

# XYWAV and XYREM REMS

## BROCHURE FOR PEDIATRIC PATIENTS AND THEIR CAREGIVERS

Important information about the  
safe use and handling of XYWAV



# XYWAV and XYREM REMS

Dear Caregiver,

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

Because of the serious risks associated with XYWAV, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS). The purpose of this REMS is to make sure the benefits of XYWAV outweigh the risks. All patients must be enrolled in the REMS to receive XYWAV. Each pediatric patient must have a caregiver who is counseled on the serious risks and safe use of XYWAV. This brochure contains information you need to know about XYWAV and will help you give XYWAV to your child correctly. Read this brochure before you start giving your child XYWAV.

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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

Reference ID: 4745184



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

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

- The Certified Pharmacy will call to:
  - Ask if your child's healthcare provider reviewed the XYWAV 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 XYWAV 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 XYWAV 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 XYWAV**

## **XYWAV** and **XYREM** REMS

If you have any additional questions about XYWAV, please call your child's healthcare provider, or you can contact the REMS toll free at 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 REMS helpful.

Sincerely,

Jazz Pharmaceuticals

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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

Reference ID: 4745184



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

XYWAV is a prescription medicine used to treat patients 7 years of age and older with narcolepsy to reduce too much daytime sleepiness and to reduce cataplexy (suddenly weak or paralyzed muscles).

### **IMPORTANT INFORMATION ABOUT XYWAV INCLUDES THE FOLLOWING:**

- When taking XYWAV, 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
- XYWAV 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 XYWAV 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)

**xywav™**   
(calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL 

## **XYWAV** and **XYREM** REMS

- 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 XYWAV 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 XYWAV. When your child first starts taking XYWAV, you and your child will need to be careful until you know how XYWAV affects him or her.
- Keep XYWAV out of the reach of children and pets. Get emergency medical help right away if a child who has not been prescribed XYWAV drinks XYWAV
- 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 XYWAV, answers important questions about how to use XYWAV properly, how to store it safely, and how to get your child's XYWAV.

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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



## WHAT IS THE XYWAV AND XYREM REMS PROGRAM?

Because of the serious risks associated with XYWAV, the FDA has required a special program called REMS for XYWAV and XYREM. Enrollment in the REMS by prescribers and patients is required by the FDA to ensure the benefits of XYWAV outweigh the risks associated with XYWAV. 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 XYWAV to the Certified Pharmacy.

The Certified Pharmacy staff will review important information about XYWAV with you. They will also answer any questions you and your child may have about XYWAV.

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



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# XYWAV and XYREM REMS

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**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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



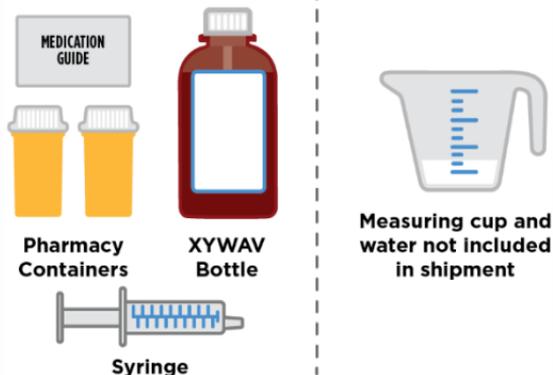
## Preparation and Administration of XYWAV

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

### WHAT WILL I GET WITH MY CHILD'S XYWAV PRESCRIPTION?

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

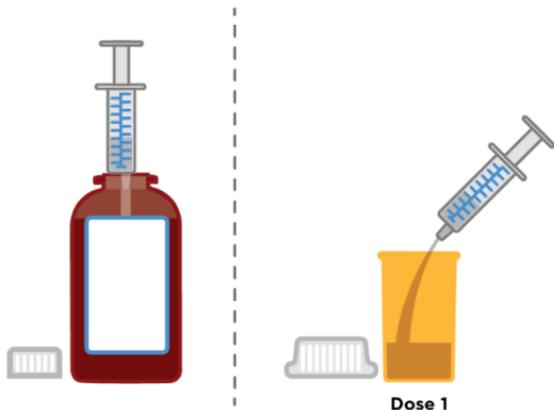
**Figure 1**



## 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 XYWAV dose, remove the syringe from the opening of the XYWAV 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 XYWAV and XYREM REMS at 1-866-997-3688.**

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



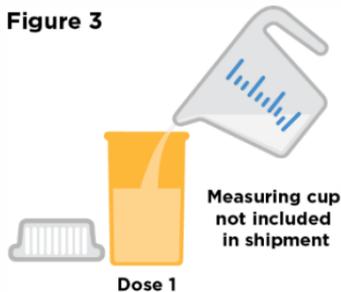
Using a measuring cup, pour about  $\frac{1}{4}$  cup of water into the pharmacy container. **Be careful to add only water to the pharmacy container and not more XYWAV.** Place the child-resistant cap provided on the filled pharmacy container and turn the cap clockwise (to the right) until it clicks 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 XYWAV bottle and store the XYWAV bottle and both prepared doses in a safe and secure place. Store in a locked place if needed. Keep the XYWAV bottle and both prepared XYWAV 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.

**Figure 3**



## **HOW DO I PREPARE MY CHILD'S DOSES?**

Wait at least 2 hours after your child eats before giving XYWAV.

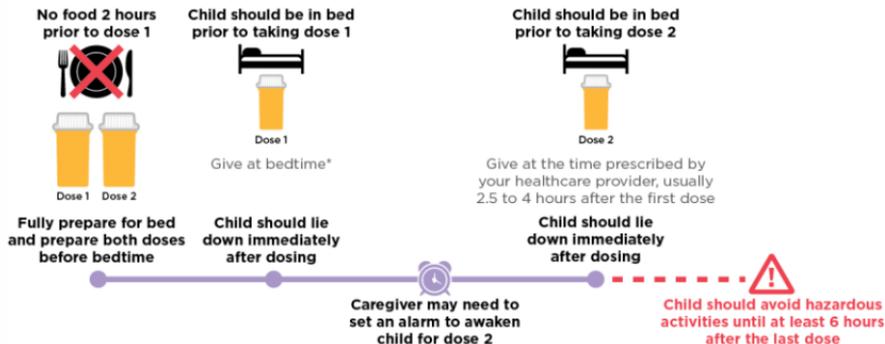
XYWAV is a medicine that can make your child sleepy quickly; therefore, give your child's doses while he or she is sitting up in bed and have your child lie down immediately after dosing and remain in bed. Ensure your child is fully prepared for bed prior to taking the first nightly dose of XYWAV (for 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 2 ½ to 4 hours later. Ensure that all XYWAV 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 XYWAV and XYREM REMS at 1-866-997-3688.**

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



**Figure 4**



\*For children who sleep more than 8 hours per night, the first dose of XYWAV 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 XYWAV each night as prescribed. If the second dose is missed, skip that dose
  - Do not give your child XYWAV again until the next night
  - Never give your child both XYWAV doses at once
- Any unused XYWAV 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

**xywav™**   
(calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL 

## HOW SOON WILL WE SEE A CHANGE IN SYMPTOMS?

After starting XYWAV, 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 XYWAV.

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

## WHAT ARE THE SIDE EFFECTS OF XYWAV?

XYWAV 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 of XYREM (which also contains oxybate like XYWAV) in children are nausea, bedwetting, throwing up, headache, weight loss, decreased appetite, dizziness, and sleepwalking. Side effects may increase with higher doses.

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

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.

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

- While taking XYWAV, your child should not drink alcohol or take medicines that cause sleepiness

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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



- Your child should not do anything that requires him or her to be fully alert for the first 6 hours after taking XYWAV. When your child first starts taking XYWAV, you and your child will need to be careful until you know how XYWAV affects him or her.
- Before starting XYWAV, tell your child's healthcare provider if your child is pregnant, or plans to become pregnant, or is breastfeeding. XYWAV passes into breast milk. You and your child's healthcare provider should decide if your child will take XYWAV or breastfeed.
- Keep XYWAV in a safe place, out of the reach of children
- Give XYWAV 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 XYWAV. 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 XYWAV before your child starts or changes any medications.

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

When your child first starts taking XYWAV, 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 XYWAV.

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(calcium, magnesium, potassium, and  
sodium oxybates) oral solution, 0.5 g/ml 

## What do I need to do if my child is taking XYREM and their doctor prescribes XYWAV FOR THEM?

- **Your child should never take both XYWAV and XYREM at the same time, it can lead to serious side effects**
- XYWAV contains the same medication as XYREM, which is called oxybate, but with less sodium
- Your child should take their XYWAV exactly as instructed by their doctor
- Prepare your child's XYWAV the same way you prepared XYREM
- Do not mix XYREM and XYWAV together. If you have unused XYREM, dispose of it before starting XYWAV. Refer to "HOW DO I PROPERLY DISPOSE OF XYWAV?" for further instructions
- The Certified Pharmacy will contact you to talk to you about how to make this change

## Storage and Safety Tips at Home

### HOW DO I STORE XYWAV?

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

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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



## HOW DO I PROPERLY DISPOSE OF XYWAV?

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

XYWAV patients have the option to return unused or expired drug. Please ask the Certified Pharmacy for more details.

If you misplace, lose, or damage your child's XYWAV dosing syringe, contact the Certified Pharmacy to have it replaced. Do not use a different syringe or try to guess the correct dose.

## XYWAV AND XYREM TAKEBACK PROGRAM

XYWAV or XYREM patients have an option to return any unused, leftover or expired XYWAV or XYREM product through a drug takeback program, upon request. Patients can request a shipper from the Certified Pharmacy. Once you receive the shipper, remember to mark out or remove your personal information from the bottle(s) and place the bottles in the shipper. For more information, please ask the Certified Pharmacy for more details.

## WHAT IF I HAVE CONCERNS ABOUT HAVING XYWAV IN MY HOME?

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



# XYWAV and XYREM REMS

## Important Information Your Child Must Know About Taking XYWAV

You can use these pages to help teach your young child what he or she needs to know about taking his or her XYWAV.

### WHAT SHOULD MY CHILD KNOW ABOUT TAKING XYWAV?

#### *Get Ready*

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



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



### *Stay In Bed*

- Drink your XYWAV 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 XYWAV
- It may take a while, or you may fall asleep quickly after taking XYWAV

**xywav**<sup>™</sup>    
(calcium, magnesium, potassium,  
and sodium oxybates) oral solution

# XYWAV and XYREM REMS

## *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 XYWAV and XYREM REMS at 1-866-997-3688.  
Please see the Medication Guide for more-detailed information about XYWAV.

Reference ID: 4745184

## *Always Remember!*

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



xywav™ ∞ III

(calcium, magnesium, potassium,  
and sodium oxybates) oral solution

## 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 XYWAV. This is especially true for teenagers and those going to college. This brochure can help you talk with your child about taking XYWAV.

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 XYWAV by a member of your child's XYWAV 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 XYWAV and XYREM REMS at 1-866-997-3688.**

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



## Enrolling Your Child in the XYWAV and XYREM REMS

### DOES MY CHILD HAVE TO ENROLL IN THIS PROGRAM?

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

### WHAT IS MY ROLE AS A CAREGIVER?

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

- Read this brochure and ask your child's healthcare provider any questions you have about XYWAV.
- Ensure that XYWAV is prepared and given only as prescribed
- Ensure that XYWAV 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 XYWAV

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(calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL 

## XYWAV and XYREM REMS

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 REMS toll free at 1-866-997-3688 to make sure that the new caregiver is counseled on the risks and safe use of XYWAV.

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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

**Reference ID: 4745184**



## Filling Your Child's XYWAV Prescription

### HOW IS MY CHILD'S PRESCRIPTION FILLED?

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

### WHAT ELSE DOES THE CERTIFIED PHARMACY DO?

Your child's healthcare provider sends your child's XYWAV 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 XYWAV, to tell you how to get your child started on XYWAV and to answer any questions about XYWAV. 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 XYWAV safely and provide a copy of the Medication Guide with each XYWAV shipment.

## **XYWAV** and **XYREM** REMS

The Certified Pharmacy will always ask you where and when you would like your child's XYWAV delivered and who will sign for the shipment. XYWAV will be shipped by an overnight service. You may be able to have your child's XYWAV 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 XYWAV.

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

### **HOW DO I GET XYWAV 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 XYWAV FOR MY CHILD?**

No. You can get your child's XYWAV only from the REMS central Certified Pharmacy.

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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



## Insurance Coverage

### WILL INSURANCE PAY FOR MY CHILD'S XYWAV?

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 XYWAV. In the unlikely event your child's insurance does not cover XYWAV 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 XYWAV 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 XYWAV?

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

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

*FOR MORE INFORMATION ABOUT XYWAV, CONTACT THE CERTIFIED PHARMACY:*

- **Phone:** 1-866-997-3688)
- **Fax:** 1-866-470-1744 (toll free)
- **Outside the US:** +314-475-6000, ext. 361 587
- **Website:** [www.XYWAVXYREMREMS.com](http://www.XYWAVXYREMREMS.com)

*TO REPORT ALL SIDE EFFECTS, YOU CAN CONTACT:*

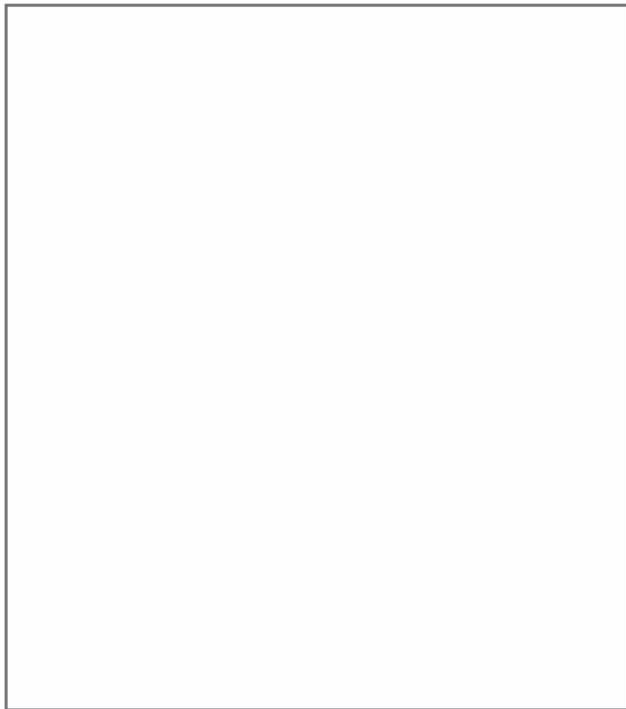
- Jazz Pharmaceuticals at 1-800-520-5568
- The FDA at 1-800-FDA-1088

*FOR EMERGENCIES:*

- Call 911

**Any questions? Please call the XYWAV and XYREM REMS at 1-866-997-3688.**

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



## KEEP THIS BOOKLET AS A HELPFUL REMINDER

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

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



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

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1