

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 the title on page 7 of the document (Recommended System Titration Overview), do the following steps:

1. Position your mouse over the graphic and, the red mouse cursor 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 ProgramSM

Physician Success ProgramSM

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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 XYREMSM (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 ProgramSM materials to the patient
- Contact the patient to:
 - confirm that Xyrem Patient Success ProgramSM 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 ProgramSM at 1-877-67 XYREMSM (1-877-679-9736)

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

SUCCESS PROGRAMSM 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 1/2 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

<input type="checkbox"/> I have read the materials in the Xyrem Physician Success Program
<input type="checkbox"/> I verify that the patient has been educated with respect to Xyrem preparation, dosing and scheduling
<input type="checkbox"/> 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
<input type="checkbox"/> 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: <input type="checkbox"/> Day <input type="checkbox"/> Evening	
Day #: _____	Evening #: _____
Insurance Company Name: _____	Phone #: _____
Insured's Name: _____	Relationship to Patient: _____
Identification Number: _____	Policy/Group Number: _____

Prescription Card: No Yes If Yes, Carrier: _____ Policy #: _____ Group: _____

Please attach copies of patient's insurance cards

Statement of Medical Necessity

Anticipated Start Date: _____ (Xyrem Success Program will call to verify date)

Pertinent medical history and clinical course:

Diagnosis (ICD9 Code):

Secondary Diagnosis (ICD9 Code)

Previous Treatments Tried and Failed:

Fax completed form to Xyrem Success Program (toll-free) XXX-XXX-XXXX
For information, call the Xyrem Team (toll-free) at 1-877-67 XYREM (XXX-XXX-XXXX)

Suggested Guidelines for Titrating Xyrem®

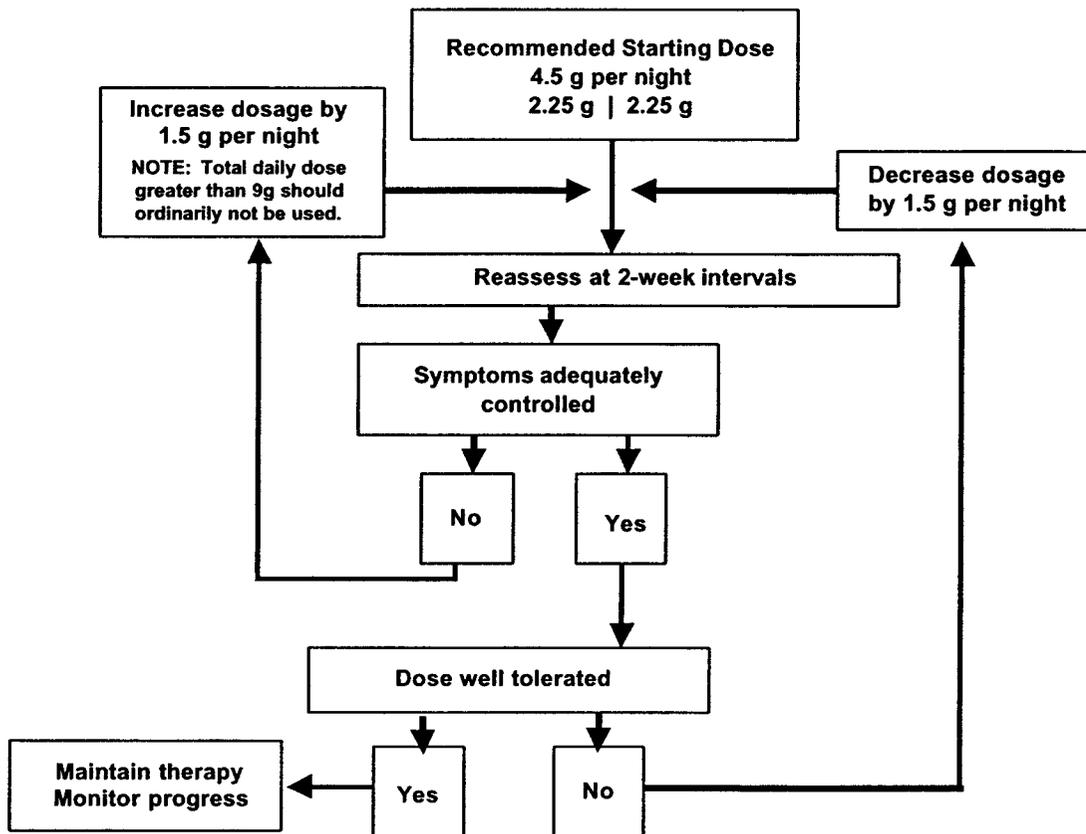
Xyrem® can be effective treatment to reduce the incidence of cataplexy associated with narcolepsy.

Xyrem® is different from other medications in that:

- It is taken nightly in two equal doses.
- It is a liquid that **must** be diluted with water (approximately 60 mL, 2 oz., ½cup or 4 tablespoons).
- Both doses are prepared before bed and kept in dosing cups with child-resistant caps.
- First Xyrem® dose is taken while sitting in bed, immediately before lying down to go to sleep.
- On awakening, 2½– 4 hours later, the second dose of Xyrem® is taken before continuing sleep.

Recommended Xyrem Titration

1. The recommended starting dose is 4.5 grams per night (4.5 g = 9 mL total dose = two nightly doses of 4.5 mL each).
2. If adequate symptom control is not achieved, increase total dose by 1.5 grams per night.
3. Dose titration may be required up to 9 grams per night.
4. It is recommended that each dose titration not exceed 1.5 grams per night.
5. It is recommended that review of dose response take place at 2-week intervals until a stable dose is achieved.
6. If unpleasant side effects occur, decrease total dose by 1.5 grams per night.
7. The maximum approved dose is 9 grams per night.
8. Improvement may be expected during the first weeks of therapy. Titration to optimal dose may take up to 8 weeks.



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

Information You Need To Know About Xyrem®

- Be diagnostically accurate. Confirm patient's diagnosis of narcolepsy with cataplexy, particularly those patients new to you and/or your practice.
- Be judicious when deciding to increase a dose. Make sure the indicators are there for increasing or altering a dose.
- Be suspicious of a pattern of excuses for refills or repeated requests for refills on an emergency basis.
- Be vigilant. Recognize that there is potential for patients to abuse Xyrem®.

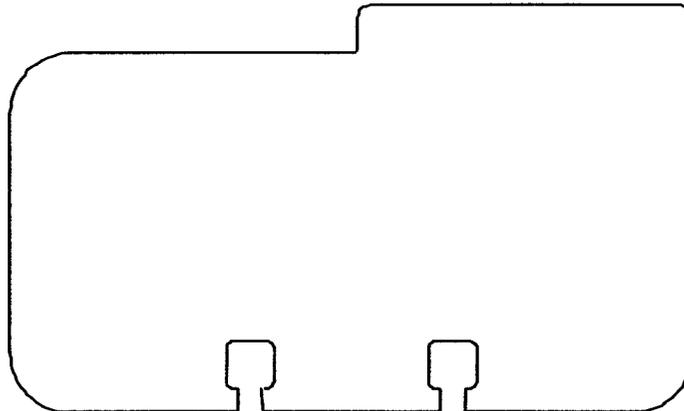
Xyrem® has been placed in a bifurcated Federal schedule. To meet legitimate medical need, when used as prescribed, Xyrem® is a Schedule III controlled substance. If used other than as is prescribed, or by individuals other than for whom it is prescribed, however, Xyrem®, like all GHB is a Schedule I controlled substance. You need to educate your patients about the bifurcated scheduling of Xyrem®; in particular, you should inform the patient about the legal penalties associated with diversion of the drug. If you have questions about this, please call 1-877-67 XYREMSM (1-877-679-9736).

Contact Information

Keep the phone number for the Xyrem Physician Success ProgramSM near at hand or in your phone record to get answers to all your questions.

Xyrem Success ProgramSM

For medical
information,
insurance
reimbursement,
prescription
information, and



any other questions,
call the Xyrem Physician Success ProgramSM.

1-877-67 XYREMSM

(1-877-679-9736)

The above card can be found on the packaging this booklet was contained in.

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Package Insert

<Full prescribing information for Xyrem® (sodium oxybate) oral solution will be inserted here.>

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

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Package Insert

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

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Medication Guide

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

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Medication Guide

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

<Back Cover>

<Orphan Medical Logo>

Dear Patient,

Your doctor has recently prescribed Xyrem[®] (sodium oxybate) oral solution for you. Xyrem[®] is a medication that has been approved for the treatment of cataplexy in patients with narcolepsy. Xyrem[®] has several unusual features including:

- Daytime cataplexy is treated by taking Xyrem[®] at night
- Twice nightly dosing: the first dose is taken at bedtime and the second dose 2½ -4 hours later
- The first dose must be taken before going to sleep, when you are in bed
- Xyrem[®] should not be taken with alcohol or other medications that cause drowsiness
- Xyrem[®] is dispensed from one central pharmacy only
- The active ingredient of Xyrem[®] (also known as gamma hydroxybutyrate or GHB) has been used as a substance of abuse. Therefore your Xyrem[®] must be used only by you, only as directed by your physician, and stored in a safe, secure place.

To support you in obtaining and using Xyrem[®] we have developed the Xyrem Patient Success ProgramSM which includes educational materials (enclosed) and a toll-free phone number: 1-877-67 XYREMSM (1-877-679-9736). The educational material contains important information on obtaining, taking and storing Xyrem[®] and an accompanying short video.

The 1-877-67 XYREMSM (1-877-679-9736) number is staffed by pharmacists who will dispense your medication and be available to answer questions you may have about Xyrem[®] and your prescription.

We hope that you will find these materials helpful in using Xyrem[®] to manage your narcolepsy.

Yours sincerely,

David Fuller, M.D.
Vice President of Medical Affairs
Orphan Medical

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

To edit picture on the last page of this document (Box entitled "Understanding More About Xyrem"), do the following steps:

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

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Patient Success ProgramSM

Your Doctor has prescribed Xyrem[®] (sodium oxybate) oral solution.

Now what?

Frequently asked questions about the use and safe handling of Xyrem[®].

Your Xyrem® Prescription

Your doctor has prescribed Xyrem®. Xyrem® contains sodium oxybate, which has been shown to reduce the number of cataplexy attacks in patients with narcolepsy. This booklet answers important questions about obtaining and taking Xyrem® and precautions to be considered when using Xyrem®.

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Will insurance pay for Xyrem®?.....	X
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Any questions? Please call 1-877-67 XYREMSM (1-877-679-9736)
Xyrem Patient Success ProgramSM

Please see FDA-approved medication guide for more detailed information.

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1. How do I obtain Xyrem®?

Who will fill Xyrem® prescriptions?

All Xyrem® prescriptions will be processed by one Central Pharmacy.

What does the Central Pharmacy do?

The Central Pharmacy will provide three main services to you.

They will:

- Provide patient counseling, dispense and ship your Xyrem®.
- Work with your insurance plan to facilitate coverage.
- Collect information about the safety of Xyrem®. Your name and any problems with Xyrem you report will be recorded.
- Provide information about Xyrem at 1-877-67 XYREMSM (1-877-679-9736).

How does the Central Pharmacy dispense Xyrem®?

- Your doctor sends the Xyrem® prescription directly to the Central Pharmacy.
- The Central Pharmacy contacts you to confirm the location of, and who will sign for, delivery of your Xyrem® as well as any insurance details.
- Xyrem® will be shipped via an overnight courier.
- When the courier arrives you, or someone you designate, must sign for the Xyrem®.

What will I receive?

In each Xyrem® carton you receive, there will be one bottle of Xyrem, a liquid measuring device, 2 dosing cups with child resistant caps and a printed medication guide. Your shipment may include more than one carton of Xyrem.

When will I receive Xyrem®?

The Central Pharmacy will call you to arrange a convenient time and location for delivery.

Could my local pharmacy provide Xyrem®?

No. The use of a Central Pharmacy is designed to reduce any diversion or illicit use of Xyrem®. However, in some cases, you may be able to have the courier deliver Xyrem® to your local pharmacy for later collection.

Will insurance pay for my Xyrem®?

In most cases, YES. A reimbursement specialist from the Central Pharmacy will contact you and your insurance plan to facilitate benefits.

**Any questions? Please call 1-877-67 XYREMSM (1-877-679-9736)
Xyrem Patient Success ProgramSM**

Please see FDA-approved medication guide for more detailed information.

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2. How do I take Xyrem[®]?

Xyrem[®] is to be taken only as directed by your physician.

When do I take Xyrem[®]?

Xyrem[®] should be taken twice nightly: the first dose is taken at bedtime while you are in bed and the second dose is taken in bed 2½ to 4 hours later.

What do I need to do before taking Xyrem[®] each night?

Please see the Xyrem[®] Medication Guide for complete details.

- **Prepare your doses:** Your doctor will have determined what dose you should take. Prior to going to bed, you will need to measure out each of your Xyrem[®] doses into the provided dosing cups and then dilute each dose with 2 oz of water. 2 oz is about 60mL, ¼ cup, or 4 tablespoons. Once you have done this you should place the child-resistant caps onto the dosing cups and put them in a safe place by your bed.
- **Set an alarm clock:** set an alarm to go off 2½ to 4 hours after your first dose to wake you up for your second dose

Can I take Xyrem[®] with food?

Food will decrease the amount of Xyrem[®] that is absorbed. Therefore you should take Xyrem well after a meal (several hours).

Can I take Xyrem[®] any time before I go to bed?

No. Xyrem[®] works quickly and therefore you need to lie down after you have taken it.

What do I do if I miss a Xyrem[®] dose?

Follow these rules if you miss a dose:

- Never take two doses of Xyrem[®] at once.
- You must leave a minimum of 2½ hours between each dose of Xyrem[®].

Will my dose change?

You and your physician will discuss your response to treatment and your physician may adjust your dose as a result. **NEVER CHANGE THE DOSE OF XYREM[®] YOURSELF.**

How soon might I see a change in my symptoms?

You can expect to see some improvement within the first weeks of Xyrem[®] therapy. However, it may take up to 8 weeks after you begin using Xyrem[®] to find the dose that is best for you.

**Any questions? Please call 1-877-67 XYREMSM (1-877-679-9736)
Xyrem Patient Success ProgramSM**

Please see FDA-approved medication guide for more detailed information.

<Page 4 text>

What side effects have been reported with Xyrem®?

The most common side effects of Xyrem® are headache, nausea, sleep problems (including sleep walking), vomiting, bed-wetting, confusion, and dizziness.

If you experience confusion, vomiting, bedwetting, sleep walking, breathing problems (at night), depression, or abnormal thinking while using Xyrem®, you should notify your doctor. These are not all the side effects you may experience with Xyrem®. If you are concerned about any possible side effects please consult your doctor.

3. Precautions needed for Xyrem® use

Xyrem® is classified as a Schedule III medication which means that it is legal to use Xyrem® as prescribed. However, Xyrem's active ingredient, sodium oxybate (also known as gamma hydroxybutyrate or GHB), has been used as a substance of abuse. Therefore your Xyrem® must be:

- used only by you.
- used only as directed by your physician.
- stored in a safe and secure place.

Because Xyrem® is classified under Schedule III it is illegal for you to sell, distribute or give your Xyrem® to anyone else, or to use your Xyrem® for purposes other than it was prescribed. Failure to adhere to these rules may result in prosecution and fines as defined in Schedule I of the Controlled Substances Act.

How do I store Xyrem®?

It is critical that Xyrem® should be kept in a secure location, out of reach of children or pets. Xyrem does not require refrigeration.

Are there any interactions with other medications?

It is very important to inform your doctors and pharmacists that you are taking Xyrem® before starting or changing any medications. Xyrem® should not be used in combination with alcohol or other medications that cause drowsiness. You should tell your doctor about any other medicines you are taking, including non-prescription medicines and any vitamins or herbal, nutritional, or dietary supplements.

What should I avoid while taking Xyrem®?

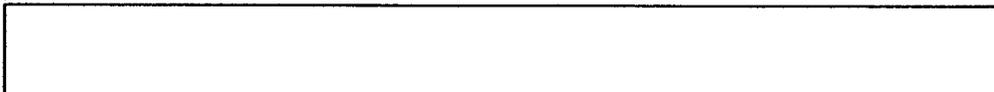
Do not drive a car, operate heavy machinery, or perform any activity that is dangerous or that requires mental alertness, for at least 6 hours after taking Xyrem®. When you first start taking Xyrem or any other sleep medicine, until you know whether the medicine will still have some carryover effect in you the next day, use extreme care while driving a car, operating heavy machinery or doing anything else that could be dangerous or needs you to be fully mentally alert.

Before starting Xyrem®, tell your health care provider if you are pregnant, breastfeeding or planning on becoming pregnant.

While taking Xyrem®, you should avoid drinking alcoholic beverages or taking medications that cause drowsiness.

How will my use of Xyrem® be monitored?

Your doctor will need to see you at least every 3 months while you are taking Xyrem®. It is critical that you keep these appointments so that your treatment can be continued safely and your prescription can be renewed.



**Any questions? Please call 1-877-67 XYREMSM (1-877-679-9736)
Xyrem Patient Success ProgramSM**

Please see FDA-approved medication guide for more detailed information.

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4. OTHER INFORMATION

Where can I get more information on Xyrem[®]?

Please call your helpline at 1-877-67 XYREMSM (1-877-679-9736)

Where can I get more information on narcolepsy or sleep disorders?

www.orphan.com

Orphan Medical, Inc.

13911 Ridgedale Drive, Suite 250

Minnnetonka, MN 55305

Phone: 1-877-679-9736

www.sleepfoundation.org

National Sleep Foundation

1522 K Street NW, Suite 500

Washington, DC 20005

Phone: 202-347-3471

www.aasmnet.org

American Academy of Sleep Medicine

6301 Bandel Road NW, Suite 101

Rochester, MN 55901

Phone: 507-287-6006

www.narcolepsynetwork.org

Narcolepsy Network

10921 Reed Hartman Highway

Cincinnati, OH 45242

Phone: 513-891-35212

Email: narnet@aol.com

www.rarediseases.org

National Organization for Rare Disorders, Inc.

P.O. Box 8923

New Fairfield, CT 06812-8923

1-800-999-6673

www.talkaboutsleeeep.com

Talk About Sleep

P.O. Box 382276

Germantown, TN 38183

Phone: 901-482-2025

Fax: 901-757-0651

**Any questions? Please call 1-877-67 XYREMSM (1-877-679-9736)
Xyrem Patient Success ProgramSM**

Please see FDA-approved medication guide for more detailed information.

Please see FDA-approved medication guide for more detailed information.

At Home Storage and Safety Tips

Keep this information folder on your desk, nightstand, or near your medicine storage area as a constant reminder to assist your safety and success with Xyrem[®] at home.

Ordering

- Xyrem[®] will be shipped via overnight courier directly to you from a central pharmacy.
- You need to confirm receipt of your Xyrem[®] shipment by signing for your Xyrem[®]. Check the shipment to be sure it is complete before signing for it.

Storage

- Always keep Xyrem[®] in its original container.
- Xyrem can be stored at room temperature. It is important that it is kept in a secure location at all times.
- It is particularly important that Xyrem[®] (like all medications) be kept out of the reach of children and pets. In case of accidental ingestion, call 911.

Preparing Xyrem[®]

- When mixing your nightly doses of Xyrem[®], use your dosing cups with child-resistant caps and return the remaining medication to a secure location. It is especially important that your second nightly dose of Xyrem[®] is left in a secure place, not within the reach of children or pets.

Disposal

- When you can no longer draw medication out of the bottle with the measuring device, it is time to throw the bottle away. **Use a marker or pen to deface the bottle label so someone else cannot use it for illicit purposes. Pour any unused Xyrem[®] down the drain. Place the empty bottle in the trash so it is not used for illegal purposes.**

Refills

- Remember to reorder your Xyrem[®] when you have only a 7-day supply remaining. Call the Patient Success Program to initiate a refill.

Problems

- If your supply of Xyrem[®] is lost or stolen, please report the incident immediately to the local police and the Xyrem Patient Success ProgramSM.
- Use only as directed. Be aware that use of your Xyrem by others is illegal.
- If you have questions, concerns, or need advice regarding Xyrem[®], call your physician or call the Patient Success Program Pharmacy.

**Any questions? Please call 1-877-67 XYREM (1-877-679-9736)
Xyrem Patient Success Program**

Please see FDA-approved medication guide for more detailed information.

Traveling Tips

Before your trip

- When packing for your trip, be sure to take a sufficient amount of Xyrem® for the length of time you will be away.
- Always travel with Xyrem® in its original container.
- Take only the number of bottles of Xyrem® needed for your stay away from home. Ensure that any remaining Xyrem® is in a secure place before you leave home.
- Xyrem® should be kept in a secure location at all times.
- If traveling internationally, be aware that Xyrem® may be subject to different regulations in other countries. Call the appropriate consulate for guidance on safe handling of your Xyrem® when you travel in their country.

During your trip

- Do not pack your Xyrem® in a suitcase that will be checked baggage. Always keep it in your possession.
- Remember to take your dispensing device and the dosing cups with child-resistant caps when traveling. In an unfamiliar environment, it is especially important that your second nightly dose of Xyrem® is not left in an unsecured place or within the reach of children or pets.
- Do not leave your Xyrem® behind when you return home.
- If you should forget your Xyrem® while traveling within the United States or need more due to an extended stay, call the Xyrem Patient Success Program.SM

Problems

- If your supply of Xyrem® is lost or stolen while traveling, please report the incident immediately to the local police and the Xyrem Patient Success Program.SM.

If you have questions, concerns, or need advice regarding Xyrem® while traveling, call the Xyrem Patient Success Program.SM.

Xyrem Patient Success ProgramSM
1-877-67 XYREMSM (1-877-679-9736)
FAX 1-XXX-XXX-XXXX

For international access call the Xyrem Patient Success Program.SM at

xx-xxx-xxx-xxxx

Any questions? Please call 1-877-67 XYREM (1-877-679-9736)
Xyrem Patient Success Program

Please see FDA-approved medication guide for more detailed information.

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Reimbursement information for patients...

The Xyrem Patient Success ProgramSM provides reimbursement assistance for patients receiving Xyrem[®].

An experienced Reimbursement Specialist will:

- Verify your benefits and eligibility
- Obtain prior authorization from your insurance company (if needed)
- File appropriate appeals on your behalf**
- Support you with all aspects of insurance

**** The Xyrem Patient Success Program's attempt to obtain coverage from a patient's third-party payer does not constitute or guarantee success in resolving denials.**

**If you have questions or need information,
don't hesitate to contact The Patient Success Program
and ask for a Reimbursement Specialist.**

1-877-67 XYREMSM (1-877-679-9736)

FAX 1-XXX-XXX-XXXX

**Any questions? Please call 1-877-67 XYREM (1-877-679-9736)
Xyrem Patient Success Program**

Please see FDA-approved medication guide for more detailed information.

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Medication Guide

<Medication Guide will be inserted here >

Any questions? Please call 1-877-67 XYREM (1-877-679-9736)

Xyrem Patient Success Program

<Back Cover text>

Fill in your Doctor's name, address, and phone number on the wallet card below. Then, carry the wallet card with you at all times to get help answering your medical, prescription, and insurance questions to aid you in

Understanding More About Xyrem®

Please let all your doctors and pharmacists know about your prescription for Xyrem®.

<Xyrem Logo here>

Understanding More About Xyrem®

For medical information, contact:
Your Doctor: _____
Address: _____
Phone: _____

For information on insurance reimbursement, prescription refills, and other questions, call the Xyrem Patient Success ProgramSM
1-877-67 XYREMSM (1-877-679-9736)

Please see FDA-approved medication guide for more detailed information.

Xyrem® Patient Video Script

The video is one of the components of the Xyrem Patient Success ProgramSM. The purpose of this video is designed solely as an instructional tool to teach the patients how to prepare and use the medication, in-home safety and issues regarding misuse of the drug.

The video contains no product promotional claims (i.e., for treatment of cataplexy), and since this is part of the overall Xyrem Patient Success ProgramSM, fair balance (i.e., adverse events) was also excluded.

Xyrem® Patient Video Script
Draft-5/2/02

Audio	Video	Titles
1. Tones or music to match logo graphics	Creative Orphan Medical logo sequence	
2. Tones or music to match logo graphics	Xyrem logo sequence	
3. Fade in music	Fade to shot of patient functioning happily in an every-day activity.	Fade in title. <u>Important Information About Xyrem® (sodium oxybate) oral solution</u>
4. For more than 8 years, Orphan Medical, has been committed to bringing innovative medical products to patients with inadequately treated or uncommon diseases.	Fade to shot of narrator, sitting on the edge of desk. An Orphan Medical logo should be prominent in the shot.	
5. Today, we are proud to extend our commitment to you.	Same as previous shot.	
6. Your physician has determined that you are a good candidate for Xyrem.	Fade to shot of physician discussing Xyrem with patient in the medical office.	
7. You are being asked to watch this video presentation before you take your first dose of Xyrem to ensure that you are confident about how to use the medication.	Fade to shot of patient placing video in VCR at home.	

- | | | |
|---|---|--|
| 8. In this video you will learn: | Fade to shot of patient sitting and watching video. | |
| 9. How to prepare and use the medication properly | Cut to shot of hands dispensing medication. | |
| 10. Proper in-home safety procedures | Cut to shot of medication being locked into a cabinet. | |
| 11. And, finally, we will discuss issues associated with the misuse or abuse of this medication. | Cut back to narrator. | |
| 12. Careful adherence to the procedures and precautions presented in this video, will ensure that Xyrem will continue to be available to you and patients like you—now, and in the years to come. | Continued shot of narrator. | |
| 13. Xyrem contains sodium oxybate, which is also known as Gamma Hydroxybutyrate or GHB. | Fade to table-top shot of Xyrem packaging, with bottle, dispensing device, and containers removed from the box and laying on the table. | Fade in title.
What is Xyrem®? |
| 14. Xyrem is unlike any other medication, and it is very important for you to follow your physician's instructions precisely and completely. | Fade to freeze-frame shot of patient in physician's office receiving instructions | Fade in title.
How to Use Xyrem® Properly
Fade out title. |
| 15. Xyrem works quickly and the effects wear off after a short period of time. Because the effects wear off quickly, you will need to take 2 doses every night. | | |
| 16. Take the first dose immediately before going to bed. | Fade to shot of patient taking first dose and then laying down in bed. | |

17. Take the second dose no earlier than two-and-a-half hours after the first dose and no later than four hours after the first dose. You may need to set an alarm clock to make sure you wake up to take the second dose
18. If you miss the second dose, skip that dose and do not take Xyrem again until the next night. Never take 2 Xyrem doses at once.
19. It is important that you take both doses each night, exactly as prescribed by your doctor.
20. It is quite possible that it will take some time to find the dose that works best for you. During this time, your physician may gradually increase or decrease your dose of Xyrem. Findings from the clinical trials suggest that this may take up to eight weeks.
21. Never, adjust or change your dose of Xyrem unless your physician tells you to. If you have questions or concerns about your dose, discuss these with your physician.
22. Your Xyrem carton contains one bottle of Xyrem oral solution, a measuring device, two dosing cups with child-resistant caps for preparing and storing your two night-time doses, and a Xyrem Medication Guide.
- Fade to shot of patient waking to take second dose.
- Fade to shot of patient waking up happily and stretching in the morning.
- Cut to shot of physician showing the patient a dosing plan.
- Fade to shot of narrator.
- Fade to table-top display of carton, bottle, dispensing syringe, and container. Highlight each component when mentioned.

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| 23. You will receive a Patient Medication Guide every time you receive a bottle of Xyrem. Please read the Medication Guide for additional important information before taking your first dose of Xyrem. | Fade to table-top display of leaflet. | |
| 24. If you have any additional questions or concerns about Xyrem, be sure to contact your physician, <u>or your pharmacist at the Xyrem Success Program toll-free at 1-877-679-9736.</u> | Cut to shot of patient dialing phone. | |
| 25. You will need to prepare both doses at bedtime. | Fade to shot of patient in pajamas assembling the components needed for preparing the doses. | Fade in title.
Prepare Both Doses at Bedtime |
| 26. Remove the Xyrem bottle, measuring device, and child-resistant cups from the box. | Cut to close-up shot of patient's hands performing the described actions. | |
| 27. Remove the measuring device from the wrapper. | Fade to shot of patient's hands performing the described actions. | |
| 28. While pushing down, turn the medicine cap counterclockwise to remove the cap. Set the bottle upright on a tabletop | Fade to shot of patient's hands performing the described actions. | |
| 29. While holding the bottle in its upright position, insert the tip of the measuring device into the center opening of the bottle and press down firmly. | Fade to shot of patient's hands performing the described actions. | |
| 30. While holding the bottle and measuring device with one hand, use the plunger to withdraw the dose that your doctor has prescribed with your other hand. Remember to keep the bottle upright or the medicine will not flow into the measuring device properly. | Fade to shot of patient's hands performing the described actions. | |

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| 31. Remove the measuring device from the bottle, and press down on the plunger to empty the medicine into one of the dosing cups and add 2 ounces of water. 2 oz is about 60mL, ¼ cup or 4 tablespoons. Set the first dose aside and prepare your second nightly dose. | Fade to shot of patient's hands performing the described actions. | |
| 32. To prepare the second dose, remove the cap from the child-resistant dosing cup, withdraw your second dose of medicine from the bottle, and empty the medicine into the second dosing cup. | Fade to shot of patient's hands performing the described actions. | <u>(NO WHITE LAB COATS THROUGHOUT NARRATOR)</u> |
| 33. Pour in approximately 2 ounces of water. | Fade to shot of patient's hands performing the described actions. | |
| 34. Put the child-resistant cap back on the second-dosing cup, and make sure the cap is secure. | Fade to shot of patient's hands performing the described actions. | |
| 35. Place this second-dose container near your bed in an area that is not accessible to children. | Cut to wider shot of patient placing second dose on bedside table. | |
| 36. Also make sure that you have securely replaced the cap on the bottle of Xyrem, and place the medication in a safe location | Fade to shot of patient securing cap right before placing medicine in a cabinet. | |
| 37. Immediately prior to going to sleep, drink the entire contents of the cup containing the first dose. Be sure you are sitting in bed while you drink it so that you can then lay down immediately afterwards. | Fade to shot of patient sitting up in bed, drinking first dose, and then laying down. | |

38. When you wake up two-and-a-half to four hours later, remove the cap from the second dosing cup, and drink the entire contents of the cup immediately before reclining to continue your sleep
39. Xyrem, like all medications, must be kept out of the reach of children and pets.
40. In case of accidental ingestion or overdose, immediately call 911 or your local poison control center.
41. When you can no longer pull medication out of the bottle with the dispensing device, it's time to throw the bottle away. Pour any unused Xyrem down the drain.
42. Use a marker or pen to deface the bottle's label so that it cannot be reused.
43. It is now safe to throw the empty bottle away.
44. To discourage the illegal use of Xyrem, the Federal government has classified it as a Schedule III substance. This means that Xyrem is only available by prescription and it must be used in the manner for which it was prescribed, and only by you.
- Fade to shot of patient waking up and taking second dose.
- Fade to freeze-frame shot of Xyrem being placed in cabinet
- Cut to shot of patient dialing 911.
- Fade to freeze-frame shot of hands trying to dispense medication from an almost empty bottle.
- Begin action.
- Cut to shot of patient marking bottle.
- Cut to shot of patient throwing bottle in the trash.
- Fade to freeze-frame shot of narrator.
- Fade in title.
Emergency Procedures
- Fade in title with freeze frame.
Safe Disposal of the Medication
- Fade out title
- Fade to shot of patient performing action as described..
- Fade in title with freeze-frame.
Xyrem® and Your Legal Liability
- Fade out title.

45. These Federal regulations, however, also provide for the prosecution and punishment of individuals who may use Xyrem irresponsibly. In fact, much harsher Schedule I penalties will be imposed on anyone found illegally obtaining, distributing and/or using Xyrem. Continue shot of narrator.
46. This means that you may be held legally responsible for careless use or illicit distribution or sale of Xyrem. So, even though you may have a valid prescription for Xyrem, if you knowingly allow friends or family to use your medication, you will be subject to these harsh penalties. Cut to shot of narrator.
47. And that's another important reason for keeping the medication away from others, as well as for storing it in a very secure place in your home. Cut to shot of Xyrem sitting out on a kitchen counter as a group of adolescents or children walk by.
48. Anyone found guilty of misusing or abusing this drug could be sentenced up to five years in prison for a first offense. A first-time offender may also be fined up to \$250,000. Fade to build graphic
- Fade in title.
- First Offense**
- Fade in additional titles as mentioned.
- 5 Years in Prison**
- \$250,000 Fine**

49. A second offense could result in up to 30 years in prison—or *life* if anyone dies or is caused serious injury. An individual may also be fined up to \$2 million for a second offense.
- Fade to build graphic
- Fade in title.
- Second Offense**
- Fade in additional titles as mentioned.
- 30 Years in Prison**
- Life in Prison**
- \$2 Million Fine**
50. While safe handling and storage of your Xyrem in your home is important, it is equally important if you plan to travel with your Xyrem. Enclosed in your packet of materials are tips on traveling with your Xyrem. Please be sure to read this material before traveling.
- Picture patient reading “Travelling Tips” pamphlet.
51. No one wants to deny you access to Xyrem, impede ongoing research, or even increase the cost of obtaining Xyrem, but all of these things are possible if we do not work together guard against the misuse and abuse of Xyrem.
- Fade to narrator.
52. That’s why we are looking to you to follow the few simple procedures described in this video presentation—to ensure that you and patients like you can continue to receive the supervised medical benefits from Xyrem.
- Fade to shot of patient happily involved in a fun activity with others.
- Fade in music.
53. For more information about the information contained in this video presentation, be sure to contact your physician or you may also call The Xyrem Success Program at 1-877-679-9736
- Continue shot of happy patient.
- Fade in title when mentioned.
- The Xyrem Success Program**
- 1-877-679-9736**

54.

Fade to black.

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/s/

Robert Temple
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