently taking, to the best of your knowledge. This can be done by completing the Medications field on the XYREM REMS Program Prescription Form or by faxing a separate page from the patient’s medical history.

NOTE: Prior to dispensing each XYREM prescription (including refills), the Certified Pharmacy will complete an online Drug Utilization Review (DUR) and, during the patient counseling process, will ask the patient about the use of other medicines. If the pharmacist learns that the patient is taking a previously undisclosed contraindicated medication (sedative hypnotics), an opioid, or more than one CNS depressant, and the prescriber has not indicated awareness of the concomitant medication, the Certified Pharmacy will contact and inform the prescriber of the concomitant medication use prior to dispensing XYREM. The pharmacist may also contact the prescriber about other concomitant medications of concern.
—Verify that you have informed the patient that the XYREM REMS Program will send him/her a copy of the XYREM Medication Guide with each prescription fill and a XYREM REMS Program Patient Quick Start Guide prior to his/her first prescription fill, if you haven’t provided one previously. These materials are available through your Jazz Pharmaceuticals Specialty Sales Consultant or may be downloaded at www.XYREMREMS.com

—Fax the completed XYREM REMS Prescription Form and all renewal/refill prescriptions to the XYREM REMS Program at 1-866-470-1744 (toll free) or mail to XYREM REMS Program, PO Box 66589, St. Louis, MO 63166-6589.

Patient Evaluation

■ 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 they are taking XYREM.
  —Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents
  —Serious adverse events
  —Signs of abuse and misuse, such as an increase in dose or frequency of dosing; reports of lost, stolen, or spoiled medication; and/or drug-seeking behavior

Refill Prescriptions

■ The Certified Pharmacy with the XYREM REMS Program will send you a XYREM REMS Program Prescription Form in advance of a patient’s prescription expiring or running out of refills. Prescription refills and renewals may also be conveyed by phone or fax and must be documented in the XYREM REMS Program Central Database.

—Fill out the form completely and clearly to ensure timely fulfillment of your patient’s prescription

—Fax the completed XYREM REMS Program Prescription Form and all subsequent prescriptions to the XYREM REMS Program at 1-866-470-1744 (toll free) or mail to XYREM REMS Program, PO Box 66589, St. Louis, MO 63166-6589
RESPONSIBILITIES OF THE XYREM REMS PROGRAM
CERTIFIED PHARMACY

FOLLOWING RECEIPT OF A PATIENT’S PRESCRIPTION, THE CERTIFIED PHARMACY WILL:

- Provide you with confirmation of each new XYREM REMS Program Prescription Form received from your office

- Contact the patient’s insurance provider to verify XYREM prescription benefits

- Prior to the first shipment, contact the patient to:
  — Confirm whether he or she has received a copy of the XYREM REMS Program Patient Quick Start Guide. The Certified Pharmacy will send a copy of the XYREM REMS Program Patient Quick Start Guide to any patient not previously receiving one from his or her prescriber.
  — Counsel the patient on expectations from XYREM therapy and how to prepare and take XYREM doses safely and effectively
  — Review important XYREM safety information and precautions for XYREM use
  — Review XYREM safe handling and storage procedures
  — Review the adverse events associated with XYREM use
  — Review the patient’s use of concomitant medications
    • You will be notified of any potential for drug interactions based on patient counseling
  — Ask if the patient has any questions about XYREM and answer the questions and/or refer the patient back to the prescriber, as appropriate

- Provide 24/7 toll-free telephone access to pharmacist support for prescribers, office staff, and patients by answering questions about safety, dosing, and patient care

- Dispense and ship XYREM by overnight service to the patient or his or her authorized adult designee

- Remind patients about monthly refills

- Contact the prescriber if a prescription refill or renewal is required

For your convenience, materials and information regarding the XYREM REMS Program are available online at www.XYREMREMS.com
Please be sure to review the Prescribing Information prior to prescribing XYREM for your patients.
GUIDELINES FOR DOSING AND TITRATING XYREM

DOsing xyrem
XYREM is a liquid medication taken orally at bedtime. Due to its short half-life, XYREM is taken in 2 equal doses at night, with the first dose taken at bedtime and the second dose taken 2.5 to 4 hours later.

- The recommended starting dose is 4.5 g/night divided into 2 equal doses of 2.25 g each
- The effective dose range is 6 g to 9 g/night
- Doses higher than 9 g/night have not been studied and should not ordinarily be administered
- The dose of XYREM should be titrated to effect
  — XYREM should be titrated in increments of 1.5 g/night at weekly intervals
- An initial XYREM dose reduction of at least 20% is recommended if divalproex sodium is prescribed to patients already taking XYREM. For patients already taking divalproex sodium, it is recommended that prescribers use a lower starting XYREM dose when introducing XYREM. Prescribers are advised to monitor patient response closely and adjust dose accordingly if concomitant use of XYREM and divalproex sodium is warranted.
- Improvement may occur during the first weeks of therapy; however, titration to an optimal dose may take longer
- Once a stable dose is established, patients should be evaluated periodically

Note: the patient’s first shipment of XYREM will be limited to a 1-month (30-day) supply, and future shipments cannot exceed a 3-month (90-day) supply.

<table>
<thead>
<tr>
<th>Dosage &amp; Titration</th>
<th>1st Dose</th>
<th>2nd Dose</th>
<th>Total Nightly Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended starting dose</td>
<td>2.25 g</td>
<td>2.25 g</td>
<td>4.5 g</td>
</tr>
<tr>
<td>3 g</td>
<td>3 g</td>
<td>6 g</td>
<td></td>
</tr>
<tr>
<td>3.75 g</td>
<td>3.75 g</td>
<td>7.5 g</td>
<td></td>
</tr>
<tr>
<td>Maximum dose</td>
<td>4.5 g</td>
<td>4.5 g</td>
<td>9 g</td>
</tr>
</tbody>
</table>

Effective Dosing Range

Patient Dosing Information:
- Inform patients that all bottles contain concentrated medication ONLY and that water for dilution is not contained in the box. Advise patients to keep XYREM in the provided bottle(s)
- Patients should prepare both nighttime doses at bedtime
  —Instruct patients to make sure that pharmacy vials are empty prior to preparing each dose
  —Each dose of XYREM should be diluted with about ½ cup of water
  —Patients should be instructed to store XYREM bottles and prepared nightly doses in a secure place out of the reach of children and pets
- Food significantly reduces the bioavailability of XYREM; therefore, doses should be taken at least 2 hours after eating
- Both doses should be taken while in bed
- The first dose should be taken at bedtime and the second dose 2.5 to 4 hours later
ADDITIONAL INFORMATION ABOUT XYREM

XYREM has been placed in a bifurcated federal schedule. XYREM is a Schedule III controlled substance when used for legitimate medical purposes, as prescribed. The active ingredient of XYREM, sodium oxybate, or gamma-hydroxybutyrate (GHB), is classified as a Schedule I controlled substance when used for any other reason or by anyone other than for whom it was prescribed. Your patients should be informed that federal law prohibits the transfer of XYREM to any persons other than the patient for whom it was prescribed. If you have any questions regarding this, please call the XYREM REMS Program toll-free at 1-866-997-3688.

Illicit use and abuse of GHB have been reported, including drug-facilitated sexual assault. Prescribers should carefully evaluate patients for a history of drug abuse and follow patients closely, observing them for signs of misuse or abuse of GHB (e.g., increase in dose or frequency of dosing, reports of lost, stolen, or spilled medication, drug-seeking behavior).

WHEN PRESCRIBING A CONTROLLED SUBSTANCE:

- Be judicious when deciding to increase a dose. Make sure the appropriate medical indicators for increasing or altering a dose are present
- Be suspicious of a pattern of excuses for additional refills or repeated requests for additional refills on an emergency basis
- Be vigilant. Recognize that there is potential to abuse XYREM

It is important you know that the XYREM REMS Program maintains records about who is prescribing XYREM. These records will be made available to any state or federal agency that requests them.

DEPENDENCE AND TOLERANCE

Dependence

- Cases of severe dependence and cravings for GHB have been reported
- There have been case reports of dependence after illicit use of GHB at frequent repeated doses
  - Doses (18 g/day to 250 g/day) were in excess of therapeutic dose range
- Abstinence syndrome has not been reported in clinical trials

Tolerance

- Open-label, long-term (≥6 months) clinical trials did not demonstrate development of tolerance
- There have been some case reports of symptoms of tolerance developing after illicit use at doses far in excess of the recommended XYREM dosage regimen

Discontinuation effects and tolerance of XYREM have not been systematically evaluated in controlled clinical trials.

For your convenience, materials and information regarding the XYREM REMS Program are available online at www.XYREMREMS.com
USE IN SPECIFIC POPULATIONS

PREGNANCY

Teratogenic Effects: Pregnancy Category C.

Nonteratogenic Effects: Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

LABOR AND DELIVERY

XYREM has not been studied in labor or delivery. In obstetric anesthesia using an injectable formulation of sodium oxybate, newborns had stable cardiovascular and respiratory measures but were very sleepy, causing a slight decrease in Apgar scores. There was a fall in the rate of uterine contractions 20 minutes after injection. Placental transfer is rapid, but umbilical vein levels of sodium oxybate were no more than 25% of the maternal concentration. No sodium oxybate was detected in the infant’s blood 30 minutes after delivery. Elimination curves of sodium oxybate between a 2-day-old infant and a 15-year-old patient were similar. Subsequent effects of sodium oxybate on later growth, development, and maturation in humans are unknown.

NURSING MOTHERS

It is not known whether sodium oxybate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when XYREM is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

GERIATRIC USE

There is limited experience with sodium oxybate in subjects 65 years and older. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease and other drug therapy.

RACE AND GENDER EFFECTS

There were too few non-Caucasian patients in the narcolepsy clinical trials to permit evaluation of racial effects on safety or efficacy. More than 90% of the subjects in the clinical trials were Caucasian.

In the narcolepsy clinical trials, with a database that was 58% female, no important differences in safety or efficacy of sodium oxybate were noted between men and women.

Please read accompanying Prescribing Information.
The XYREM REMS Program is here to support you, your staff, and your patients.
For assistance, call 1-866-997-3683 (toll-free)
PATIENT COUNSELING INFORMATION

Prior to initiating therapy, counsel each patient regarding the serious risks and safe use, handling, and storage of XYREM using the XYREM REMS Program Patient Quick Start Guide and encourage all patients to read the XYREM Medication Guide.

- Inform patients that XYREM is available only through the central pharmacy certified under a restricted distribution program called the XYREM REMS Program and provide them with the telephone number and website for more information about XYREM and the XYREM REMS Program.
- Confirm that patients understand the serious risks and safe use conditions of XYREM and that you have answered any questions the patient has about XYREM by having the patient sign and date the XYREM REMS Program Patient Enrollment Form. Inform the patient that regular follow-up is recommended.

As a component of the XYREM REMS Program, the contents of the XYREM Medication Guide are reviewed with every patient by the XYREM REMS Program Certified Pharmacy before initiating treatment with XYREM.

To ensure safe and effective use of XYREM, you should provide your patient with the following guidance:

**ALCOHOL OR SEDATIVE HYPNOTICS**
Advise patients not to drink alcohol or take other sedative hypnotics if they are taking XYREM.

**SEDATION**
Inform patients that after taking XYREM they are likely to fall asleep quickly (often within 5 minutes and usually within 15 minutes), but the time it takes to fall asleep can vary from night to night. The sudden onset of sleep, including in a standing position or while rising from bed, has led to falls resulting in injuries, in some cases requiring hospitalization. Instruct patients to remain in bed following ingestion of their first dose, and not to take their second dose until 2.5 to 4 hours later.

**FOOD EFFECTS ON XYREM**
Food significantly decreases the bioavailability of sodium oxybate. Inform patients to take the first dose at least 2 hours after eating.

**RESPIRATORY DEPRESSION**
Inform patients that XYREM can be associated with respiratory depression even at recommended doses and with concurrent use of XYREM with other CNS depressants.

**OPERATING HAZARDOUS MACHINERY**
Inform patients that until they are reasonably certain that XYREM does not affect them adversely (e.g., impair judgment, thinking, or motor skills) they should not operate hazardous machinery, including automobiles or airplanes.

**SUICIDALITY**
Instruct patients or families to contact a healthcare provider immediately if the patient develops depressed mood, markedly diminished interest or pleasure in usual activities, significant change in weight and/or appetite, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, or suicidal ideation.

**SLEEPWALKING**
Instruct patients and their families that XYREM has been associated with sleepwalking and to contact their healthcare provider if this occurs.
SODIUM INTAKE
Instruct patients who are sensitive to sodium intake (e.g., those with heart failure, hypertension, or renal impairment) that XYREM contains a significant amount of sodium and they should limit their sodium intake.

SAFE HANDLING, STORAGE, AND DISPOSAL
- Discuss safe and proper use of XYREM and dosing information with patients prior to the initiation of treatment
- Instruct patients to store XYREM bottles and XYREM doses in a secure place, out of reach of children and pets
- Patients should be instructed to divide their total nightly dose into 2 separate doses. They should not further divide each of the 2 separate doses
- Patients should be informed that they should be seen by their healthcare provider frequently to review dose titration, symptom response, and adverse reactions
- Instruct patients to store XYREM at room temperature, between 59°F and 86°F
- Inform patients that they may safely dispose of XYREM down the sink or toilet drain
- Inform patients that they must report all instances of lost or stolen XYREM to the local police and to the XYREM REMS Program