

For people living
with **idiopathic
hypersomnia (IH)**

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

**NOW,
IH MEANS
I'M HERE**



**Discover XYWAV, the first and only
FDA-approved treatment for adults
living with IH. It's taken at night to help
treat IH symptoms during the day.**

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 idiopathic hypersomnia (IH) in adults.

Important Safety Information

WARNING: Taking XYWAV with other central nervous system (CNS) depressants such as medicines used to make you 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 have any of these serious side effects.

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

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

Why consider XYWAV?

- No other treatment has been studied and approved by the FDA for the treatment of IH
- XYWAV is a prescription medicine taken at night to help treat the daytime symptoms of IH
- With XYWAV, dosing can be individualized for you

XYWAV has been studied across several aspects of IH that may affect you:



Excessive daytime sleepiness (EDS)



Severity of IH symptoms, including:

- Long sleep time
- Cognitive impairment
- Sleep inertia

No other treatment has been studied and approved by the FDA for the treatment of IH in adults. Ask your doctor if XYWAV may be right for you.

- **The efficacy and safety of XYWAV was studied in 115 people aged 19-75 with IH**
- **All people in the clinical trial started treatment with XYWAV.** XYWAV was adjusted to a stable dose (the dose that worked best for each person). Then they were randomly assigned to:
 - Continue treatment with XYWAV
 - OR
 - Stop taking XYWAV for 2 weeks. These people were switched to a placebo, a treatment that is inactive. This was to see if there was a difference in their symptoms

It's important to know...

This trial was *double-blinded*. That means neither the investigators who ran the trial nor the people in the trial knew who got XYWAV or who got placebo during the period of the trial that measured how well XYWAV worked.

Explore more about how XYWAV was studied in IH at [XYWAV.com/idiopathic-hypersomnia/what-is-xywav](https://xywav.com/idiopathic-hypersomnia/what-is-xywav)

Important Safety Information (continued)

Do not take XYWAV if you take other sleep medicines or sedatives (medicines that cause sleepiness), drink alcohol, or have 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.

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

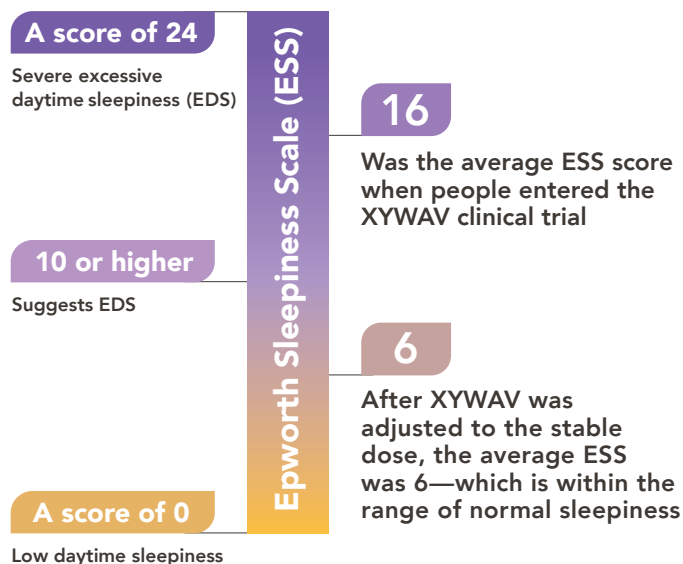
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What changes in excessive daytime sleepiness (EDS) were seen in people during the XYWAV clinical trial?

- EDS is measured by a screener called the **Epworth Sleepiness Scale (ESS)**
- The ESS measures EDS on a scale from **0 to 24**

During the first part of the trial:



Stable dose = the dose of XYWAV that worked best for each person.

Note: The information collected during the first part of the trial was not meant to measure how well XYWAV worked.

Important Safety Information (continued)

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.

During the period of the trial that measured how well XYWAV worked:

The average ESS score of people who **continued** XYWAV was **7 POINTS LESS** than for people who **stopped** taking XYWAV—for **significantly less daytime sleepiness**

In people who **stopped** taking XYWAV:
Daytime sleepiness increased by an average of 7 points

Average ESS score of

13

In people who **continued** taking XYWAV:
Daytime sleepiness increased by an average of just 1 point

Average ESS score of

7

Results shown here used average scores, which were then rounded up or down. That's why the difference between scores may not always appear to add up.

Source: Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep*. 1991;14(6):540-545.

The Epworth Sleepiness Scale is intended to measure for EDS, a symptom of IH. It is not intended to make an IH diagnosis.

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Understand the common side effects and safety of XYWAV

The most common side effects in adults treated with XYWAV (occurring in $\geq 5\%$ of patients) were:

- Nausea
- Headache
- Anxiety
- Dizziness
- Insomnia
- Excessive sweating (hyperhidrosis)
- Decreased appetite
- Vomiting
- Dry mouth
- Diarrhea
- Fatigue
- Sleepiness (somnolence)
- Tremor
- Parasomnia

Most common side effects were studied from trial entry through the end of the stable-dose period.

For patients who remained on treatment with XYWAV, these side effects tended to occur early and diminish over time.

Learn more about the safety and tolerability of XYWAV at [XYWAV.com/idiopathic-hypersomnia/side-effects](https://xywav.com/idiopathic-hypersomnia/side-effects)

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.
- **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 have or had depression or have tried to harm yourself. **Call your doctor right away if you have 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.

With XYWAV, dosing can be individualized to your needs

Here's what you should know:

- XYWAV is a liquid taken at bedtime
- It is most often taken twice nightly (at bedtime and 2 ½ to 4 hours later). It can also be taken once nightly (just at bedtime)
- Your doctor will help you decide which dosing regimen is best for you

Are people with idiopathic hypersomnia really able to follow a twice-nightly dosing regimen?

Yes! During the period of the trial that measured how well XYWAV worked, almost 8 out of 10 people (77%) were following a twice-nightly dosing regimen. Your doctor can help adjust your twice-nightly or once-nightly dosing to a regimen that is right for you.

Please refer to the Medication Guide for detailed information about preparing and taking XYWAV.

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JazzCares® for XYWAV offers you access to information, resources, and programs that can help support you while you are taking XYWAV.

Resources include:

- myWAV, the 24/7 digital tool for personalized support and motivation
- Savings and financial support, including the XYWAV Coupon Program (eligibility requirements and terms and conditions apply)
- A JazzCares Nurse Case Manager to support you in your treatment journey
- Prescription refill reminders
- Information and support resources for caregivers and loved ones



Want to connect with someone with idiopathic hypersomnia (IH) who is taking XYWAV? Ask about the XYWAV Mentor Program today!

For more details, call the XYWAV Mentor Program at **1-866-539-3946** or sign up at [XYWAV.com/stay-connected](https://www.xywav.com/stay-connected)

Important Safety Information (continued)

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

Keep track of your IH symptoms to help your doctor treat your condition.

For most people, IH is a lifelong condition. But how severe or bothersome your symptoms are may change over time.

Keep your doctor informed of your symptoms—as well as your treatment goals. Together, you can decide on the treatment plan that may be best for you.

Keeping your doctor informed can help you both decide if XYWAV may be right for you.

The XYWAV and XYREM REMS

Because of the risks of central nervous system depression, abuse, and misuse, XYWAV is available only by prescription and filled through the Certified Pharmacy in the XYWAV and XYREM REMS.

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, or call 1-800-FDA-1088.

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Ask your doctor about XYWAV today!

Not sure where to start? Find some ideas to have a more informed conversation with your doctor. Download a discussion guide at XYWAV.com/idiopathic-hypersomnia/patient-resources

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Jazz Pharmaceuticals

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