

Read this **Quick Start Guide** and the sodium oxybate Medication Guide carefully before you start taking sodium oxybate.

YOUR DOCTOR HAS PRESCRIBED  
**SODIUM OXYBATE ORAL SOLUTION**

Frequently asked questions about the safe use and handling of sodium oxybate

**SODIUM OXYBATE REMS PROGRAM**  
Sodium oxybate oral solution  
**For Patients**

Dear Patient,

Welcome to the Sodium Oxybate REMS Program. You are receiving these materials because your healthcare provider has prescribed sodium oxybate oral solution for you. Sodium oxybate is a medicine used to treat excessive daytime sleepiness and/or cataplexy in patients with narcolepsy.

Because of the serious risks associated with sodium oxybate, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for sodium oxybate. The purpose of the Sodium Oxybate REMS Program is to make sure the benefits of sodium oxybate outweigh the risks. All patients must be enrolled in the Sodium Oxybate REMS Program to receive sodium oxybate. This *Quick Start Guide* and the sodium oxybate Medication Guide contain information you need to know about sodium oxybate and will help you to use sodium oxybate correctly. Read this *Quick Start Guide* and the sodium oxybate Medication Guide before you start taking sodium oxybate.

After your healthcare provider sends your enrollment form to the Sodium Oxybate REMS Program and first prescription for sodium oxybate to your certified pharmacy, you will receive a call from your certified pharmacy of the Sodium Oxybate REMS Program to tell you how the Sodium Oxybate REMS Program helps you get started with taking sodium oxybate and to answer any questions you may have about sodium oxybate.

You will also speak with appropriate staff at a certified pharmacy, who will go over your insurance information with you. Before you can receive your first shipment of sodium oxybate, a pharmacist at a certified pharmacy must confirm whether you have read and understood this *Quick Start Guide*, ask you about your medical history and other medications you may be taking, and give you advice on how to prepare and take your sodium oxybate and how to store it safely. **You must take this call before you can get your sodium oxybate.**

Please call your healthcare provider if you have questions about sodium oxybate, or you can contact the Sodium Oxybate REMS Program toll free at 855-705-2424. You can reach your certified pharmacy through this number 24 hours a day, 7 days a week with any questions.

We hope you find this information and the Sodium Oxybate REMS Program services helpful.

Sincerely,

Sodium Oxybate sponsors

**SODIUM OXYBATE REMS PROGRAM**  
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**WARNING: Sodium oxybate can cause  
serious side effects.**

**Do not drink alcohol or take other medicines that make you sleepy.**

Sodium oxybate is a prescription medicine used to treat patients with narcolepsy to reduce too much daytime sleepiness and to reduce cataplexy (suddenly weak or paralyzed muscles).

**Important information about sodium oxybate includes the following:**

- When taking sodium oxybate, do not drink alcohol or take other medicines that slow your breathing or mental activity or make you sleepy. You could have serious side effects
- Sodium oxybate can cause serious side effects, including trouble breathing while asleep, confusion, unusual or disturbing thoughts, depression, and passing out, even at recommended doses. Tell your healthcare provider if you have any of these problems while taking sodium oxybate
- Abuse of sodium oxybate can lead to dependence (a physical need to take the drug), craving for the medicine, and severe withdrawal symptoms (symptoms that start when the drug is stopped, especially when it is stopped suddenly)

(continued on next page)

- Patients usually fall asleep in about 5 to 15 minutes, although some patients have reported falling asleep more quickly (without first feeling drowsy) and others take more time. The time that it takes to fall asleep might be different from night to night. You should take each dose of sodium oxybate while in bed. Take the first dose at bedtime and the second 2 ½ to 4 hours later. You may need to set an alarm to awaken for the second dose
- Do not drive a car, use heavy machinery, fly an airplane, or do anything that is dangerous or that requires you to be alert for the first 6 hours after taking sodium oxybate. When you first start taking sodium oxybate, be careful until you know how sodium oxybate affects you
- Keep sodium oxybate out of the reach of children and pets. Get emergency medical help right away if a child drinks your sodium oxybate
- Report all side effects to your healthcare provider

**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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Please see the Medication Guide for more detailed information about sodium oxybate.

### **What will you find in this booklet?**

This booklet answers important questions about how to get your sodium oxybate, how to use sodium oxybate properly, and how to store it safely. It also gives you important information about sodium oxybate.

### **What is the Sodium Oxybate REMS Program?**

Because of the serious risks associated with sodium oxybate, the FDA has required a special program called REMS for sodium oxybate. Enrollment in the Sodium Oxybate REMS Program by prescribers, pharmacies, and patients is required by the FDA to ensure the benefits of sodium oxybate outweigh the risks associated with sodium oxybate. You are enrolled in the program when your healthcare provider sends the enrollment form you signed in his or her office to the Sodium Oxybate REMS Program. At that time, your healthcare provider also sent your prescription for sodium oxybate to a certified pharmacy.

Certified pharmacy staff will review important information about sodium oxybate with you. They will also answer any questions you may have about sodium oxybate.

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**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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## **ENROLLING IN THE SODIUM OXYBATE REMS PROGRAM**

### **What am I required to do in this program?**

As a patient, your responsibility is to discuss the safe use of sodium oxybate with your healthcare provider and to read this *Sodium Oxybate REMS Program Patient Quick Start Guide* before receiving your first sodium oxybate prescription. Be sure to let your healthcare provider know if you are taking other medications or if you have any conditions that might affect your breathing.

You must also read the sodium oxybate Medication Guide that you will receive with each prescription from your certified pharmacy.

### **Do I have to enroll in this program?**

You will be required to sign an enrollment form at your healthcare provider's office in order to receive sodium oxybate. You must verify that you have been counseled by your healthcare provider on the serious risks and safe use of sodium oxybate and that you were able to ask your healthcare provider any questions you have about sodium oxybate.

## **FILLING YOUR SODIUM OXYBATE PRESCRIPTION**

### **How is my prescription filled?**

All sodium oxybate prescriptions are filled only by pharmacies certified in the Sodium Oxybate REMS Program.

### **What does a certified pharmacy do?**

Your healthcare provider sends your sodium oxybate prescription directly to a certified pharmacy.

After your healthcare provider sends in your first prescription of sodium oxybate, you will receive a call from your certified pharmacy to tell you how the Sodium Oxybate REMS Program helps you get started with taking sodium oxybate and to answer any questions you may have about sodium oxybate. A staff member from your certified pharmacy will call you to complete a *Patient Counseling Checklist*. The *Patient Counseling Checklist* will include information about other medications that you are taking and other medical conditions that might increase your risk of serious side effects. Your certified pharmacy will go over the information about how to use sodium oxybate safely and provide a copy of the Medication Guide with each sodium oxybate shipment.

Your certified pharmacy will always ask you where and when you would like your sodium oxybate delivered and who will sign for the shipment. Sodium oxybate will be shipped by an overnight service. When the courier arrives, you or an adult you name must sign for your sodium oxybate.

**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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## **FILLING YOUR SODIUM OXYBATE PRESCRIPTION (cont'd)**

### **What will I get with my sodium oxybate prescription?**

With each prescription, you will get 1 or more bottles of sodium oxybate (each bottle, whether full or partial, has the concentrated medicine), a sodium oxybate-specific dosing syringe for drawing up your sodium oxybate dose, 2 empty pharmacy containers with child-resistant caps, and a printed Medication Guide.

### **How do I get my sodium oxybate refills?**

Your certified pharmacy will contact you when it is close to your refill time. You may also call your certified pharmacy to schedule your refills.

### **Can my local pharmacy provide sodium oxybate?**

No. You can get your sodium oxybate only from a Sodium Oxybate REMS Program certified pharmacy. You may be able to have your sodium oxybate shipped to your place of work or to a local overnight carrier hub for pickup. Saturday deliveries may also be an option for you. Your certified pharmacy will work with you on the best options available.

## **INSURANCE COVERAGE**

### **Will insurance pay for my sodium oxybate?**

In most cases, YES. A staff member from your certified pharmacy will call and work with your insurance company to help you get coverage for sodium oxybate.

### **What is the pharmacy's role with my insurance?**

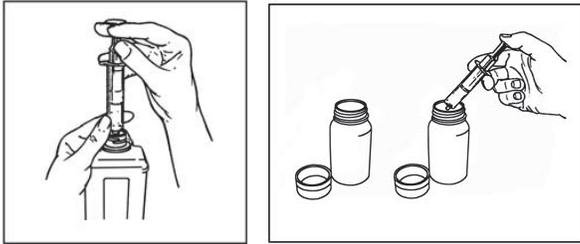
An experienced staff member will:

- Go over your prescription benefits and coverage
- Tell you what your co-pay is, if applicable
- Work with your healthcare provider on prior authorizations, if required by your insurance company

Your certified pharmacy's attempt to get coverage from a third-party payer does not guarantee that you will get coverage.

## HOW DO I TAKE MY SODIUM OXYBATE?

Take sodium oxybate only as your healthcare provider tells you to take it.



\*For illustration purposes only. Your product may look different.

### How do I prepare my doses?

Before going to bed, draw up each of your sodium oxybate doses with the syringe that comes in your shipment. Add each sodium oxybate dose into 1 of the 2 empty pharmacy containers by pushing down on the plunger. Be sure each pharmacy container is empty before adding sodium oxybate into it.

## HOW DO I TAKE MY SODIUM OXYBATE? (cont'd)

### How do I prepare my doses? (cont'd)

**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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Add about  $\frac{1}{4}$  cup of water to each dose of sodium oxybate. Then place the child-resistant caps onto the pharmacy containers and turn each cap clockwise (to the right) until it clicks and locks in its child-resistant position.

Then put the 2 prepared doses in a safe place by your bed, out of the reach of children and pets.

Place the cap back on the sodium oxybate bottle and store it in a safe and secure place (locked up if needed), out of the reach of children and pets.

Sodium oxybate should always be stored in the bottle provided. Rinse out the syringe and pharmacy containers with water after each use.

### **How do I take my doses?**

Food will lower the amount of sodium oxybate that passes into your body. You should allow at least 2 hours after a meal before taking your first dose of sodium oxybate.

Sodium oxybate is a medicine that can make you sleepy quickly; therefore, take your doses while you are in bed. Take the first dose at bedtime and the second dose 2 ½ to 4 hours later. As with any medicine that causes sleepiness, if you continue evening activities after taking your dose, such as watching television or walking around, you may experience light-headedness, dizziness, nausea, confusion, or other unpleasant feelings.

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## **HOW DO I TAKE MY SODIUM OXYBATE? (cont'd)**

### **What should I do if I miss a sodium oxybate dose?**

- It is very important to take both doses of sodium oxybate each night, as prescribed. If you miss the second dose, skip that dose
  - Do not take sodium oxybate again until the next night
  - Never take both sodium oxybate doses at once
- Any unused sodium oxybate doses that you prepared but didn't take must be thrown away within 24 hours from the time you first prepared your doses

### **How soon will I see a change in my symptoms?**

After starting sodium oxybate, it may take a few weeks or longer to see your symptoms improve. It may also take time to find the right dose that works for you. It is important that you talk with your healthcare provider often when you first start taking sodium oxybate.

Tell your healthcare provider if you don't feel any improvements while taking sodium oxybate. Sodium oxybate may not be right for you.

### **What are the side effects of sodium oxybate?**

Sodium oxybate can cause serious side effects, including breathing problems (slower breathing, trouble breathing, and short periods of no breathing while asleep), mental health problems (confusion, seeing or hearing things that are not real, unusual or disturbing thoughts, feeling anxious or upset, depression, thoughts of suicide), and sleepwalking. If you have any of these side effects, call your healthcare provider right away.

The most common side effects with sodium oxybate are nausea, dizziness, throwing up, bedwetting, and diarrhea. Side effects may increase with higher doses.

These are not the only possible side effects with sodium oxybate. If you are worried about any possible side effects with sodium oxybate, talk with your healthcare provider or the pharmacist at one of the certified pharmacies. You should report all side effects by contacting your healthcare provider, the Sodium Oxybate REMS Program at 855-705-2424, or the FDA at 1-800-FDA-1088.

**Any questions? Please call the  
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## HOW DO I TAKE MY SODIUM OXYBATE? (cont'd)

### Are there any precautions I should take while on sodium oxybate?

- While taking sodium oxybate, do not drink alcohol or take medicines that cause sleepiness
- Do not drive a car, use heavy machinery, or do anything that is dangerous or requires you to be alert, for the first 6 hours after taking sodium oxybate. When you first start taking sodium oxybate, be careful until you know how it will affect you
- Before starting sodium oxybate, tell your healthcare provider if you are pregnant, or plan to become pregnant, or if you are breastfeeding. It is not known whether sodium oxybate can pass through your breast milk
- Keep your sodium oxybate in a safe place, out of the reach of children
- Take sodium oxybate while in bed

Tell your healthcare provider and pharmacist about any other medicines you are taking, including prescription and non-prescription medicines, vitamins, and supplements.

It is also important to tell other healthcare providers, including pharmacists, that you are taking sodium oxybate before you start or change any medications.

**How often should my healthcare provider check my progress with sodium oxybate?**

When you first start taking sodium oxybate, you may need to talk to your healthcare provider often until he or she has determined the best dose for you. You can expect that your dose may need to be adjusted. After your dose has been established, your healthcare provider should check on you every 3 months while you are taking sodium oxybate.

**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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## **STORAGE AND SAFETY TIPS AT HOME**

### **How do I store sodium oxybate?**

- Always store sodium oxybate in its original bottle
- Store sodium oxybate at room temperature. Do not refrigerate sodium oxybate
- Keep sodium oxybate in a safe place, out of the reach of children and pets. Get emergency medical help (call 911) right away if a child drinks your sodium oxybate

### **How do I properly dispose of sodium oxybate?**

When you have finished a bottle, pour any unused sodium oxybate down the sink or toilet drain. Mark out over the prescription label with a marker to protect your confidentiality before putting the empty bottle in the trash.

If you misplace, lose, or damage your sodium oxybate dosing syringe, contact your certified pharmacy to have it replaced. Do not use a different syringe or try to guess the correct dose.

### **What if I have concerns about having sodium oxybate in my home?**

- If your sodium oxybate is lost or stolen, report the incident right away to the local police and to your certified pharmacy
- Use sodium oxybate only as your healthcare provider tells you. Remember that use of your sodium oxybate by others is illegal
- If you have any questions or concerns, or if you need advice about sodium oxybate, call your healthcare provider or your certified pharmacy

**Any questions? Please call the Sodium Oxybate REMS Program at 855-705-2424.**

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### **Where can I get more information about sodium oxybate?**

For more information about sodium oxybate, contact the Sodium Oxybate REMS Program

- **Phone:** 855-705-2424
- **Fax:** 800-353-0987 (toll free)
- **Outside the US:** +1-855-705-2424
- **Website:** [www.SodiumOxybateREMSProgram.com](http://www.SodiumOxybateREMSProgram.com)



----- **Keep this booklet as a helpful reminder** -----

If you have questions or need information,  
contact the Sodium Oxybate REMS Program

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