

# Talking to your doctor about XYWAV for IH

Your idiopathic hypersomnia (IH) is unique, and your needs are, too. Talking about your symptoms with your doctor can be tough. This guide can help. Print and fill it out. Then discuss it with your doctor to see if XYWAV may be right for you.

## Keeping track of your symptoms can help you and your doctor come up with a treatment plan together.

Have you experienced any of these symptoms?  
(Check all that apply and circle the ones that bother you most.)

- Excessive daytime sleepiness, or EDS**—feeling very sleepy during the day
- Non-restorative sleep**—not feeling rested when you wake up
- Sleep inertia**—also known as “sleep drunkenness”; feeling severely groggy or confused when you try to wake up
- Cognitive impairment**—often described as “brain fog” (inability to think clearly or focus throughout the day)
- Ability to sleep for many hours** of the day (for some people, 11 hours or more)
- Long, unrefreshing naps**

People living with IH still experience these symptoms despite sleeping a normal (or more than normal) amount each night.

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**.

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

# How severe are your idiopathic hypersomnia (IH) symptoms?

There are 2 screeners that can help you measure your IH symptoms:

- **The Epworth Sleepiness Scale (ESS):** It measures your level of excessive daytime sleepiness (EDS). The ESS is a common test used by doctors to help assess a person’s level of tiredness
- **The Idiopathic Hypersomnia Severity Scale (IHSS):** It measures the frequency and severity of your IH symptoms. The IHSS is a unique screener—it is the only one validated specifically to measure IH symptoms

You can download a free ESS and IHSS at:

[XYWAV.com/idiopathic-hypersomnia/patient-resources](http://XYWAV.com/idiopathic-hypersomnia/patient-resources)

Use these tools to help measure your symptom severity. Then share the results with your doctor.

Today's Date	ESS Score	IHSS Score

Write down any questions about your scores or additional notes here:

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### 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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## Why consider XYWAV?

- No other treatment has been studied and approved by the FDA for the treatment of IH in adults
- 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



### Severity of IH symptoms, including:

- Long sleep time
- Cognitive impairment
- Sleep inertia

## What are the possible side effects of XYWAV?

In the clinical trial, the most common side effects in adults treated with XYWAV (occurring in  $\geq 5\%$  of patients) were:

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

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

In patients who remained on treatment, side effects tended to occur early and diminish over time.

### 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.

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## How do I take XYWAV?

- 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.

Write down any additional questions about XYWAV dosing here:

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### 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.

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## Other questions about XYWAV you may want to ask your doctor at your next visit might include:

- What were the clinical trial results with XYWAV in adults living with idiopathic hypersomnia (IH)?
- When could I start to see a change in symptoms?
- What support is available if XYWAV is right for me?

Write down any additional questions you have for your doctor about XYWAV or IH here:

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**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.**

### 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.

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.

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