Read this **Quick Start Guide** and he XYREM Medication Guide carefully before you start taking XYREM.

YOUR DOCTOR HAS PRESCRIBED

XYREM® (sodium oxybate) oral solution

- Frequently asked questions about the safe use and handling of XYREM

XYREM (sodium oxybate) oral solution
REMS PROGRAM
for patients

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Dear Patient,

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

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

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After your healthcare provider sends in your enrollment form and first prescription for XYREM, you will receive a call from the Certified Pharmacy of the XYREM REMS Program to tell you how the XYREM REMS Program helps you get started with taking XYREM and to answer any questions you may have about XYREM.

You will also speak with appropriate staff at the Certified Pharmacy, who will go over your insurance information with you. Before you can receive your first shipment of XYREM, a pharmacist at the 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 XYREM and how to store it safely. **You must take this call before you can get your XYREM.**

Please call your healthcare provider if you have questions about XYREM, or you can contact the XYREM REMS Program toll free at 1-866-XYREM88® (1-866-997-3688). You can reach a pharmacist at this number 24 hours a day, 7 days a week with any questions.

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

Sincerely,

Jazz Pharmaceuticals

WARNING: XYREM can cause serious side effects.
Do not drink alcohol or take other medicines that make you sleepy

XYREM 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 XYREM includes the following:

- When taking XYREM, 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
- XYREM 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 XYREM
- Abuse of XYREM 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 XYREM while in bed. Take the first dose at bedtime and the second 2½ 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 XYREM. When you first start taking XYREM, be careful until you know how XYREM affects you
- Keep XYREM out of the reach of children and pets. Get emergency medical help right away if a child drinks your XYREM
- Report all side effects to your healthcare provider

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

What will you find in this booklet?

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

What is the XYREM REMS Program?

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

The Certified Pharmacy staff will review important information about XYREM with you. They will also answer any questions you may have about XYREM.

TABLE OF CONTENTS

Enrolling in the XYREM REMS Program

What am I required to do in this program?.....10

Do I have to enroll in this program?.....10

Filling Your XYREM Prescription

How is my prescription filled?.....10

What does the Certified Pharmacy do?.....11

What will I get with my XYREM prescription?.....12

How do I get my XYREM refills?.....12

Can my local pharmacy provide XYREM?.....12

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

TABLE OF CONTENTS (cont'd)

Insurance Coverage

Will insurance pay for my XYREM?.....13

What is the pharmacy's role with my insurance?.....13

How Do I Take My XYREM?

How do I prepare my doses?.....14

How do I take my doses?.....16

What should I do if I miss a XYREM dose?.....17

How soon will I see a change in my symptoms?.....17

What are the side effects of XYREM?.....18

Are there any precautions I should take while on XYREM?.....19

How often should my healthcare provider check my progress with XYREM?.....20

Storage and Safety Tips at Home

How do I store XYREM?.....21

How do I properly dispose of XYREM?.....21

What if I have concerns about having XYREM in my home?.....22

Getting More Information

Where can I get more information about XYREM?.....23

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

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ENROLLING IN THE XYREM REMS PROGRAM

What am I required to do in this program?

As a patient, your responsibility is to discuss the safe use of XYREM with your healthcare provider and to read this XYREM REMS Program Patient Quick Start Guide before receiving your first XYREM 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 XYREM Medication Guide that you will receive with each prescription from the 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 XYREM. You must verify that you have been counseled by your healthcare provider on the serious risks and safe use of XYREM and that you were able to ask your healthcare provider any questions you have about XYREM.

FILLING YOUR XYREM PRESCRIPTION

How is my prescription filled?

All XYREM prescriptions are filled only by the XYREM REMS Program Certified Pharmacy.

What does the Certified Pharmacy do?

Your healthcare provider sends your XYREM prescription directly to the Certified Pharmacy.

After your healthcare provider sends in your first prescription of XYREM, you will receive a call from the Certified Pharmacy to tell you how the XYREM REMS Program helps you get started with taking XYREM and to answer any questions you may have about XYREM. A staff member from the 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 which might increase your risk of serious side effects. The Certified Pharmacy will go over the information about how to use XYREM safely and provide a copy of the Medication Guide with each XYREM shipment.

The Certified Pharmacy will always ask you where and when you would like your XYREM delivered and who will sign for the shipment. XYREM will be shipped by an overnight service. When the courier arrives, you or an adult you name must sign for your XYREM.

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

FILLING YOUR XYREM PRESCRIPTION (cont'd)

What will I get with my XYREM prescription?

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

How do I get my XYREM refills?

The Certified Pharmacy will contact you when it is close to your refill time. You may opt-in to receive text, e-mail, or automated voice reminders. You may also call the Certified Pharmacy at 1-866-997-3688 to schedule your refills.

Can my local pharmacy provide XYREM?

No. You can get your XYREM only from the XYREM REMS Program central Certified Pharmacy. You may be able to have your XYREM shipped to your place of work or to a local overnight carrier hub for pickup. Saturday deliveries may also be an option for you. The Certified Pharmacy will work with you on the best options available.

INSURANCE COVERAGE

Will insurance pay for my XYREM?

In most cases, YES. A staff member from the Certified Pharmacy will call and work with your insurance company to help you get coverage for XYREM. In the unlikely event your insurance does not cover XYREM or you can't afford the out-of-pocket costs, ask the Certified Pharmacy about available financial assistance programs.

What is the pharmacy's role with my insurance?

An experienced staff member will:

- Call you to go over your prescription benefits and coverage
- Tell you what your co-pay is, if applicable
- Tell you about any XYREM prescription savings plans for which you may qualify
- Work with your healthcare provider on prior authorizations, if required by your insurance company
- Provide information about any financial help that may be available to you

The 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 XYREM?

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

How do I prepare my doses?

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

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

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HOW DO I TAKE MY XYREM? (cont'd)

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

Add about ¼ cup of water to each dose of XYREM. 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 XYREM bottle and store it in a safe and secure place (locked up if needed), out of the reach of children and pets.

XYREM 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 XYREM that passes into your body. You should allow at least 2 hours after a meal before taking your first dose of XYREM.

XYREM 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 2½ 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.

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

HOW DO I TAKE MY XYREM? (cont'd)

What should I do if I miss a XYREM dose?

- It is very important to take both doses of XYREM each night, as prescribed. If you miss the second dose, skip that dose
  - Do not take XYREM again until the next night
  - Never take both XYREM doses at once
- Any unused XYREM 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 XYREM, 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 XYREM.

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

What are the side effects of XYREM?

XYREM 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 XYREM are nausea, dizziness, throwing up, bedwetting, and diarrhea. Side effects may increase with higher doses.

These are not the only possible side effects with XYREM. If you are worried about any possible side effects with XYREM, talk with your healthcare provider or the pharmacist at the XYREM REMS Program.

You should report all side effects by contacting your healthcare provider, Jazz Pharmaceuticals at 1-800-520-5568, or the FDA at 1-800-FDA-1088.

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

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HOW DO I TAKE MY XYREM? (cont'd)

Are there any precautions I should take while on XYREM?

- While taking XYREM, 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 XYREM. When you first start taking XYREM, be careful until you know how it will affect you
- Before starting XYREM, tell your healthcare provider if you are pregnant, or plan to become pregnant, or if you are breastfeeding. It is not known whether XYREM can pass through your breast milk
- Keep your XYREM in a safe place, out of the reach of children
- Take XYREM 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 XYREM before you start or change any medications.

How often should my healthcare provider check my progress with XYREM?

When you first start taking XYREM, 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 XYREM.

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

STORAGE AND SAFETY TIPS AT HOME

How do I store XYREM?

- Always store XYREM in its original bottle
- Store XYREM at room temperature. Do not refrigerate XYREM
- Keep XYREM 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 XYREM

How do I properly dispose of XYREM?

When you have finished a bottle, pour any unused XYREM 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 XYREM dosing syringe, contact the 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 XYREM in my home?

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

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

Where can I get more information about XYREM?

For more information about XYREM, contact the XYREM REMS Program:

- **Phone**: 1-866-XYREM88® (1-866-997-3688)
- **Fax**: 1-866-470-1744 (toll free)
- **Outside the US**: +314-475-6000, ext 361 587
- **Website**: www.XYREMREMS.com

NOTES

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

Please see the Medication Guide for more detailed information about XYREM.

Keep this booklet as a helpful reminder

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

Any questions? Please call the XYREM REMS Program at 1-866-997-3688.

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