



For pediatric patients 7 years  
and up with narcolepsy

**xywav®**   
(calcium, magnesium, potassium,  
and sodium oxybates) oral solution 

**Address the high-sodium  
elephant in the room  
with XYWAV, the only  
low-sodium oxybate\***

**Explore why you should consider your child's sodium intake when  
treating cataplexy and/or excessive daytime sleepiness in narcolepsy**

\*XYWAV has 131 mg of sodium per maximum recommended 9-g nightly dose, while the equivalent dose of high-sodium oxybate XYREM® (sodium oxybate) oral solution contains ~1640 mg—a difference of ~1509 mg every single day.

#### INDICATIONS AND USAGE

XYWAV® (calcium, magnesium, potassium, and sodium oxybates) oral solution, 0.5 g/mL total salts (equivalent to 0.413 g/mL of oxybate) is a prescription medicine used to treat the following symptoms in people 7 years of age or older with narcolepsy:

- sudden onset of weak or paralyzed muscles (cataplexy)
- excessive daytime sleepiness (EDS)

#### Important Safety Information

**WARNING: Taking XYWAV with other central nervous system (CNS) depressants such as medicines used to make you or your child fall asleep, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol, or street drugs, may cause serious medical problems, including trouble breathing (respiratory depression), low blood pressure (hypotension), changes in alertness (drowsiness), fainting (syncope), and death.**

The active ingredient of XYWAV is a form of gamma-hydroxybutyrate (GHB). Abuse or misuse of illegal GHB alone or with other drugs that cause changes in alertness (or consciousness) has caused serious side effects. These effects include seizures, trouble breathing (respiratory depression), changes in alertness (drowsiness), coma, and death. Call your doctor right away if you or your child has any of these serious side effects.

Because of these risks, you have to go through the XYWAV and XYREM REMS to have your or your child's prescription for XYWAV filled.

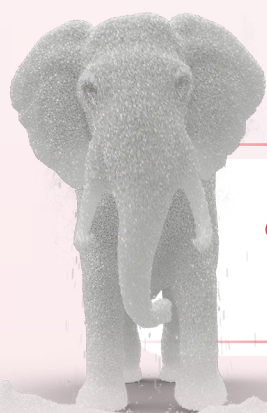
Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.

## Consider your child's sodium intake when looking at the sodium levels in oxybate treatments

A majority of Americans between the ages of 7 and 18 years are exceeding HHS/USDA daily sodium recommendations		
Age Range (years)	Recommended Maximum Daily Sodium Intake	Average Sodium Intake*
7-8	1500 mg	2655 mg
9-13	1800 mg	3241 mg
14-18	2300 mg	3382 mg

\*Based on USDA Dietary Guidelines for Americans 2020-2025.

HHS/USDA = US Department of Health and Human Services and US Department of Agriculture.



**Consider your child's long-term cardiovascular health:  
Children who consume too much sodium may be more likely  
to develop hypertension, putting them at a  
higher risk for cardiovascular disease later in life**

### Important Safety Information (continued)

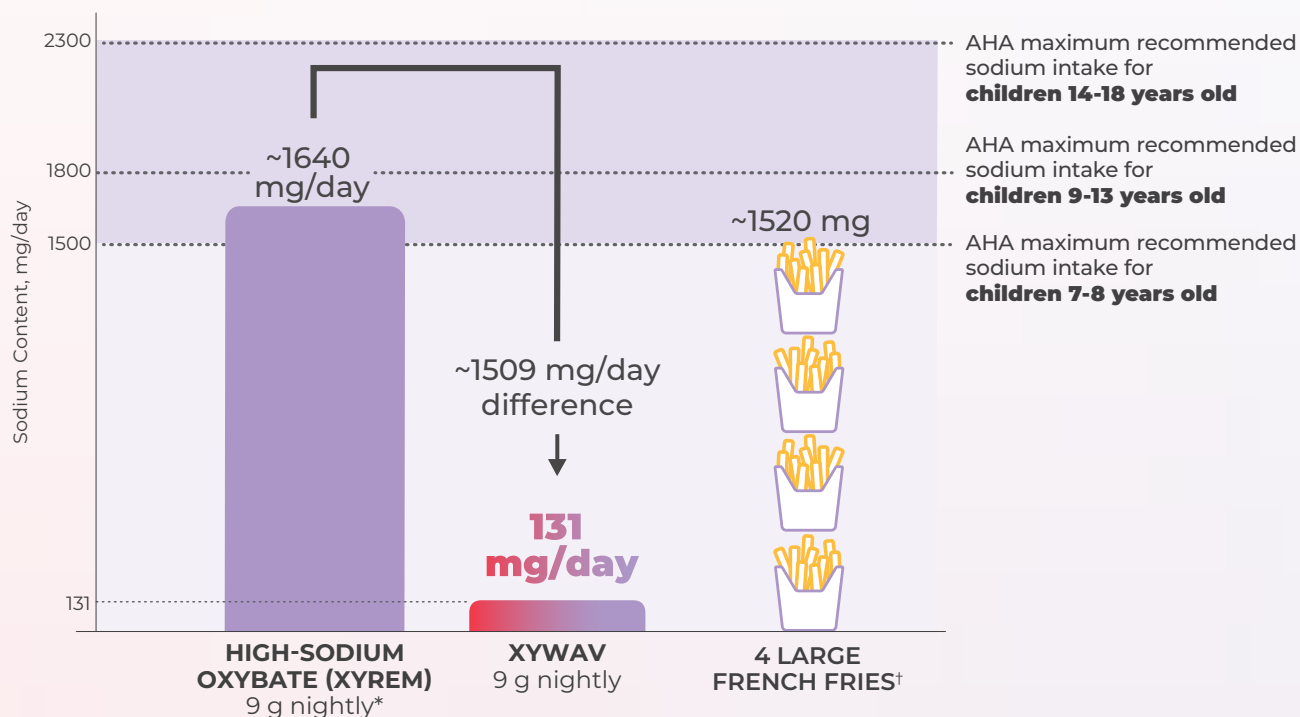
**Do not take XYWAV if you take or your child takes** other sleep medicines or sedatives (medicines that cause sleepiness), drinks alcohol, or has a rare problem called succinic semialdehyde dehydrogenase deficiency.

Keep XYWAV in a safe place to prevent abuse and misuse. Selling or giving away XYWAV may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Anyone who takes XYWAV should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery, or flying an airplane, for at least 6 hours after taking XYWAV. Those activities should not be done until you know how XYWAV affects you or your child.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**

## The difference in sodium content between a 9-g dose of XYREM, a high-sodium oxybate, and XYWAV is nearly the sodium equivalent of 4 orders of large french fries\*†



\*XYREM® (sodium oxybate) oral solution contains ~1640 mg of sodium at the maximum recommended 9-g nightly dose.

†Based on an average of 380 mg of sodium in 1 large serving of french fries according to a 2012 USDA analysis of 3 fast-food chains.

AHA = American Heart Association.

**Ready to address the high-sodium elephant in the room?  
When considering an oxybate therapy for your child,  
it may be time to ask their doctor about XYWAV**

### Important Safety Information (continued)

**XYWAV can cause serious side effects, including the following:**

- **Breathing problems, including** slower breathing, trouble breathing, and/or short periods of not breathing while sleeping (sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they use XYWAV.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**

## XYWAV, taken at night, is thought to work during sleep to help improve 2 common symptoms of narcolepsy during the day



XYWAV is the first and only low-sodium oxybate approved by the FDA for treating cataplexy and/or EDS in people ages 7 years and older with narcolepsy. The exact way XYWAV works for the treatment of cataplexy and EDS in people with narcolepsy is unknown



XYWAV can be taken in addition to daytime medications like stimulants. Be sure to discuss with your child's doctor any additional medications your child is taking or plans to take

## Ask your child's doctor about the effectiveness and safety of XYWAV



The safety and effectiveness of XYWAV for the treatment of cataplexy and/or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy have been established

XYWAV has not been studied in children. The approval of XYWAV in children is based on the XYREM® (sodium oxybate) oral solution clinical trials. XYWAV has the same active ingredient as XYREM

EDS = excessive daytime sleepiness; FDA = US Food and Drug Administration.

### Important Safety Information (continued)

**XYWAV can cause serious side effects, including the following:**

- **Mental health problems, including** confusion, seeing or hearing things that are not real (hallucinations), unusual or disturbing thoughts (abnormal thinking), feeling anxious or upset, depression, thoughts of killing yourself or trying to kill yourself, increased tiredness, feelings of guilt or worthlessness, or difficulty concentrating. Tell your doctor if you or your child have or had depression or have tried to harm yourself or themselves. **Call your doctor right away if you have or your child has symptoms of mental health problems or a change in weight or appetite.**

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**



## Only XYWAV is clinically superior to XYREM, a high-sodium oxybate, on the basis of safety

The FDA has determined that:



XYWAV is clinically superior to XYREM by means of greater safety because XYWAV contains significantly less sodium than XYREM



The differences in sodium content between XYWAV and XYREM at recommended doses will be clinically meaningful in reducing cardiovascular diseases for many people with narcolepsy who suffer from cataplexy and/or EDS\*

\*XYREM® (sodium oxybate) oral solution is a high-sodium oxybate. The decision of the FDA Office of Orphan Products Development (OOPD) is based on findings that XYWAV provides a greatly reduced chronic sodium burden compared with XYREM. There are no head-to-head data for XYWAV and XYREM.

EDS = excessive daytime sleepiness; FDA = US Food and Drug Administration.

**Taking XYWAV instead of a high-sodium oxybate will reduce  
your child's excessive sodium burden,  
which is a risk factor for cardiovascular disease**

### Important Safety Information (continued)

**XYWAV can cause serious side effects, including the following:**

- **Sleepwalking.** XYWAV can cause sleepwalking, which can cause injuries. Call your doctor if this occurs.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**

## XYWAV and XYREM REMS

Because of the risks of CNS depression, abuse, and misuse, XYWAV is available by prescription only through a certified specialty pharmacy in the XYWAV and XYREM REMS. Prescribers and patients must enroll in the program to receive XYWAV.

The XYWAV and XYREM REMS is designed to ensure that prescribers and patients are educated on and understand the risks and safe use conditions of XYWAV and agree to follow the requirements of the program.



Before your child receives XYWAV, your child's doctor or pharmacist will make sure that you understand how to take XYWAV safely and effectively. If you have any questions about XYWAV, ask your child's doctor or call the XYWAV and XYREM REMS at 1-866-997-3688

**Your child's first XYWAV shipment will include instructions to help you correctly give your child their XYWAV treatment**

CNS = central nervous system; REMS = Risk Evaluation and Mitigation Strategy.

### Important Safety Information (continued)

XYWAV can cause physical dependence and craving for the medicine when it is not taken as directed. These are not all the possible side effects of XYWAV.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**

## The safety of XYWAV in children

XYWAV hasn't been tested in clinical trials for narcolepsy in children. However, it's been shown to be safe and effective for treating cataplexy and/or excessive daytime sleepiness in children ages 7 years and older with narcolepsy. The use of XYWAV is supported by XYREM clinical trials.

The safety and effectiveness of XYWAV in children under 7 years old with narcolepsy haven't been established.

### Side Effects Observed in ≥5% of Pediatric Population in XYREM Pediatric Clinical Trial

The most common side effects of XYREM (which also contains oxybate like XYWAV) in children include:

nausea (20%)	weight decrease (13%)
bedwetting (19%)	decreased appetite (9%)
vomiting (18%)	dizziness (8%)
headache (17%)	sleepwalking (6%)

The safety profile for children taking XYWAV is expected to be similar to that of adults taking XYWAV and children taking XYREM. For more information, please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning, and Medication Guide.

### Side Effects Observed in ≥5% of Adult Patients in XYWAV Adult Clinical Trial\*

The most common side effects of XYWAV in adults include:

headache (20%)	diarrhea (6%)
nausea (13%)	excessive sweating <sup>‡</sup> (6%)
dizziness (10%)	anxiety <sup>§</sup> (5%)
decreased appetite (8%)	vomiting (5%)
parasomnia <sup>†</sup> (6%)	

XYREM® (sodium oxybate) oral solution is a high-sodium oxybate.

\*Adverse reactions related to XYWAV were reported less frequently, as an overall incidence, in patients on XYREM at study entry than in XYREM-naïve patients.

<sup>†</sup>Includes abnormal dreams, abnormal sleep-related event, rapid eye movements sleep abnormal, sleep paralysis, sleep talking, sleep terror, sleep-related eating disorder, somnambulism.

<sup>‡</sup>Includes hyperhidrosis and night sweats.

<sup>§</sup>Includes anxiety, agitation, panic attack, tension.

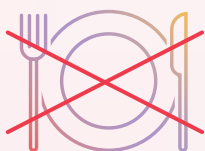
**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**

## Important things to keep in mind for your child's treatment

You and your child may need to make important changes and lifestyle choices when taking XYWAV. XYWAV is taken in 2 doses, once at bedtime and again 2.5 to 4 hours later. Beyond being able to properly prepare and give your child their 2 doses of XYWAV, their treatment may involve making some adjustments depending on the kind of daily activities you and your child are used to.

## Helpful tips for giving your child XYWAV

Both doses of XYWAV must be given while your child is in bed because XYWAV can cause sleep very quickly. Some people fall asleep within 5 minutes, and most people fall asleep within 15 minutes. Make sure that all other nightly routines, such as brushing teeth or chores, are completed before you give your child the first nightly dose of XYWAV.



### Do not give with food

Food can affect how much XYWAV is absorbed. It's important to set and follow a regular eating schedule that allows at least 2 hours to pass before giving your child their first dose each night



### Prepare during your child's nightly routine

XYWAV is a liquid that needs to be mixed with water each night, and both doses must be given while your child is in bed because XYWAV can cause people to fall asleep within 5 minutes to 15 minutes. Read the Instructions for Use in the [Medication Guide](#) for details on how to take XYWAV

## Important Safety Information (continued)

**Do not take XYWAV if you take or your child takes** other sleep medicines or sedatives (medicines that cause sleepiness), drinks alcohol, or has a rare problem called succinic semialdehyde dehydrogenase deficiency.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**



## Important things to keep in mind for your child's treatment (continued)



### Set an alarm for the second dose

After giving your child the first dose, setting an alarm can help you wake up to give your child the second dose of XYWAV 2½ to 4 hours after the first. You should never give your child both doses of XYWAV at the same time. If for any reason your child misses their second dose, it should be skipped, and XYWAV should not be taken again until the next night.

An alarm clock may be provided with the first shipment of XYWAV for convenience. You should always follow your healthcare provider's instructions for giving your child XYWAV.



### Store in a safe place

Keep XYWAV in a safe place to prevent abuse and misuse. Selling or giving away XYWAV may harm others and is against the law. Tell your doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs. Store XYWAV in the original bottle prior to mixing with water. After mixing with water, store XYWAV in the pharmacy containers with child-resistant caps provided by the pharmacy. Once mixed, the XYWAV solution should be taken within 24 hours.



### Check in with your child's healthcare provider

It's important to regularly check in with your child's doctor to let them know if your child's symptoms are improving and about any side effects.



### Avoid certain situations after treatment

XYWAV can make your child sleepy very quickly and impair their judgment for some time after treatment. Anyone who takes XYWAV should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery, or flying an airplane, for at least 6 hours after taking XYWAV. Those activities should not be done until you know how XYWAV affects your child.



### Alcohol should not be consumed at any time while taking XYWAV

The combination of XYWAV and drinking alcohol can result in serious side effects.

## Important Safety Information (continued)

Keep XYWAV in a safe place to prevent abuse and misuse. Selling or giving away XYWAV may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including BOXED Warning.**



## JazzCares® is committed to supporting your child's treatment journey

If you've started your child's XYWAV treatment, JazzCares is committed to supporting their journey with access to information, personalized resources, and programs that can help support you all throughout treatment.



### PERSONALIZED RESOURCES

Provide your family with personalized information and ongoing support during your child's treatment journey



### NURSE AND PHARMACY SUPPORT

Access to a JazzCares Nurse Case Manager and a pharmacist from the very beginning to provide your child support throughout treatment

## JazzCares may help find a financial assistance program that fits your family's needs



### THE XYWAV COUPON PROGRAM

>99% of commercially insured patients can pay as little as \$5 for XYWAV\*†‡§



### THE XYWAV QUICK START VOUCHER

Your child could receive a free 1-month supply of XYWAV with the Quick Start Voucher\*‡§



### THE XYWAV BRIDGE PROGRAM

Your child may be eligible for up to 120 days of free XYWAV while waiting for coverage approval\*‡§



### THE XYWAV PATIENT ASSISTANCE PROGRAM

Your child may be eligible to gain access to free medication when insurance coverage is an issue§



Scan to learn more about **JazzCares**

Making a difference in Patients' lives, one Patient at a time

\*For patients with commercial insurance (HMO, PPO, employer-sponsored, etc).

†Subject to a maximum annual benefit.



‡You must be a resident of the US, Puerto Rico, or other US territory.

§You must be enrolled in the XYWAV and XYREM REMS.

Jazz Pharmaceuticals reserves the right to terminate or modify this program at any time with or without notice. Please see the Terms and Conditions at [JazzCares.com/patients/XYWAV/](https://JazzCares.com/patients/XYWAV/).

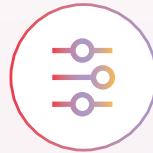
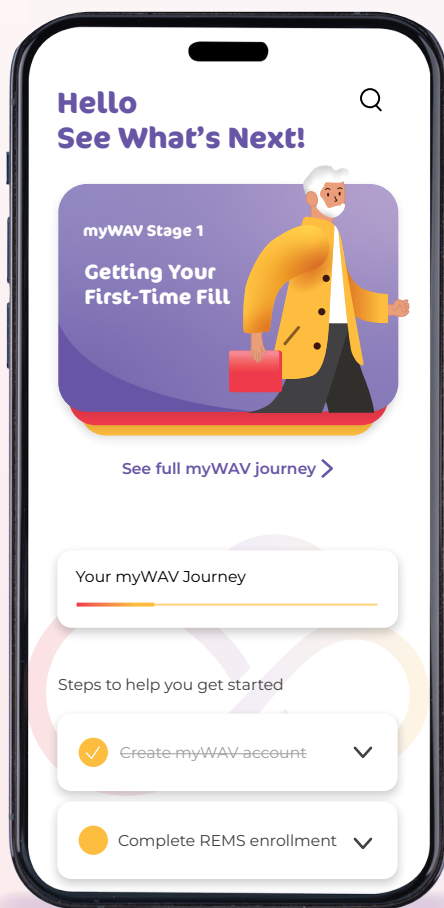
Please see additional Important Safety Information throughout and full [Prescribing Information](#), including **BOXED Warning**.



BY THE MAKER OF  
**xywav**<sup>®</sup>   
(calcium, magnesium, potassium,  
and sodium oxybates) oral solution 

## The myWAV app provides smart support at your fingertips

After your child is prescribed XYWAV, the myWAV app serves as an extra level of support to help you:



**KEEP TRACK** of  
their symptoms



**ORGANIZE** instructions  
for use and important  
treatment tips



**ACCESS** additional  
support programs



Watch a video to find out  
how the myWAV app can  
help you and your child

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including **BOXED Warning**.



**Real patients, real stories, real inspiration**

Watch  
**Grace**  
share her experience\*



**STANDUP CHAMPIONS**

\*Compensated for her time.

Please see Important Safety Information throughout and full  
[Prescribing Information](#), including BOXED Warning.