

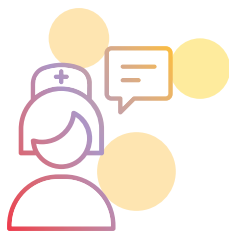
For HCPs who prescribe XYWAV for cataplexy and/or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy, or for adults with idiopathic hypersomnia

Your JazzCares[®] Nurse Educator provides live, personalized support for your patients on XYWAV

The JazzCares Nurse Educator supports you, your patients, and your team

The JazzCares Nurse Educator will:

- Provide tailored education and support to your patients during initiation and throughout XYWAV treatment
- Engage in one-on-one training to empower patients around how to take XYWAV compliantly as prescribed
- Assist patients in identifying and overcoming potential compliance obstacles
- Help your patients stay on track and take control of their disease management
- Connect patients to the resources that can help them stay on track with XYWAV: reimbursement specialists, 24/7 pharmacy support, and other tools that can address their individual needs
- Communicate insights and updates to you from patient engagements
- Provide you with in-depth information about JazzCares



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 indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy, and for the treatment of idiopathic hypersomnia (IH) in adults.

Important Safety Information

WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION and ABUSE AND MISUSE.

• **Central Nervous System Depression**

XYWAV is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with XYWAV at recommended doses. Many patients who received XYWAV during clinical trials in narcolepsy and idiopathic hypersomnia were receiving CNS stimulants.

• **Abuse and Misuse**

The active moiety of XYWAV is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.

Because of the risks of CNS depression and abuse and misuse, XYWAV is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS.

Staying connected in the XYWAV experience

Your patient, your office, and your JazzCares Nurse Educator

Whether your patients are new to oxybate treatment or are patients with cataplexy or excessive daytime sleepiness in narcolepsy who are transitioning to XYWAV® from XYREM® (sodium oxybate) oral solution, they will likely have questions. The start of treatment is an especially crucial time in a patient's journey. The JazzCares Nurse Educator provides important support during the first several months, meeting with each patient, determining that patient's specific needs, and providing education to address those individual needs.

The JazzCares Nurse Educator provides educational in-services for you and your staff and follows up with you about their engagements with your patient. That helps ensure you, your staff, and your patient are all on the same page in terms of your patient's XYWAV experience.

Important Safety Information (cont'd)

Contraindications


XYWAV is contraindicated in combination with sedative hypnotics or alcohol and in patients with succinic semialdehyde dehydrogenase deficiency.



The JazzCares® Nurse Educator will contact your patients

Encourage your patients to meet with their JazzCares Nurse Educator to support them throughout their treatment

The JazzCares Nurse Educator is not involved in treating the patient or offering healthcare advice.

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

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

JazzCares® offers your patient education and nursing support from the moment XYWAV is prescribed

The JazzCares Nurse Educator and JazzCares Nurse Case Manager work together to provide support for your patients throughout their treatment experience

Once your patient has a XYWAV prescription:

- A dedicated **JazzCares Nurse Case Manager** will welcome your patient to the program and check in with them periodically to help them address any practical challenges
- A **JazzCares Nurse Educator** will then contact your patient to set up an in-person or virtual visit
- At your patient's initial visit, their **JazzCares Nurse Educator** will help ensure that they have the information and tools they need during initiation and throughout XYWAV treatment
- The **JazzCares Nurse Educator** will help you stay connected with your patient by discussing their educational visits with you

Make sure your patients are ready to take advantage of this important nursing support program



If a patient does not have a **signed JazzCares Patient Authorization** on file, or if they are not sure, they should visit [JazzCaresConsent.com](https://www.jazzcares.com/consent) or call the JazzCares nursing support team at **1-866-997-3688**.

Important Safety Information (cont'd)

Warnings and Precautions

- **CNS Depression:** Use caution when considering the concurrent use with other CNS depressants. If concurrent use is required, consider dose reduction or discontinuation of one or more CNS depressants (including XYWAV). Consider interrupting XYWAV treatment if short-term opioid use is required. After first initiating treatment and until certain that XYWAV does not affect them adversely, caution patients against hazardous activities requiring complete mental alertness or motor coordination such as operating hazardous machinery, including automobiles or airplanes. Also caution patients against these hazardous activities for at least 6 hours after taking XYWAV. Patients should be queried about CNS depression-related events upon initiation of XYWAV therapy and periodically thereafter.
- **Abuse and Misuse:** XYWAV is a Schedule III controlled substance. The rapid onset of sedation, coupled with the amnesic features of GHB particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (eg, assault victim).



The JazzCares® Nurse Educator:

Live, personalized XYWAV support for your patients,
and ongoing engagement with helpful education for you and your staff

We're here for you and your patients. You and your staff are encouraged to engage with your JazzCares Nurse Educator and reach out to them anytime.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Respiratory Depression and Sleep-Disordered Breathing:** XYWAV may impair respiratory drive, especially in patients with compromised respiratory function. In overdoses of oxybate and with illicit use of GHB, life-threatening respiratory depression has been reported. Increased apnea and reduced oxygenation may occur with XYWAV administration in adult and pediatric patients. A significant increase in the number of central apneas and clinically significant oxygen desaturation may occur in patients with obstructive sleep apnea treated with XYWAV. Prescribers should be aware that sleep-related breathing disorders tend to be more prevalent in obese patients, in men, in postmenopausal women not on hormone replacement therapy, and among patients with narcolepsy.
- **Depression and Suicidality:** In clinical trials in adult patients with narcolepsy and IH, depression and depressed mood were reported in patients treated with XYWAV. In most cases, no change in XYWAV treatment was required. Two suicides and two attempted suicides occurred in adult clinical trials with oxybate (same active moiety as XYWAV). One patient experienced suicidal ideation and two patients reported depression in a pediatric clinical trial with oxybate. **Monitor patients for the emergence of increased depressive symptoms and/or suicidality while taking XYWAV, which require careful and immediate evaluation.**
- **Other Behavioral or Psychiatric Adverse Reactions:** Monitor patients for impaired motor/cognitive function or the emergence of or increase in anxiety and/or confusion. The emergence or increase in the occurrence of behavioral or psychiatric events in patients taking XYWAV should be carefully monitored.
- **Parasomnias:** In clinical trials, parasomnias including sleepwalking were reported in adult patients treated with XYWAV. Parasomnias, including sleepwalking, also have been reported in a pediatric clinical trial with sodium oxybate (same active moiety as XYWAV) and in postmarketing experience with sodium oxybate. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered.

Most Common Adverse Reactions

The most common adverse reactions (occurring in $\geq 5\%$ of XYWAV-treated patients in adult clinical trials in either narcolepsy or IH) were nausea, headache, dizziness, anxiety, insomnia, decreased appetite, hyperhidrosis, vomiting, diarrhea, dry mouth, parasomnia, somnolence, fatigue, and tremor.

In the pediatric clinical trial with XYREM (same active moiety as XYWAV) in patients 7 years of age and older with narcolepsy, the most common adverse reactions ($\geq 5\%$) were nausea (20%), enuresis (19%), vomiting (18%), headache (17%), weight decreased (13%), decreased appetite (9%), dizziness (8%), and sleepwalking (6%). The safety profile in pediatric patients with XYWAV is expected to be similar to that of adult patients treated with XYWAV and to that of pediatric patients treated with XYREM.



Jazz Pharmaceuticals

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