NOTE: All text between the symbols "<" and ">" are editorial comments for the sole purpose of aiding FDA reviewers. This text is NOT intended to be printed.

To edit picture on page 2 of this document (Recommended Xyrem Titration flowchart), do the following steps:

1. Position your mouse over the graphic, click the right mouse button and choose "Edit Picture".
2. Make modifications.
3. Return to main document by clicking "Close Picture" in the Edit Picture sub-window that appears when you are editing a picture.

<Front Cover>

Xyrem Success Program[SM]

Physician Success Program[SM]

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Prescribing Xyrem® – A Brief Guide

The procedure for writing and dispensing Xyrem® (sodium oxybate) oral solution prescriptions is outlined below. The Central Pharmacy is always available at 1-877-67 XYREM℠ (1-877-679-9736) to support you, your staff and your patients to answer any questions.

Before Prescribing Xyrem®

- Read Physician Success Program material. You must acknowledge that you have read these materials before an initial patient prescription can be filled. The enclosed "Prescription and Enrollment Form" has a designated area for you to do this.

Prescribing Requirements

- You must verify that each patient you prescribe Xyrem® for has been educated with respect to Xyrem® preparation, dosing and scheduling.
- Prescriptions for Xyrem® must be rewritten at least every 3 months. The required starting dose is 4.5 grams, with titration up to 9 grams.
- Patients must be seen at least every 3 months
- You must complete the enclosed "Xyrem Post-Marketing Patient Evaluation" form at the 3 month and 6 month visits

How Do I Prescribe Xyrem®?

- Complete Xyrem® Patient Prescription form (including statement of medical necessity).
- Obtain patient's signature on the Assignment of Benefits (AOB) form. This is completed only for the initial prescription.
- Fax completed prescription and AOB form to Central Pharmacy at 1-XXX-XXX-XXXX.
- Fax subsequent prescriptions to the Central Pharmacy at 1-XXX-XXX-XXXX.

Central Pharmacy Role

Following receipt of your prescription the Central Pharmacy will:

- Contact you or your office to confirm prescription details and collect additional information (if needed).
- Contact the patients insurance provider to verify patient benefits and eligibility.
- Send Xyrem Patient Success Program℠ materials to the patient
- Contact the patient to:
  - confirm that Xyrem Patient Success Program℠ materials have been read
  - confirm Xyrem® delivery details.
  - reinforce preparation, administration and storage instructions.
  - advise patient of the availability of the Xyrem® Helpline.
- Dispense and ship Xyrem® to the patient or their designee.
- Maintain a patient and prescriber registry.

If you have any questions please call the Xyrem Physician Success Program℠ at 1-877-67 XYREM℠ (1-877-679-9736)

Please see full prescribing information for Xyrem® (sodium oxybate) oral solution.

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SUCCESS PROGRAM[SM]

Prescription and Enrollment Form

Prescriber Information

Prescriber's Name: _____ Office Contact: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

License Number: _____ DEA Number: _____

MD Specialty: _____

Prescription Form

Patient Name: _____ SS#: _____ DOB: _____ Sex: M/F

Address: _____

City: _____ State: _____ Zip: _____

Rx: Xyrem Oral Solution (500 mg/mL) 180 mL bottle Quantity: _____ months supply

Sig: Take _____ gms p.o. diluted in 60mL water at h.s. and then again 2 ½ to 4 hours later.

Refills (circle one): 0 1 2 (maximum of 3 month supply)

_____ Date: _____ / _____ / _____

Prescriber's Signature

Physician Declaration – Please check each box [redacted]

- ☐ I have read the materials in the Xyrem Physician Success Program
- ☐ I verify that the patient has been educated with respect to Xyrem preparation, dosing and scheduling
- ☐ I understand that Xyrem is approved for the treatment of cataplexy in patients with narcolepsy, and that safety or efficacy has not been established for any other indication
- ☐ I understand that the safety of doses greater than 9 gm/day has not been established

Please remember to complete the Post-Marketing Evaluation Program at months 3 and 6 of therapy

Patient Information

Best time to contact patient: ☐ Day ☐ Evening

Day #: _____ Evening #: _____

Insurance Company Name: _____ Phone #: _____

Insured's Name: _____ Relationship to Patient: _____

Identification Number: Policy/Group Number:

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