An Established Partner

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

Infrastructure Built to Serve

The infrastructure behind a product matters: the dedicated support available, how continuity is protected, and how the experience is for plans, prescribers, and patients.

XYWAV is supported by a dedicated patient support program through JazzCares. These elements are designed to provide a coordinated support model.

INDICATIONS AND USAGE

XYWAV 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.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED Warning.

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The XYWAV and XYREM REMS

An FDA-Required Program—No Change for Your Members

The XYWAV and XYREM REMS (Risk Evaluation and Mitigation Strategy) is a safety program that manages the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of XYWAV and XYREM. The XYWAV and XYREM REMS is required by the Food and Drug Administration (FDA) to ensure the potential benefits of XYWAV and XYREM outweigh the risks.



All HCPs who prescribe XYWAV must be certified in the XYWAV and XYREM REMS.



XYWAV is dispensed only by the REMS Certified Pharmacy and shipped directly to REMS-enrolled patients.



Patients prescribed XYWAV must be enrolled in the XYWAV and XYREM REMS with documentation of safe use.

Further information on the XYWAV and XYREM REMS is available at www.XYWAVXYREMREMS.com or 1-866-997-3688.

Important Safety Information (cont'd)

Contraindications

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

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Centralized Distribution

One Certified Pharmacy. A Consistent Process.



XYWAV is distributed exclusively through a single certified pharmacy, Express Scripts Specialty Distribution Services (ESSDS), Jazz's certified specialty pharmacy partner of more than 20 years.

- **A structured, repeatable enrollment-to-refill process:** the prescriber submits the prescription, insurance and cost-savings eligibility are verified, and a Certified Pharmacy pharmacist completes safety counseling before the first shipment goes out.
- **Flexible, tracked delivery:** patients can choose delivery to home, workplace, or a local carrier hub, with overnight shipping and a signature-on-delivery safeguard.
- **Built-in continuity safeguards:** refill reminders are managed by the pharmacy, and any product damaged in transit due to a defect is promptly replaced at no cost to the patient.

For plans, this means a Certified Pharmacy working to deliver a consistent distribution experience, from enrollment and dispensing to delivery and refills.

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.

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Continuity of Care with JazzCares

Continued Investment:

Jazz continues to invest in the XYWAV treatment experience, offering patients access to JazzCares support resources designed to guide them from treatment start through ongoing management:

- **myWAV app —** An optional 24/7 digital tool that helps patients get started on important steps, organizes their schedule, insurance details, and treatment tips, and tracks shipments and treatment calls in one place. Patients can link their myWAV account to the Certified Pharmacy to unlock additional features.
- **XYWAV Mentor Program —** Connects patients 1-on-1 with a peer who is also taking XYWAV for support, practical tips, and shared experience. The Mentor Program is available to patients after they've been prescribed XYWAV and completed the JazzCares Patient Consent Form.
- **Treatment initiation and titration support —** JazzCares Nurses may work with each patient to provide personalized education on administration, dosing and titration, and what to expect when starting XYWAV.

Supporting Your Members on XYWAV

Patients prescribed XYWAV have access to a larger team of nurses, educators, and pharmacists. JazzCares offers non-medical support—managing coverage logistics, providing prior authorization and appeals support, financial assistance for eligible patients, Certified Pharmacy coordination, and patient education.

For plans, this means stabilized patients have a dedicated support structure working to achieve treatment continuity.

Important Safety Information (cont'd)

Warnings and Precautions

- CNS Depression (cont'd): 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 amnestic features of GHB particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (eg, assault victim).

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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 ≥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 (≥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.

Please see full Prescribing Information, including BOXED Warning.

Jazz Pharmaceuticals

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