XYREM REMS Program

Certified Pharmacy Training

Modules A and B

All XYREM REMS Program Certified Pharmacy staff must complete **Module A** and the Module A Knowledge Assessment. Pharmacists must also complete **Module B** and the Module B Knowledge Assessment.

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Dear XYREM REMS Program Certified Pharmacy Staff,

Welcome to the XYREM REMS Program, which has been approved by the Food and Drug Administration (FDA) as a Risk Evaluation and Mitigation Strategy (REMS).

The XYREM REMS Program

The FDA has determined that a REMS is necessary to ensure that the benefits of XYREM® (sodium oxybate) oral solution outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of XYREM by:

1. Informing prescribers, pharmacists, and patients of:
   - The risk of significant central nervous system (CNS) and respiratory depression associated with XYREM
   - The contraindication of use of XYREM with sedative hypnotics and alcohol
   - The potential for abuse, misuse, and overdose associated with XYREM
   - The safe use, handling, and storage of XYREM

2. Ensuring that pharmacy controls exist prior to filling prescriptions for XYREM that:
   - Screen for concomitant use of sedative hypnotics and other potentially interacting agents
   - Monitor for inappropriate prescribing, misuse, abuse, and diversion of XYREM
   - Notify prescribers when patients are receiving concomitant contraindicated medications or when there are signs of potential abuse, misuse, or diversion.

This training provides information about the XYREM REMS Program that includes important information about XYREM and the responsibilities of the Certified Pharmacy staff involved in the dispensing of XYREM.

XYREM is approved for:

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

XYREM may be prescribed only by prescribers enrolled in the XYREM REMS Program and dispensed only to patients enrolled in the XYREM REMS Program.

Sincerely,

Jazz Pharmaceuticals

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XYREM REMS Program

Certified Pharmacy Training Module A

Training for Pharmacy Staff Involved in the XYREM REMS Program

All XYREM REMS Program Certified Pharmacy staff must complete training on **Module A** and successfully complete the associated Knowledge Assessment. Training must be completed annually.

MODULE A: XYREM REMS PROGRAM

Important Safety Information

Indications and Usage

XYREM® (sodium oxybate) oral solution is a central nervous system (CNS) depressant that is indicated for the following:

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

XYREM may be prescribed only by prescribers enrolled in the XYREM REMS Program and dispensed only to patients enrolled in the XYREM REMS Program.

How Supplied

XYREM is shipped from the XYREM REMS Program Certified Pharmacy directly to patients. Each shipment to a patient will contain:

- The prescribed amount of medication, contained in one or more bottles of XYREM
- A press-in-bottle adaptor (PIBA) inserted into the bottle by the Certified Pharmacy
- A XYREM-specific grams-based oral measuring device (plastic syringe) to measure out each nightly dose
- Two empty pharmacy vials with child-resistant caps for preparation of both nightly doses (Xyrem dose mixed with water)
- A XYREM Medication Guide

Controlled Substance Scheduling

The active ingredient in XYREM is sodium oxybate or gamma-hydroxybutyrate (GHB, a known drug of abuse). GHB has been used to facilitate sexual assaults. Because of its rapid sedative effects (particularly when mixed with alcohol) and its colorless and odorless appearance, GHB has been used to "spike" the drinks of unsuspecting victims. Because of its abuse potential, GHB is designated a controlled substance by the Drug Enforcement Administration (DEA) and has been placed in a bifurcated federal schedule:

- GHB products approved by the FDA, such as XYREM, and used as prescribed for therapeutic purposes are Schedule III drugs

The active ingredient of XYREM is classified as a Schedule I controlled substance when used for any other reason or by anyone other than for whom it was prescribed. Federal law prohibits the transfer of XYREM to any persons other than the patient for whom it was prescribed.

Boxed Warning

WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION and MISUSE AND ABUSE.

XYREM (sodium oxybate) is a CNS depressant. In clinical trials at recommended doses obtundation and clinically significant respiratory depression occurred in XYREM-treated patients. Almost all of the patients who received XYREM during clinical trials in narcolepsy were receiving central nervous system stimulants.

XYREM® (sodium oxybate) is the sodium salt of gamma hydroxybutyrate (GHB). Abuse of GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.

Because of the risks of CNS depression, abuse, and misuse, XYREM is available only through a restricted distribution program called the XYREM [REMS] Program, using a centralized pharmacy. Prescribers and patients must enroll in the program. For further information go to www.XYREMREMS.com or call 1-866-XYREM88® (1-866-997-3688).

Contraindications

- XYREM is contraindicated in:
  - Patients who take sedative hypnotic agents
  - Patients who drink alcohol while using XYREM
  - Patients with succinic semialdehyde dehydrogenase deficiency, a rare disorder of inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia.

Warnings and Precautions

CNS Depression

- XYREM is a CNS depressant.
- Concurrent use of XYREM with other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating anti-epileptic drugs, 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, Misuse, and Diversion

- The active ingredient of XYREM, sodium oxybate or GHB, is 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.
- 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).
- Patients should be carefully evaluated for a history of substance abuse. Patients with a history of drug abuse should be closely monitored for signs of misuse or abuse of GHB (e.g., increase in dose or frequency of dosing, drug-seeking behavior, feigned cataplexy).

For complete safety information, please see the full Prescribing Information for XYREM.

XYREM REMS Program Requirements

XYREM may be prescribed only by prescribers enrolled in the XYREM REMS Program and dispensed only to patients enrolled in the XYREM REMS Program. Because of the risks of central nervous system depression, abuse, misuse, and diversion, XYREM is available only through a restricted distribution program called the XYREM REMS Program.

Required Components of this program include:

- Use of the central Certified Pharmacy.
- Healthcare Providers who prescribe XYREM must have completed the XYREM REMS Program Prescriber Enrollment Form and must comply with the requirements of the XYREM REMS.
- To receive XYREM, patients must be enrolled in the XYREM REMS Program and be counseled on the serious risks and safe use of XYREM treatment. Patients are enrolled by prescribers who must fill out and submit the XYREM REMS Program Patient Enrollment Form. Prescribers must also complete and submit the XYREM REMS Program Prescription Form for all new XYREM prescriptions and for XYREM prescriptions for patients restarting XYREM treatment after not receiving XYREM for 6 months or more.
- Further information is available at www.XYREMREMS.com.

Overview of Certified Pharmacy Responsibilities

Database

The Certified Pharmacy will utilize the secure and validated XYREM REMS Program Central Database containing the following types of information:

- Patient and prescriber enrollment
- Patient medical history
- Prescription
- Risk management
- Shipment
- Interactions with patients and prescribers.

Enrollment Processing and Maintenance

- Prescriber and patient enrollment forms are sent to the XYREM REMS Program by the prescriber.
- Information from the enrollment forms is maintained in the Central Database.
- No duplicate patients may be enrolled:
    - When a new Patient Enrollment Form is received, the Central Database must be searched to determine if the patient is already enrolled in the XYREM REMS Program.
    - If a match (duplicate patient) is found, the Certified Pharmacy will contact the patient and/or prescriber(s) to determine why a duplicate enrollment form was sent to the program.
    - If abuse, misuse, or diversion is suspected, the new enrollment will not be processed, the prescriber(s) will be notified, and a XYREM REMS Program Risk Management Report (RMR) will be completed and submitted to Jazz Pharmaceuticals.
- Patients must confirm that they have been counseled on the serious risks and safe use of XYREM; the Certified Pharmacy will provide counseling if it was not provided by the prescriber.
- The Certified Pharmacy will notify the prescriber of successful enrollment in the XYREM REMS Program, and that he or she is eligible to prescribe XYREM.
    - If there is a delay in shipping while a question about the prescriber's credentials is being resolved, the patient will be notified by the Certified Pharmacy.
    - If the prescription cannot be filled because a question about the prescriber's credentials could not be resolved, the patient will be notified by a XYREM REMS Program pharmacist.
    - The prescriber will be notified that he/she cannot be enrolled due to credential verification failure.
- The Certified Pharmacy will notify the prescriber of successful patient enrollment in the XYREM REMS Program.
- Enrollment status is maintained in the XYREM REMS Program Central Database.
    - The Certified Pharmacy will confirm that the prescriber's DEA and state license numbers are active and that the prescriber has provided all REMS-required attestations.
    - A prescriber may be disenrolled from the program for expired DEA or state licensures or for noncompliance with the XYREM REMS Program.

- Following enrollment the patient remains in the XYREM REMS Program unless the Certified Pharmacy and/or the prescriber determines that the patient should be disenrolled.
- A patient may be disenrolled from the program for noncompliance with the XYREM REMS Program, including for multiple suspicious early refill requests, or other information that indicates abuse, misuse, or diversion.
- The Certified Pharmacy will contact a prescriber if an enrollment form is received for a patient previously disenrolled from the program at prescriber request, or for suspicions of abuse, misuse, or diversion, and will provide the prescriber with all relevant patient history.

Prescription Processing

- Upon receipt of a XYREM REMS Program Prescription Form, the prescription information will be entered into the Central Database.
- The Certified Pharmacy will validate all prescriptions prior to dispensing XYREM. This includes verifying that:
  - The prescription form is complete and signed by the prescriber.
  - The prescriber is enrolled in the XYREM REMS Program and has active DEA and state license numbers.
  - The patient is enrolled in the XYREM REMS Program and has no other active XYREM prescriptions.
    - If the Certified Pharmacy receives overlapping prescriptions for XYREM for a patient, the Certified Pharmacy will notify and consult each prescriber.
      - Prescriptions are considered overlapping when more than one prescription for XYREM is received for a patient from multiple prescribers within an overlapping timeframe.
    - If the Certified Pharmacy suspects abuse, misuse, or diversion, the prescription will not be filled, the prescriber will be notified, and an RMR will be completed.
    - There are valid reasons why a patient may have overlapping prescriptions, including if the patient moves or changes prescribers, or if the prescriber sends in a new prescription prior to the completion of all refills.
      - The Certified Pharmacy will ensure that under these situations a patient does not receive multiple overlapping shipments of XYREM.
  - The prescription form was received from the prescriber's office.
  - The prescription is dated within the last 6 months.
  - The prescription is for only a one-month supply on a patient's first XYREM fill and no more than a 3-month supply on subsequent fills.
  - There are no discrepancies or concerns with the dosing and titration.
    - If there are discrepancies, or if the prescription form is incomplete, the Certified Pharmacy must contact the prescriber.
- Once the prescription is validated, the Certified Pharmacy will contact the patient to schedule shipment and complete the required counseling
  - For a new patient, the Certified Pharmacy provides the XYREM REMS Program Patient Quick Start Guide if the patient has not already received it from his or her prescriber.
  - A pharmacist must counsel the patient by completing the XYREM REMS Program Patient Counseling Checklist prior to the initial dispensing of XYREM.

Shipping

All XYREM is shipped to patients (or their adult designee) by an overnight service with receipt signature required.

- The patient may request an alternate shipping address, which is subject to approval by a pharmacist
- See How Supplied for details of the contents of each XYREM shipment
- Daily tracking reports are generated to confirm the receipt of each order shipped
- Lost shipments are investigated.

Monitoring for Inappropriate Prescribing, Abuse, Misuse, and Diversion

The Certified Pharmacy must conduct detailed monitoring on an ongoing basis of patients and prescribers for signs of inappropriate prescribing, abuse, misuse and diversion. The Certified Pharmacy will:

- Document early refill requests and instances of patient and prescriber behavior that suggest potential abuse, misuse, or diversion by completing a Risk Management Report (RMR). This information is maintained in the Central Database
- Review the patient's RMR history and alerts in the Central Database prior to granting an early refill request or if abuse, misuse, or diversion is suspected.
- Discuss early refill requests or other patient incidents with the prescriber so that the prescriber can make a decision to allow or deny the early refill, or to take some other action based on the patient's behavior and history.
- Report all RMRs to Jazz Pharmaceuticals.
- Determine whether an alert should be placed in the patient's profile within the Central Database for repeated reports of lost, stolen, destroyed, or spilled drug for review prior to shipping XYREM.
- Inform a XYREM REMS Program pharmacist immediately if Certified Pharmacy staff suspects patients or prescribers of abuse, misuse, or diversion.

Adverse Event Reporting

- Everyone on the Certified Pharmacy staff has an essential role to play in the process of collecting information on potential adverse events for reporting to Jazz Pharmaceuticals. Potential adverse events must be reported to Jazz Pharmaceuticals within one business day. Jazz Pharmaceuticals reports adverse event information to the FDA.

Ongoing Patient Education

Patients in the XYREM REMS Program have access to ongoing education while taking XYREM:

- 24-hour toll-free telephone help line staffed by a XYREM REMS Program pharmacist
- Continued contact with the Certified Pharmacy for every refill
- XYREM REMS Program website (www.XYREMREMS.com).

XYREM REMS Program

Certified Pharmacy Training Module B

Xyrem REMS Program Training for Pharmacists Involved in the Dispensing of XYREM

All XYREM REMS Program Certified Pharmacy pharmacists must complete training on Module B (in addition to Module A) and successfully complete the associated Knowledge Assessment. For all pharmacists who dispense XYREM, training must be completed annually.

MODULE B: XYREM REMS PROGRAM TRAINING FOR PHARMACISTS

All pharmacists involved in dispensing XYREM must complete the following additional training at least annually. The XYREM REMS Program and functional training for pharmacists typically ranges from three to four weeks, depending upon job function and individual learning curve. Training may be extended as information retention of the trainee dictates. Training will be conducted by a pharmacist currently specializing in the Xyrem REMS Program. Upon completion of formal training, a new pharmacist employee will perform assigned duties with a senior pharmacist employee as a resource and a mentor. The mentor will observe and monitor the performance of duties by the new employee to ensure competency. These duties will include:

- Execution of the XYREM REMS Program Patient Counseling Checklist
- Detailed monitoring including completion of an RMR
- Follow-up interactions with patients and prescribers
- System documentation

The mentoring senior pharmacist will release the trainee from observation upon confirmation that the new pharmacist employee has mastered the required skills.

XYREM REMS Program Requirements

XYREM may be prescribed and dispensed only to patients enrolled in the XYREM REMS Program. Because of the risks of central nervous system depression, abuse, misuse, and diversion, XYREM is available only through a restricted distribution program called the XYREM REMS Program.

Required components of this program include:

- Use of a central Certified Pharmacy
- Healthcare providers who prescribe XYREM must complete and submit the following to the XYREM REMS Program:
    - The XYREM REMS Program Prescriber Enrollment Form
    - The XYREM REMS Program Patient Enrollment Form
    - Prescriptions for XYREM on the XYREM REMS Program Prescription Form
        - Prescription refills and renewals may be conveyed by phone or fax and must be documented in the XYREM REMS Program Central Database.
- To receive XYREM, patients must be:
    - Enrolled in the XYREM REMS Program
    - Prescribed XYREM by a prescriber enrolled in the XYREM REMS Program
    - Counseled on the serious risks and safe use of XYREM
    - Have only one active XYREM prescription.

Certified Pharmacy Responsibilities

The central Certified Pharmacy will:

- Limit the first prescription fill to a one-month supply of XYREM and no more than a 3-month supply for subsequent prescription fills
- Report potential adverse events to the XYREM REMS Program
- Notify prescribers when there are signs of potential abuse or misuse or when patients are taking sedative hypnotics, other CNS depressants, or other potentially interacting agents of which the prescriber is not already aware
- Utilize the Central Database containing the following:
    - Complete patient and prescriber enrollment information
    - Patient information including:
        - Name and two additional identifiers (date of birth, phone number, address, gender)
        - Current and previous prescribers
        - Comorbid conditions and concomitant medications reported by the patient
        - Prescription history
    - Prescription information including:
        - Date
        - Dose
        - Titration instructions
        - Number of refills
        - Directions
        - Total quantity (volume and number of days' supply)
        - Concomitant medications
    - Risk Management Reports (RMRs)
    - Shipment information, including:
        - Dates of shipments
        - Dates of shipment receipts
        - Patient addresses
        - Designee information
        - Number of shipments sent daily
        - Quantity of XYREM dispensed daily
    - Documentation of interactions with prescribers, patients, and other parties.

These data must be available to the Certified Pharmacy for review on an ongoing basis to ensure that XYREM is dispensed to enrolled patients only after completion and documentation of safe use conditions. In certain cases, a pharmacist must access a patient's or prescriber's historical data in the Central Database and review it prior to dispensing XYREM.

Patient Counseling and Screening

- The Certified Pharmacy must complete the XYREM REMS Program Patient Counseling Checklist (documented in the Central Database) prior to shipment of XYREM.
    - For initial prescriptions, and for patients who are restarting after not receiving Xyrem for 6 or more months, the XYREM REMS Program Patient Counseling Checklist must be completed in its entirety.
    - For prescription renewals and refills, if the patient has indicated a change in his or her health or medications, the patient will be transferred to the pharmacist and Steps 1, 3, 4, and 5 of the Counseling Checklist must be completed.
- Each time a pharmacist completes the XYREM REMS Program Patient Counseling Checklist, the pharmacist must:
    - Verify that early refill requests have been thoroughly questioned and approved through the RMR procedure (see below).
    - Screen the patient for concomitant use of contraindicated medications (sedative hypnotics), alcohol, other CNS depressants, and other potentially interacting agents.
        - The pharmacist asks the patient if he or she is taking any other medications and can consult external pharmacy databases to identify drug interactions or prescriptions for other drug products that might have been filled at different pharmacies before filling the prescription.
        - If patient use of a contraindicated medication or other potentially interacting agent is confirmed, and if the prescriber has not indicated prior knowledge, then the pharmacist will notify and consult the prescriber about the risks of concomitant medication use prior to shipping XYREM.
    - Screen the patient for other medical conditions.
        - The pharmacist asks the patient what other medical conditions he or she has.
        - If the patient indicates that he or she has a certain medical condition listed on the XYREM REMS Program Patient Counseling Checklist, the pharmacist counsels the patient, and notifies the prescriber about the medical condition prior to shipping XYREM.
    - Document the results of the patient screening, all reported concomitant medications and comorbid medical conditions, the action(s) taken, and the date the checklist is completed in the Central Database.
    - Document the completion of the XYREM REMS Program Patient Counseling Checklist in the Central Database.
- Patients will also have access to a XYREM REMS Program pharmacist via the 24/7 toll-free telephone help line.

Clinical Usage Clarifications

The pharmacist must:

- Review the information on each XYREM REMS Program Prescription Form
- Notify and consult the prescriber if there are any clinical usage clarifications required, such as:
    - Dose over maximum recommended dose (9 g/night)
    - Non-standard doses or instructions
    - Possible errors in dosing or titration amounts or directions

If the issue is not resolved with the prescriber, the pharmacist may consult with the Pharmacist in Charge at the Certified Pharmacy and with Jazz Pharmaceuticals.

Prescription Refills

- Up to 5 refills are allowed on a XYREM prescription (per DEA regulations for CIII controlled substances).
- Refills may be conveyed by phone or fax from the prescriber and must be documented in the Central Database.
- Changes in dose require a new prescription
- Refill orders are opened at the Certified Pharmacy when the patient has approximately 10 days of therapy remaining from the previous shipment.
    - A Certified Pharmacy technician will contact the patient and schedule a shipment. The technician will ask the patient if there has been any change in his or her medications or medical history.
    - If the patient indicates a change, the technician will transfer him or her to a pharmacist who must complete Steps 1, 3, 4, and 5 of the counseling checklist. The patient should be counseled on the use or diagnosis of:
        - Sedative hypnotics (for example, diazepam, phenobarbital, or zolpidem)
        - CNS depressants: including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating anti-epileptic drugs, general anesthetics, and muscle relaxants
        - Alcohol
        - Sleep apnea
        - Asthma, COPD, or other conditions affecting his or her breathing
        - Other current medical conditions
    - The pharmacist must document refill counseling information and confirmation of prescriber consultation or notification in the Central Database.
- All patient requests for early refills are to be questioned and documented by the pharmacist.
    - An early refill request is a request for XYREM shipment prior to the date of the next shipment.
    - Requests to accommodate shipment logistics (scheduled delivery date falls on a Sunday, holidays, and vacations) are not considered early refills.
    - If the early refill is required due to a dosage increase, a pharmacist must:
        - Confirm the new dosage with the prescriber prior to processing the prescription.
    - If an early refill is requested for any other reason, a pharmacist must:
        - Discuss the request with the patient to evaluate his/her compliance with therapy, assessing for misuse, abuse, and diversion
        - Evaluate the patient's record in the Central Database and review the patient's prior XYREM Risk Management Report history to identify previous reports of early refills or other incidents suggestive of abuse, misuse, and diversion
        - Contact the prescriber to discuss the request and any prior early refill requests or incidents suggestive of abuse, misuse, and diversion
        - Send new shipments of XYREM to the patient only if approved by the prescriber
        - Send new shipments to replace XYREM reported stolen by a patient only after obtaining a copy of the police report filed by the patient
        - Document the discussion and outcome in the Central Database by completing a XYREM REMS Program Risk Management Report.

Monitoring and Assessing for Signs of Abuse, Misuse, and Diversion

- Risk management events must be documented in the Central Database by completing a XYREM REMS Program Risk Management Report.
    - Risk management events are reported or discovered events outside the norm that give rise to a reasonable suspicion of abuse, misuse, or diversion
    - Examples of events that should generate an RMR include but are not limited to:
        - Requests for early refills
        - Patient's misuse or abuse of product
        - Lost, stolen, destroyed, or spilled drug
        - Delivery to incorrect address and not returned
        - Patient claims that product was not delivered while carrier shows receipt of delivery
        - Product tampering
        - Counterfeit product
        - Contaminated product
        - Inquiries and/or arrests by law or regulatory enforcement agencies associated with the misuse, abuse, or diversion of the product
        - Crimes related to the product
    - RMRs must document:
        - Patient and prescriber identifying information (patient names to be concealed)
        - Reason for report
        - Certified Pharmacy actions
        - Prescriber contact
        - Supporting documentation (if applicable, such as a police report, fire report, DEA Form 106, or shipper investigation report)
    - If abuse, misuse, or diversion is suspected, the pharmacist must review the patient's RMR history and discuss the incident with the prescriber prior to shipping XYREM.
    - Repeated reports of lost, stolen, destroyed, or spilled drug will be documented as an alert to the patient record stored in the Central Database and will be accessible to the dispensing pharmacist for review prior to shipping drug.
    - The Certified Pharmacy and/or prescriber may disenroll a patient from the XYREM REMS Program after review and discussion of incidents suggestive of abuse and misuse.
    - All RMRs must be reported to Jazz Pharmaceuticals.

Shipping Procedures

- XYREM must be shipped via an overnight service with receipt signature required.
    - XYREM is shipped directly to the patient or adult designee (≥18 years, or ≥21 years if required by carrier) if the patient is not available to receive the order.
- The patient may request an alternate shipping address, which is then subject to approval by a pharmacist.
- If the patient requests Saturday delivery, the Certified Pharmacy will verify with the overnight shipping service that it is available for the shipping address.

- Each XYREM shipment includes:
  - The prescribed amount of medication, contained in one or more bottles of XYREM
  - A press-in-bottle adaptor (PIBA) that is inserted into the bottle by the Certified Pharmacy
  - A XYREM-specific grams-based oral measuring device (plastic syringe) to measure out each nightly dose
  - Two empty pharmacy vials with child-resistant caps for preparation of both nightly doses (XYREM dose mixed with water)
  - A XYREM Medication Guide.
- Daily tracking reports are generated to confirm the receipt of each order shipped during the previous 48 hours. Saturday deliveries are confirmed the following Monday.
  - A patient will be contacted if there is no proof of patient or designee signature, if the patient or designee on file did not sign for the shipment, or if there is a potential incomplete delivery.
  - If a shipment is reported lost, an investigation will be launched to find it.

Inventory Control

The XYREM inventory must be reconciled at the start and end of each business day and recorded in the Central Database. A physical count must match the count in the Central Database. If not, no other patient orders can be processed until an investigation is completed and approved by the Pharmacist in Charge.