

XYREM REMS

BROCHURE FOR PEDIATRIC PATIENTS AND THEIR CAREGIVERS

Important information about the
safe use and handling of XYREM



XYREM[®]
[sodium oxybate] oral solution ^{III}

Dear Caregiver,

Welcome to the XYREMREMS Program. You are receiving these materials because your child's healthcare provider has prescribed XYREM® (sodium oxybate) oral solution, 0.5 g/mL, for your child. XYREM is a medicine used to treat cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. XYREM may only be given to patients enrolled in the XYREM REMS Program.

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). 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. Each pediatric patient must have a caregiver who is counseled on the serious risks and safe use of XYREM. This brochure contains information you need to know about XYREM and will help you give XYREM to your child correctly. Read this brochure before you start giving your child 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.



After your child's healthcare provider sends in your child's enrollment form and first prescription for XYREM, you will receive a call from the Certified Pharmacy of the XYREM REMS Program to counsel you on the serious risks and safe use of Xyrem, to tell you how the XYREM REMS Program helps you get your child started with taking XYREM, and to answer any questions you or your child may have about XYREM.

A few things must happen before you receive your child's first shipment of XYREM:

- The Certified Pharmacy will call to:
 - Ask if your child's healthcare provider reviewed the XYREM REMS Program Brochure for Pediatric Patients and Their Caregivers with you
 - Explain that you will receive this brochure with your child's first shipment, and that all drug shipments will include the XYREM Medication Guide
 - Ask you about your child's medical history and other medications he or she may be taking
 - Give you advice on how to prepare and give XYREM to your child and how to store it safely
 - Go over your child's insurance information
- **You must take this call before you can get your child's XYREM**



If you have any additional questions about XYREM, please call your child's healthcare provider, 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 helpful.

Sincerely,

Jazz Pharmaceuticals

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

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



**WARNING: XYREM can cause serious side effects.
Your child should not drink alcohol or take other medicines that
cause sleepiness**

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, your child should not drink alcohol or take other medicines that may slow his or her breathing or mental activity or make him or her sleepy. Your child could have serious side effects
- XYREM can cause serious side effects, including slow breathing or changes in alertness. Call your child's doctor right away if your child has any of these serious side effects
- 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)

- 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 give each dose of XYREM while your child is sitting up in bed and have your child lie down immediately after. Give the first dose at the time prescribed by your child's healthcare provider, and the second dose 2 ½ to 4 hours later. You may need to set an alarm to awaken to give the second dose
- Your child should not do anything that requires him or her to be fully alert for the first 6 hours after taking XYREM. When your child first starts taking XYREM, you and your child will need to be careful until you know how XYREM affects him or her.
- Keep XYREM out of the reach of children and pets. Get emergency medical help right away if a child who has not been prescribed XYREM drinks XYREM
- Report all side effects to your child's healthcare provider

WHAT WILL YOU FIND IN THIS BROCHURE?

This brochure provides information on the serious risks and safe use of XYREM, answers important questions about how to use XYREM properly, how to store it safely, and how to get your child's 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.



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. Your child is enrolled in the program when your child's healthcare provider sends in your signed enrollment form. At that time, your child's healthcare provider also will send your child's 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 and your child may have about XYREM.

Table of Contents

PREPARATION AND ADMINISTRATION OF XYREM	11
What will I get with my child's XYREM prescription?	11
How do I prepare my child's doses?	12
How do I give my child's doses?	14
What do I do if my child misses a dose?	15
How soon will we see a change in symptoms?	16
What are the side effects of XYREM?	16
Are there any precautions that should be taken while my child is on XYREM?	17
HOW OFTEN SHOULD MY CHILD'S HEALTHCARE PROVIDER CHECK ON MY CHILD'S PROGRESS ON XYREM?	18
STORAGE AND SAFETY TIPS AT HOME	19
How do I store XYREM?	19
How do I properly dispose of XYREM?	19
What if I have concerns about having XYREM in my home?	19

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

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



IMPORTANT INFORMATION YOUR CHILD MUST KNOW ABOUT TAKING XYREM	20
What should my child know about taking XYREM?	20
INCLUDING YOUR CHILD IN HIS OR HER CARE	24
How can I prepare my child to be able to carry out one or more safe use activities?	24
ENROLLING YOUR CHILD IN THE XYREM REMS PROGRAM	25
Does my child have to enroll in this program?	25
What am I required to do in this program?	25
How is my child's prescription filled?	27
What else does the Certified Pharmacy do?	27
How do I get XYREM refills for my child?	28
Can my local pharmacy provide XYREM for my child?	28

INSURANCE COVERAGE	29
Will insurance pay for my child's XYREM?	29
What is the pharmacy's role with my child's insurance?	29
CONTACT INFORMATION	30
Whom should I contact with concerns or for more information about XYREM?	30

Any questions? Please call the XYREM® REMS Program at 1-866-997-3688.
Please see the Medication Guide for more-detailed information about XYREM.



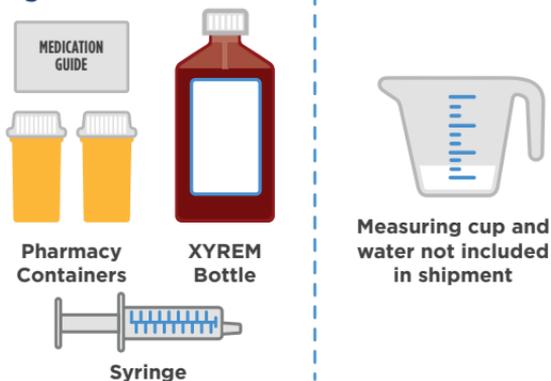
Preparation and Administration of XYREM

XYREM should be prepared and taken only as prescribed by your child's healthcare provider.

WHAT WILL I GET WITH MY CHILD'S XYREM PRESCRIPTION?

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

Figure 1

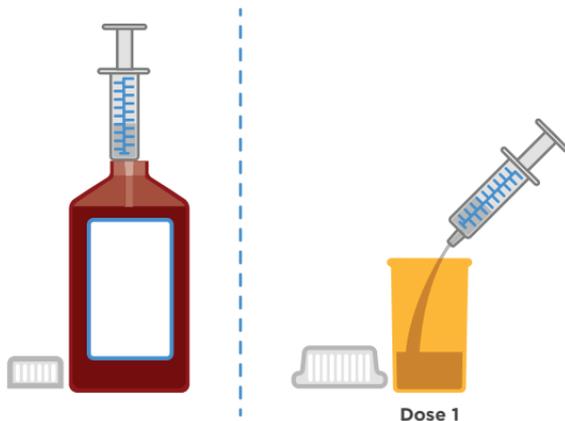


XYREM[®]
(sodium oxybate) oral solution

HOW DO I PREPARE MY CHILD'S DOSES?

Place the bottle on a hard, flat surface and grip the bottle with one hand and firmly press the syringe into the center opening of the bottle with the other. Pull back on the plunger until the medication flows into the syringe and the liquid level is aligned with the corresponding tick mark for your child's dose. After you draw up the first XYREM dose, remove the syringe from the opening of the XYREM bottle. Empty all of the medicine from the syringe into one of the provided **empty** pharmacy containers by pushing down on the plunger until it stops (Figure 2).

Figure 2



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

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

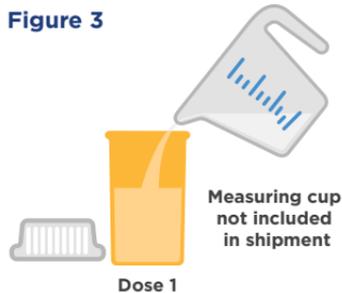


Using a measuring cup, pour about $\frac{1}{4}$ cup of water into the pharmacy container. **Be careful to add only water to the pharmacy container and not more XYREM.** Place the child-resistant cap provided on the filled pharmacy container and turn the cap clockwise (to the right) until it clicks and locks in its child-resistant position.

Repeat the steps described above by drawing up the amount of medicine prescribed for your child's second dose; emptying the syringe into the second pharmacy container, adding about $\frac{1}{4}$ cup of water, and closing the pharmacy container.

Put the cap back on the XYREM bottle and store the XYREM bottle and both prepared doses in a safe and secure place. Store in a locked place if needed. Keep the XYREM bottle and both prepared XYREM doses out of the reach of children and pets.

Rinse out the syringe and pharmacy containers with water after each use. Please refer to the Instructions for Use within the Medication Guide for additional details.



HOW DO I GIVE MY CHILD'S DOSES?

You should allow **at least** 2 hours after your child eats a meal before giving the first dose of XYREM.

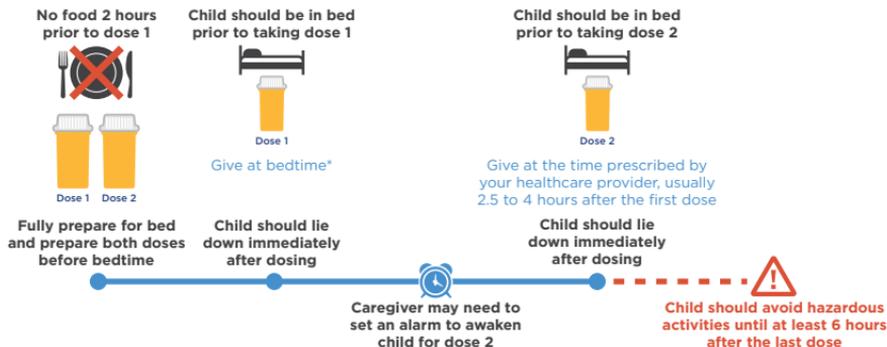
XYREM is a medicine that can make your child sleepy quickly; therefore, give your child's doses while he or she is sitting up in bed and have your child lie down immediately after dosing and remain in bed. Ensure your child is fully prepared for bed prior to taking the first nightly dose of XYREM (for example, has brushed teeth, gone to the bathroom). Give the first dose at the time prescribed by your child's healthcare provider, and the second dose 2½ to 4 hours later. Ensure that all XYREM doses are kept in a safe place until given. If your child continues evening activities after taking his or her dose, such as watching television or walking around, your child may experience light-headedness, dizziness, nausea, confusion, or other unpleasant feelings. Have the child lie down immediately after dosing and remain in bed (Figure 4).

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

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



Figure 4



*For children who sleep more than 8 hours per night, the first dose of XYREM may be given at bedtime or after an initial period of sleep.

WHAT DO I DO IF MY CHILD MISSES A DOSE?

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

HOW SOON WILL WE SEE A CHANGE IN SYMPTOMS?

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

Tell your child's healthcare provider if you or your child do not see any improvements.

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 your child has any of these side effects, call your child's healthcare provider right away.

The most common side effects with XYREM in pediatric patients are bedwetting, nausea, headache, throwing up, and weight loss. Side effects may increase with higher doses.

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

You should report all side effects by contacting your child's 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.



ARE THERE ANY PRECAUTIONS THAT SHOULD BE TAKEN WHILE MY CHILD IS ON XYREM?

- While taking XYREM, your child should not drink alcohol or take medicines that cause sleepiness
- Your child should not do anything that requires him or her to be fully alert for the first 6 hours after taking XYREM. When your child first starts taking XYREM, you and your child will need to be careful until you know how XYREM affects him or her.
- Before starting XYREM, tell your child's healthcare provider if your child is pregnant, or plans to become pregnant, or is breastfeeding. XYREM passes into breast milk. You and your child's healthcare provider should decide if your child will take XYREM or breastfeed.
- Keep XYREM in a safe place, out of the reach of children
- Give XYREM to your child while he or she is sitting up in bed and have your child lie down immediately and remain in bed after dosing

Tell your child's healthcare provider and pharmacist about any other medicines he or she is taking, including if your child begins a new medicine while taking XYREM. This would include prescription and non-prescription medicines, vitamins, and supplements.

It is also important to tell other healthcare providers, including pharmacists, that your child is taking XYREM before your child starts or changes any medications.

How Often Should My Child's Healthcare Provider Check on My Child's Progress On XYREM?

When your child first starts taking XYREM, you may need to talk to his or her healthcare provider often until he or she has determined the best dose for your child. You can expect that your child's dose may need to be adjusted. After your child's dose has been established, his or her healthcare provider should check on your child every 3 months while 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 not prescribed XYREM drinks XYREM

HOW DO I PROPERLY DISPOSE OF XYREM?

To properly dispose of XYREM, pour any unused XYREM down the sink or toilet drain. Mark out all personal information on the prescription label, including the XYREM name, to make it unreadable before putting the empty bottle in the trash.

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

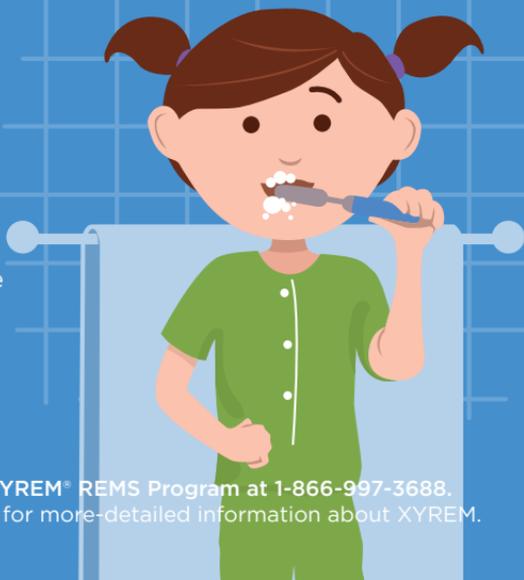
Important Information Your Child Must Know About Taking XYREM

You can use these pages to help teach your young child what they need to know about taking their XYREM.

WHAT SHOULD MY CHILD KNOW ABOUT TAKING XYREM?

Get Ready

- Get ready for bed before you drink your XYREM
- Finish your bedtime routine before you get in bed and drink 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.



Stay In Bed

- Drink your XYREM while sitting up in bed. Lie down right away after you drink it and stay in bed
- Call for a grown-up if you want to get out of bed after taking XYREM
- It may take a while, or you may fall asleep quickly after taking XYREM

Be Careful

- Be careful in the morning
- Call for a grown-up to help you if you still feel sleepy in the morning



Any questions? Please call the XYREM® REMS Program at 1-866-997-3688.
Please see the Medication Guide for more-detailed information about XYREM.

Always Remember!

- Don't share your XYREM with anyone else
 - This medicine is only for you!
- Don't drink too much XYREM
 - Never drink more than one of your XYREM cups at a time
 - Only drink XYREM from your XYREM cup
- Tell a grown-up how you are feeling and about any changes in how you are feeling



Including Your Child in His or Her Care

HOW CAN I PREPARE MY CHILD TO BE ABLE TO CARRY OUT ONE OR MORE SAFE USE ACTIVITIES?

It is important for your child to take an active part in the safe use of his or her XYREM. This is especially true for teenagers and those going to college. This brochure can help you talk with your child about taking XYREM.

Before your child moves away from your home (for example, going away to college), talk with your healthcare provider and the Certified Pharmacy about additional ways to ensure safe use, handling, and storage. To help prepare your child for this transition, make sure that he or she is counseled about the serious risks and safe use of XYREM by a member of your child's XYREM healthcare team (for example, your child's healthcare provider or the Certified Pharmacy). Your child should also read this brochure and ask his or her healthcare provider any questions he or she may have.

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

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



Enrolling Your Child in the XYREM REMS Program

DOES MY CHILD HAVE TO ENROLL IN THIS PROGRAM?

Yes. In order for your child to receive XYREM, your healthcare provider will have you sign an enrollment form and will send the form to the XYREM REMS Program. You must verify that you have been counseled by your child's healthcare provider on the serious risks and safe use of XYREM and that you were able to ask your child's healthcare provider any questions you have about XYREM. You may choose to have your child also receive counseling from your healthcare provider on the serious risks and safe use of XYREM.

WHAT AM I REQUIRED TO DO IN THIS PROGRAM?

As a caregiver of a pediatric patient who is in the XYREM REMS Program, you are required to:

- Read this brochure and ask your child's healthcare provider any questions you have about XYREM.
- Ensure that XYREM is prepared and given only as prescribed
- Ensure that XYREM is kept in a safe place, away from children and pets, and protected from theft

- Notify your child's healthcare provider right away if you notice any serious side effects while your child is taking XYREM

Also be sure to let your child's healthcare provider know if your child is taking other medicines or if your child has any medical conditions that might affect his or her breathing.

If you need to give your responsibilities as your child's caregiver to someone else, please notify your child's healthcare provider. You also can contact the XYREM REMS Program toll free at 1-866-XYREM88® (1-866-997-3688) to make sure that the new caregiver is counseled on the risks and safe use of 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 Child's XYREM Prescription

HOW IS MY CHILD'S PRESCRIPTION FILLED?

All XYREM prescriptions are filled and shipped directly to your home only by the XYREM REMS Program Certified Pharmacy.

WHAT ELSE DOES THE CERTIFIED PHARMACY DO?

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

You will then receive a call from the Certified Pharmacy to counsel you on the serious risks and safe use of XYREM, to tell you how to get your child started on XYREM and to answer any questions about XYREM. A staff member from the Certified Pharmacy will call you to complete a counseling checklist. The counseling checklist will include information about other medicines that your child is taking and other medical conditions that might increase your child's 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 child's XYREM delivered and who will sign for the shipment. XYREM will be shipped by an overnight service. You may be able to have your child's 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 to find the best options available. When the courier arrives, you or another adult you previously named must sign for your child's XYREM.

Finally, the Certified Pharmacy will call you soon after you receive your child's first XYREM shipment to confirm receipt and answer any questions you may have about your child's first few days taking XYREM.

HOW DO I GET XYREM REFILLS FOR MY CHILD?

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

CAN MY LOCAL PHARMACY PROVIDE XYREM FOR MY CHILD?

No. You can get your child's XYREM only from the XYREMREMS Program central 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.



Insurance Coverage

WILL INSURANCE PAY FOR MY CHILD'S XYREM?

In most cases, YES. A staff member from the Certified Pharmacy will call and work with your child's insurance company to help you get coverage for your child's XYREM. In the unlikely event your child's 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 CHILD'S INSURANCE?

An experienced staff member will:

- Call you to go over your child's 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 child's healthcare provider on prior authorizations, if required by the 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.

Contact Information

WHOM SHOULD I CONTACT WITH CONCERNS OR FOR MORE INFORMATION ABOUT XYREM?

FOR QUESTIONS ABOUT SIDE EFFECTS OR FOR MORE INFORMATION ABOUT XYREM, CONTACT YOUR CHILD'S HEALTHCARE PROVIDER:

Name: _____

Phone: _____

Email: _____

FOR MORE INFORMATION ABOUT XYREM, CONTACT THE CERTIFIED PHARMACY:

- **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

TO REPORT ALL SIDE EFFECTS, YOU CAN CONTACT:

- Jazz Pharmaceuticals at 1-800-520-5568
- The FDA at 1-800-FDA-1088

FOR EMERGENCIES:

- Call 911

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.

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



The pharmacy may ask you to measure how much XYREM is left in your bottle. Please use this ruler to give them this information.

4

3

2

1