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2. Sodium oxybate

Sodium oxybate

Pronunciation: soe-dee-um ox-i-bate
Generic name: sodium oxybate
Brand names: Xyrem, Lumryz, Xywav

Dosage form: oral solution, oral extended-release suspension **Drug class:** Miscellaneous anxiolytics, sedatives and hypnotics

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Uses Side effects Before taking Dosage Overdose What to avoid FAQ

What is sodium oxybate?

Sodium oxybate (brand name Xyrem or Lumryz) may be used to treat narcolepsy symptoms such as **suddenly weak or paralyzed muscles** (cataplexy) or **excessive daytime sleepiness (EDS)**. Sodium oxybate is available in 2 brands: Xyrem (an oral solution) and Lumryz (an extended-release oral suspension); both FDA-approved for adults and children aged 7 and older.

• See What is the Difference Between Lumryz vs Xyrem? for more information.

Sodium oxybate is also available in combination with other oxybate salts as Xywav, which is a low-sodium form of Xyrem (see What is the difference between Xywav and Xyrem?). Xywav is used to treat narcolepsy or idiopathic hypersomnia.

Sodium oxybate may also be called oxybate sodium.

Sodium oxybate's mechanism of action (moa) for cataplexy involves slowing down overactive processes in the brain. The moa of sodium oxybate in narcolepsy involves increasing the amount of time the body spends in a deep sleep at night, reducing how much sleepiness occurs during the day. Sodium oxybate belongs to the drug class called central nervous system (CNS) depressants.

Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB), a substance that goes under various street names such as G, Easy Lay, Georgia Home Boy, Goop, and Grievous Bodily Harm, and is also known as the Date Rape drug. Sodium oxybate is only available through prescribers who are part of a restricted distribution program called Xywav and Xyrem REMS. Extended-release oxybate sodium is available through the Lumryz REMS Program. Once you have been properly informed about the medications, your medication will be mailed to you from a central or certified pharmacy.

Sodium oxybate gained FDA approval on July 17, 2002, under the brand name Xyrem. Sodium oxybate is only available as the brands Xyrem and Lumryz, or when in combination with other oxybate salts, Xywav. There is no generic sodium oxybate.

What is sodium oxybate used for?

Sodium oxybate is used for narcolepsy.

Sodium oxybate (**Xyrem** brand) is used to treat narcolepsy symptoms such as cataplexy or EDS in patients 7 years of age and older.

Sodium oxybate (**Lumryz** brand) is used to treat narcolepsy symptoms such as cataplexy or EDS in patients 7 years of age and older.

Sodium oxybate in combination with calcium oxybate, magesium oxybate, and potassium oxybate (**Xywav** brand) as a low sodium oxybate formulation, is used to treat narcolepsy symptoms such as cataplexy or EDS in patients 7 years of age and older. Xywav is also used to treat idiopathic hypersomnia (IH) in adults.

Sodium oxybate side effects

The most common side effects of sodium oxybate in adults include:

- nausea
- dizziness
- sleepiness
- bedwetting
- headache
- vomiting
- tremor.

The most common side effects of sodium oxybate in children include:

- nausea
- · weight loss
- · bedwetting
- · decreased appetite
- vomiting
- dizziness
- headache
- sleepwalking.

Side effects may increase when taking higher doses of sodium oxybate.

Serious side effects and warnings

Sodium oxybate carries a Boxed Warning for central nervous system (CNS) depression and abuse and misuse.

Sodium oxybate can cause **CNS depression**, which could lead to death. It can affect your breathing and make you breathe too slowly or shallowly, leading to CNS depression and the build-up of carbon dioxide in your blood. Sodium oxybate may also cause obtundation, which is a lethargic-like state where your responses are slowed, you have less

interest in your environment, and you sleep more than normal. The risk of CNS depression is higher if you or your child take sodium oxybate with other 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. Seek emergency medical attention if you or your child develop:

- trouble breathing (respiratory depression)
- low blood pressure (hypotension)
- · changes in alertness (drowsiness)
- fainting (syncope).

Sodium oxybate is a **federally controlled substance (Cill [Schedule III])**. The active ingredient of sodium oxybate is a form of gamma-hydroxybutyrate (GHB) that is also a federally controlled substance (CI). Abuse of illegal GHB, either alone or with other CNS depressants may cause serious medical problems, including:

- seizures
- trouble breathing (respiratory depression)
- changes in alertness (drowsiness)
- coma
- · death.

Call your doctor right away if you or your child has any of these serious side effects.

Anyone who takes sodium oxybate 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 sodium oxybate. Those activities should not be done until you know how sodium oxybate affects you or your child.

Keep sodium oxybate in a safe place to **prevent abuse and misuse**. Selling or giving away sodium oxybate 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.

Because of the risk of CNS depression, abuse, and misuse, sodium oxybate is available only by prescription and filled through a central or certified pharmacy in the **Xywav and Xyrem REMS Program** or **Lumryz REMS Program**.

Sodium oxybate may cause other **breathing problems**, including slower breathing, trouble breathing, 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 sodium oxybate.

Mental health problems, reported by people taking sodium oxybate, include:

- 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
- · difficulty concentrating.

Call your doctor right away if you have symptoms of mental health problems or a change in weight or appetite.

Sodium oxybate can cause people to **Sleepwalk**. Sleepwalking can cause injuries. Call your doctor if you start sleepwalking.

It is not known if the brand of sodium oxybate called Xyrem is safe and effective in children less than 7 years of age. The brand of sodium oxybate called Lumryz is not approved for anyone under the age of 18 years.

Sodium oxybate side effects (more detail)

Related/similar drugs

Xyrem

Xyrem (sodium oxybate) is an oral prescription solution that may be used to treat cataplexy or ...

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Xywav

Xywav is used for the treatment of cataplexy and excessive daytime sleepiness (EDS) in patients ...

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•••

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Provigil

Provigil promotes wakefulness and is used to treat excessive daytime sleepiness caused by ...

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Lumryz

Lumryz (sodium oxybate) is used for the treatment of patients with narcolepsy. Includes Lumryz side ...

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Calcium oxybate/magnesium oxybate/potassium oxybate/sodium oxybate

Calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate are used to treat ...

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17 Reviews

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Armodafinil

Armodafinil may be used to improve wakefulness in adults who are very sleepy due to narcolepsy ...

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Before taking

Do not take sodium oxybate if you or your child:

- takes other sleep medicines or sedatives (medicines that cause sleepiness)
- · drinks alcohol
- has a rare problem called succinic semialdehyde dehydrogenase deficiency.

Before taking sodium oxybate, tell your doctor about all medical conditions, including if you or your child:

- have a history of drug abuse.
- have short periods of not breathing while sleeping (sleep apnea)
- has trouble breathing or has lung problems. You or your child may have a higher chance of having serious breathing problems when taking sodium oxybate.
- have or had depression or have tried to harm yourself or themselves. You or your child should be watched carefully
 for new symptoms of depression.
- has or has had behavioral or other psychiatric problems such as anxiety, seeing or hearing things that are not real (hallucinations), feeling more suspicious (paranoia), acting aggressive, being out of touch with reality (psychosis), or agitation
- have liver problems

- are on a salt-restricted diet. Sodium oxybate contains a lot of sodium (salt) and may not be right for you or your child
- · have high blood pressure
- · have heart failure
- · have kidney problems
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Pregnancy

It is not known if sodium oxybate can harm your unborn baby.

Breastfeeding

Sodium oxybate passes into breast milk. Talk to your healthcare provider about the best way to feed your baby.

Sodium oxybate pregnancy and breastfeeding warnings (more detail)

How should I take sodium oxybate?

Always read the Instructions for use in your **Xyrem Medication Guide** or **Lumryz Medication Guide** before you take sodium oxybate. Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with sodium oxybate and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions.

Take sodium oxybate exactly as your doctor tells you to take it.

Instructions for use, Xyrem oral solution

Take Xyrem exactly as your healthcare provider tells you to take it. Xyrem can cause physical dependence and craving for the medicine when it is not taken as directed. Never change the dose without talking to your doctor.

- Xyrem is taken at night in 2 doses. The first dose is at bedtime, the second dose is 2½ to 4 hours later. Wait at least 2 hours after eating before taking Xyrem and it should be the last thing you do before going to bed.
- You will need to split your prescribed Xyrem dose into 2 separate pharmacy containers for mixing. All shipped bottles
 of Xyrem contain concentrated medicine and require water for mixing.
- You will need to mix Xyrem with water before you take or give your child the dose.
- Safely store the prepared Xyrem doses and take them within 24 hours after mixing. If the prepared dose was not taken within this time, throw the mixture away.
- Both Xyrem doses should be taken while in bed.
- The pharmacy containers may be rinsed out with water and emptied into the sink drain.

Xyrem dosage for adults: Take the first Xyrem dose at bedtime while you are in bed and lie down immediately.

 Take the second Xyrem dose 2½ to 4 hours after the first Xyrem dose. You may want to set an alarm clock to make sure you wake up to take the second Xyrem dose. You should remain in bed after taking the first and second doses of Xyrem.

- As soon as you take it, lie down in bed because Xyrem may cause you to fall asleep quickly (some people fall asleep within 5 minutes and most fall asleep within 15 minutes). The time it takes you to fall asleep may be different from night to night.
- Avoid getting out of bed after taking Xyrem. Falling asleep quickly, including while standing or while getting up from the bed, has led to falls with injuries that have required some people to be hospitalized.

Xyrem dosage for children: Give the first Xyrem dose to your child at bedtime or after an initial period of sleep, while your child is in bed and have them lie down immediately.

• Give the second Xyrem dose 2½ to 4 hours after the first Xyrem dose. You may want to set an alarm clock to make sure you wake your child up to give the second Xyrem dose. Your child should remain in bed after taking the first and second doses of Xyrem.

Instructions for use, Lumryz extended-release oral suspension

Take Lumryz exactly as your healthcare provider tells you to take it. Lumryz can cause physical dependence and craving for the medicine when it is not taken as directed. Never change the dose without talking to your doctor.

• Lumryz extended-release oral suspension contains two types of granules that work in 2 ways. Immediate-release granules start working as you fall asleep and controlled-release granules start working later. This means you do not have to wake yourself up for a second dose.

Lumryz is taken by mouth 1 time at bedtime. Wait at least 2 hours after eating before taking Lumryz and it should be the last thing you do before going to bed.

- Lumryz is supplied in a premeasured packet that must be mixed with water (do not use hot water) and then shaken in the provided mixing cup for at least 60 seconds (1 minute).
- The mixture will appear slightly milky and some granules will stick together, even when fully mixed. It will taste salty.
- After mixing, take the Lumryz mixture right away or within 30 minutes.
- As soon as you take it, lie down in bed because Lumryz may cause you to fall asleep quickly (some people fall
 asleep within 5 minutes and most fall asleep within 15 minutes). The time it takes you to fall asleep may be different
 from night to night.
- Avoid getting out of bed after taking Lumryz. Falling asleep quickly, including while standing or while getting up from
 the bed, has led to falls with injuries that have required some people to be hospitalized.
- Detailed Sodium oxybate dosage information

What happens if I miss a dose?

If you or your child misses the second Xyrem dose, skip that dose and do not take or give Xyrem again until the next night. Never take or give 2 Xyrem doses at 1 time.

If you miss a dose of Lumryz, do not take the dose too late at night. Just skip that dose and go back to your regular dosing schedule the next night.

What happens if I overdose?

If you take too much sodium oxybate, call your doctor or go to the nearest hospital emergency room right away.

What shall I avoid when taking sodium oxybate?

Anyone who takes sodium oxybate 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 sodium oxybate. Those activities should not be done until you know how Xyrem affects you or your child.

What other drugs affect sodium oxybate?

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially, tell your doctor if you take other medicines to help you sleep (sedatives) or that may make you sleepy, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol, or street drugs. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine. See the sodium oxybate prescribing information for a full list of interactions.

Sodium oxybate storage

Xyrem storage

Store Xyrem in the original bottle prior to mixing with water. After mixing with water, store Xyrem in pharmacy containers with child-resistant caps provided by the pharmacy.

- Store at room temperature between 68°F to 77°F (20°C to 25°C).
- Xyrem solution prepared after mixing with water should be taken within 24 hours.

When you have finished using a Xyrem bottle:

- empty any unused Xyrem down the sink drain
- · cross out the label on the Xyrem bottle with a marker
- place the empty Xyrem bottle in the trash

Xyrem comes in a child-resistant package. Keep Xyrem and all medicines out of the reach of children and pets.

Lumryz storage

Store Lumryz in the original packet prior to mixing with water. After mixing with water, store Lumryz in the mixing cup provided in each kit.

- Store at room temperature between 68°F to 77°F (20°C to 25°C).
- Once mixed, Lumryz suspension should be taken within 30 minutes of preparation.
- When you have finished using the Lumryz packet, throw it away (dispose of it) in the trash.

Lumryz comes in a child-resistant package. Keep out of the reach of children and pets

Sodium oxybate ingredients

Xyrem ingredients

Xyrem active ingredients: sodium oxybate (oxybate sodium)

Xyrem inactive ingredients: purified water and malic acid

Lumryz ingredients

Lumryz active ingredients: sodium oxybate (oxybate sodium)

Lumryz inactive ingredients: carrageenan, hydrogenated vegetable oil, hydroxyethyl cellulose, magnesium stearate, malic acid, methacrylic acid copolymer, microcrystalline cellulose, povidone, xanthan gum.

Who makes sodium oxybate?

Jazz Pharmaceuticals, Inc., distributes the Xyrem brand of sodium oxybate.

Avadel CNS Pharmaceuticals, LLC., distributes the Lumryz brand of sodium oxybate.

Popular FAQ

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What is Lumryz REMS?	~

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References

- 1. Sodium oxybate. Medline Plus.
- 2. Xyrem Medication Guide
- 3. Xyrem Prescribing Information
- 4. Xywav Prescribing information
- 5. Lumryz Medication Guide

- 6. Lumryz Prescribing Information
- 7. GHB. Department of Justice/Drug Enforcement Administration.
- 8. Lumryz.com
- 9. Understanding Xyrem

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Other brands

Xyrem, Lumryz

Professional resources

- · Sodium Oxybate monograph
- Sodium Oxybate Oral Solution (FDA)

Other brands

Xyrem

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ঝ Risk data available

CSA Schedule*

3 Moderate abuse potential

Approval History

Drug history at FDA

User Reviews & Ratings

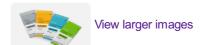
7.8 / 10

127 Reviews

Images

Xyrem (sodium oxybate) 0.5 g per mL (0.5 g/mL of sodium oxybate equivalent to 0.413 g/mL of oxybate)





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