# **Talk to Your Doctor**

Your doctor is the best source of information about your condition and the treatment plan that's right for you. Use this discussion guide at your visit to help you have an informed conversation.

Caregivers of children with narcolepsy can also use this guide with their children's doctors.

## Talk about the narcolepsy symptoms of cataplexy and excessive daytime sleepiness (EDS)

Cataplexy is sudden, usually brief muscle weakness with strong emotions, such as laughter. It is estimated that about 70% of people with narcolepsy have cataplexy. EDS is the inability to stay awake and alert during the day, causing periods of an uncontrollable need for sleep or making you feel very drowsy. It is the main symptom of narcolepsy, and everyone with narcolepsy has EDS.

## If you are currently taking sodium oxybate oral solution, discuss whether transitioning to lower-sodium XYWAV may be right for you

XYWAV has the same amount of oxybate as sodium oxybate oral solution, with 92% less sodium in each nightly dose. If you are currently taking sodium oxybate oral solution and are interested in lowering your daily sodium intake, talk to your doctor about XYWAV.

## Talking to your doctor about XYWAV

**Review the following list of questions and discuss them with your doctor to help you have an informed conversation.** Some important information about XYWAV is provided here, but your doctor is your best source of information and will be able to give you more in-depth and personalized answers.

## Approved Use

XYWAV<sup>®</sup> (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 <u>Prescribing Information</u>, including BOXED Warning, and <u>Medication Guide</u>.



# xywav®

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

## Talking to your doctor about XYWAV (continued)



#### What is XYWAV?

It's the first and only lower-sodium oxybate. XYWAV 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)

#### Is XYWAV effective for the symptoms I have?

The efficacy and safety of XYWAV for the treatment of cataplexy and EDS in adult patients with narcolepsy was demonstrated in a clinical trial.

#### How do I take XYWAV?

XYWAV is a liquid that you take at night in 2 separate doses, while in bed, 2½ to 4 hours apart, or as instructed by your doctor. Never take 2 XYWAV doses at the same time. Before you take your first nightly dose of XYWAV, you need to prepare both doses for the night. You should remain in bed after taking the first and second doses of XYWAV. Be sure to follow your doctor's instructions. See the <u>Medication Guide</u> for more details about taking XYWAV.

#### Why should I consider XYWAV?

XYWAV contains the same amount of oxybate as XYREM<sup>®</sup> (sodium oxybate) oral solution. Oxybate is the part of both medications that is responsible for their effects. However, XYWAV contains 92% less sodium than sodium oxybate. If you are currently taking XYREM and are interested in lowering your daily sodium intake, talk to your doctor about XYWAV.

#### How much sodium is in XYREM and in XYWAV?

The maximum nightly recommended dose of sodium oxybate (9 g per night) has 1640 mg of sodium. The same dose of XYWAV contains 131 mg.

#### Can I take XYWAV with other medications?

Tell your doctor about all the medicines you take or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take or your child takes other medicines to help you or your child sleep (sedatives). Know the medicines you take or your child takes. Keep a list of them to show your doctor and pharmacist when you get or your child gets a new medicine.

#### How will I know if XYWAV is working for me?

Consult with your doctor to see if XYWAV is working for you. Together you can determine the best way to track your progress over time. For example, you can compare your Epworth Sleepiness Scale (ESS) scores from before and during treatment, you can evaluate any reduction in cataplexy episodes, or you can watch for personal benchmarks, like not falling asleep during a meeting or a movie. The ESS is a questionnaire adults can take that helps measure their levels of daytime sleepiness.

#### What are the most common side effects of XYWAV?

The most common side effects of XYWAV in adults include headache, nausea, dizziness, decreased appetite, parasomnia (a sleep disorder that can include abnormal dreams, abnormal rapid eye movement (REM) sleep, sleep paralysis, sleep talking, sleep terror, sleep-related eating disorder, sleepwalking, and other abnormal sleep-related events), diarrhea, excessive sweating (hyperhidrosis), anxiety, and vomiting. The most common side effects of XYREM (which also contains oxybate like XYWAV) in children include nausea, bedwetting, vomiting, headache, weight decrease, decreased appetite, dizziness, and sleepwalking. These are not all the possible side effects of XYWAV. For more information, ask your doctor or pharmacist.

## Your XYWAV dose may be individualized by your doctor.

#### 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 <u>Prescribing Information</u>, including BOXED Warning, and <u>Medication Guide</u>.

## Talking to your doctor about XYWAV (continued)



## What are some of the medical or lifestyle restrictions I should know about when taking XYWAV?

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. 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.

#### What else do I need to know about XYWAV?

Asking this question will give your doctor the opportunity to share any additional information or advice he or she thinks is important based on your medical history. Also be sure to read the <u>Medication Guide</u>.

#### What support is available for people taking XYWAV?

JazzCares<sup>®</sup> for XYWAV offers a wide range of information, resources, and support. JazzCares Nurse Case Managers at the Certified Pharmacy are another resource for XYWAV information. Also, Jazz Pharmaceuticals is committed to helping make sure that those who may benefit from XYWAV affordably get it. Several different options are available for qualified patients. Ask your doctor and visit <u>XYWAV.com</u> to help find the support you need.

#### 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.

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.

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

The most common side effects of XYWAV in adults include headache, nausea, dizziness, decreased appetite, parasomnia (a sleep disorder that can include abnormal dreams, abnormal rapid eye movement (REM) sleep, sleep paralysis, sleep talking, sleep terror, sleep-related eating disorder, sleepwalking, and other abnormal sleep-related events), diarrhea, excessive sweating (hyperhidrosis), anxiety, and vomiting.

The most common side effects of XYREM (which also contains oxybate like XYWAV) in children include nausea, bedwetting, vomiting, headache, weight decrease, decreased appetite, dizziness, and sleepwalking.

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 <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.

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