

**CONSUMER INFORMATION**  
**Product Monograph Part III**

**XYREM<sup>®</sup>**  
**Sodium oxybate**  
**500 mg/mL, Oral solution**

**Orphan Medical, Inc.**

**Submission Control No. 088659**

The Consumer Information Section (Part III) of the Product Monograph for XYREM<sup>®</sup> has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on August 5, 2005 and does not necessarily reflect the most current information for the product.

**For the most up-to-date product information, please consult your health care professional.**

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

## INFORMATION FOR THE CONSUMER

### **Xyrem® (ZīE-rem)**

**(sodium oxybate) oral solution 500 mg/mL**

**It is very important that you carefully read and follow all instructions before using Xyrem.** You are encouraged to read this leaflet again before each refill as there may be new information. This information does not take the place of talking with your doctor or pharmacist about your medical condition or your treatment. Your doctor should instruct you in the safe and effective use of Xyrem. If you have any questions about Xyrem, ask your doctor or pharmacist. Do not throw away this Patient Package Insert or any other information on Xyrem that your doctor or pharmacist have provided. You may need to refer to the information again later.

### **What is the most important information I should know about Xyrem?**

- The Xyrem Success Program, developed by the manufacturer of Xyrem, includes recommendations to doctors and pharmacists for educating patients on the safe and proper use of Xyrem. Through the Xyrem Success Program, educational materials will be provided to you by your doctor or pharmacist. Your doctor should confirm with you that you have read and understood these materials. During the course of Xyrem therapy, you should be seen by your doctor every 3 months, and an account of any side effects you may have experienced should be taken.
- Xyrem is available only by prescription and is a federally controlled drug. This means that it is illegal for you to sell, distribute, or give your Xyrem to anyone else, or for you to use your Xyrem for purposes other than for what it was prescribed.
- It is critical to keep Xyrem out of the reach of children.
- Xyrem may cause you to fall asleep quickly. Therefore, take Xyrem only at bedtime and while in bed. Do not drive a car, operate heavy machinery, or

perform any activity that requires mental alertness for at least 6 hours after taking Xyrem, until you know whether it makes you sleepy the next day.

- The active ingredient in Xyrem is gamma-hydroxybutyrate (GHB), a chemical that has been abused (misused). Abuse can cause serious medical problems, including trouble breathing, seizures (convulsions), loss of consciousness, coma, and death. Abuse of Xyrem could also lead to dependence, craving for the medicine, and severe withdrawal symptoms.

### **What is Xyrem?**

Xyrem is a brand of medicine used to reduce the number of cataplexy (weak or paralyzed muscles) attacks in patients with narcolepsy.

### **Who should not take Xyrem?**

Do not take Xyrem if you:

- take other sleep medicines or sedatives (medicines that cause sleepiness).
- have a rare condition called succinic semialdehyde dehydrogenase deficiency.
- If you are allergic to Xyrem or any of its ingredients.

Do not drink alcohol while you are taking Xyrem.

### **What should I tell my doctor before taking Xyrem?**

Talk to your Doctor if you:

- have had depression. You may be more likely to get depressed taking Xyrem.
- have liver problems. Your dose may need to be adjusted.
- have sleep apnea, snoring, or breathing or lung problems. You may be more likely to get serious side effects.
- are on a salt restricted diet, have high blood pressure, or heart failure. Xyrem contains significant levels of sodium (salt) and may not be right for you.

- are pregnant or plan to become pregnant or are breastfeeding. It is not known whether Xyrem can pass through your milk and harm the baby.

Tell your doctor or pharmacist about all the medicines you take, including prescription and non-prescription medicines, and natural health products.

### **How should I take Xyrem?**

- Take Xyrem exactly as prescribed by your doctor.
- To take Xyrem, you must first mix it with water. See "**Directions for using Xyrem**".
- Xyrem may work fast. Take Xyrem only at bedtime and while in bed. Do not walk around after taking your dose of Xyrem.
- Take Xyrem two times each night. Take the first dose right at bedtime and the second dose 2 ½ to 4 hours later. You may need to set an alarm clock to make sure you wake up to take the second dose.
- It is important that you take both doses each night, exactly as prescribed by your doctor.
- Food will decrease the amount of Xyrem that is absorbed by your body. Therefore, it is best to take Xyrem at least two hours after your last meal prior to bedtime.
- You have been prescribed a starting dose of Xyrem. You and your physician will discuss your response to treatment including any side effects you may be experiencing, and your physician may adjust your dose as a result.  
**Never change the dose of Xyrem yourself.**
- 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 for your doctor to find the dose that is best for you.

### **What should I avoid while taking Xyrem?**

- Do not drink alcohol or take sedatives. Alcohol and certain medicines can increase the chance of dangerous side effects. Tell your doctor or

pharmacist about all the medicines you take including non-prescription medicines and natural health products.

- Do not drive a car, operate heavy machinery, or perform any activity that requires mental alertness for at least 6 hours after taking Xyrem. When your first start taking Xyrem, use extreme care while undertaking similar activities the next day.

#### **What should I do if I miss a dose of Xyrem?**

- If you miss the second dose, skip that dose and do not take Xyrem again until the next night. Never take two Xyrem doses at once.

#### **What should I do in the case of overdose?**

- If you take more Xyrem than prescribed or take it by accident, seek medical help.

#### **What are the possible side effects of Xyrem?**

- The most common side effects of Xyrem are headache, nausea, dizziness, sleep problems, confusion, vomiting, and some patients experience infrequent bed-wetting during the night. To help prevent bed-wetting, make sure you go to the bathroom before taking your first dose of Xyrem.
- Tell your doctor if you develop these less common side effects: sleepwalking (confused behavior during the night that may include walking around and doing other activities while not aware of what you are doing), increased sleepiness during the day, snoring, you stop breathing for a short time while you sleep (sleep apnea), breathing problems, depression, abnormal thinking, confusion, and loss of consciousness.

These are not all of the side effects of Xyrem. If you are concerned about any possible side effects consult your doctor or pharmacist.

### **Effects of abusing (misusing) Xyrem (GHB)**

- GHB (gamma-hydroxybutyrate) can be a drug of abuse if used improperly, and some people who repeatedly abuse GHB become addicted to it. People who repeatedly abuse GHB at high frequency and at high doses can develop withdrawal symptoms. These symptoms include the need to continue taking the drug, anxiety, trouble sleeping, and abnormal thinking.

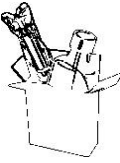
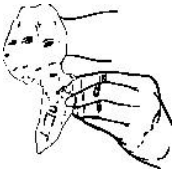

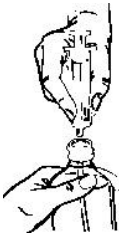
### **How should I store Xyrem?**

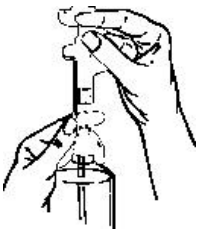

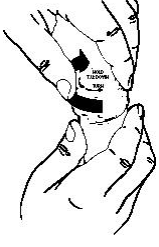
Always store Xyrem at room temperature (15°- 30°C), in the original bottle in a safe and secure place (locked up if appropriate), out of the reach of children and pets. Return any unused Xyrem to your pharmacy for proper disposal. Do not pour it down the drain. **Always place your nightly doses of Xyrem safely out of the reach of children.**

### **Directions for Using Xyrem**

**CAUTION: Be very careful not to leave your Xyrem in a place where children or pets can get to it.**

The Xyrem carton contains 1 bottle of medicine, 2 dosing cups with child-resistant caps, 1 liquid measuring device and printed product information.

<p><b>Step 1</b></p> <p>Remove the Xyrem bottle and the measuring device from the box (See Figure 1).</p>	 <p>Figure 1</p>
<p><b>Step 2</b></p> <p>Remove the measuring device from the wrapper (See Figure 2).</p>	 <p>Figure 2</p>
<p><b>Step 3</b></p> <p>Remove the bottle cap by pushing down while turning the cap counterclockwise (to the left). (See Figure 3).</p> <p>After removing the cap, set the bottle upright on a tabletop.</p>	 <p>Figure 3</p>
<p><b>Step 4</b></p> <p>While holding the bottle in its upright position, insert the tip of the measuring device into the center opening on top of the bottle and press down firmly (See Figure 4).</p>	 <p>Figure 4</p>

<p><b>Step 5</b></p> <p>While holding the bottle and measuring device down with one hand, draw up the prescribed dose with the other hand by pulling on the plunger.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Xyrem is a liquid and your individual prescription contains a description of your dose in mL. Use the description in mL to determine the proper dose on the measuring device.</li> <li>• Medicine will not flow into the measuring device unless you keep the bottle in its upright position (See Figure 5).</li> </ul>	 <p>Figure 5</p>
<p><b>Step 6</b></p> <p>Remove the measuring device from the center opening of the bottle. Empty the medicine from the measuring device into one of the dosing cups provided by pushing on the plunger. Then add in approximately 60 mL or 2 ounces (oz) of water (or enough to fill <math>\frac{3}{4}</math> of the cup). Repeat the process with the second dosing cup (See Figure 6).</p>	 <p>Figure 6</p>
<p><b>Step 6 (continued)</b></p> <p><b>Prepare both doses before bedtime.</b> Place the caps provided on the dosing cups and turn each cap clockwise (to the right) until it clicks and locks into its child-resistant position (See Figure 7).</p> <p>Recap the Xyrem bottle and store it in a safe and secure place (locked up if appropriate), out of the reach of children. Rinse out the liquid measuring device with water.</p>	 <p>Figure 7</p>



**Step 7**

Right before going to sleep, place your second dose in a secure location (locked up if appropriate) near your bed. You may need to set an alarm so you wake up to take your second dose no earlier than 2 ½ hours and no later than 4 hours after your first dose.



Figure 8

Remove the cap from the first dosing cup by pressing down on the child-resistant locking tab (See Figure 8) and turning the cap counterclockwise (to the left). Drink the entire first dose while sitting in bed, recap the cup, and then lie down right away (See Figure 9).



Figure 9

**Step 8**

When you wake up 2 ½ to 4 hours later, remove the cap from the second dosing cup. While sitting in bed, drink all of the second dose; recap the second cup and then lie down to continue sleeping.

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Patent Pending