

HIGHLIGHTS OF PRESCRIBING INFORMATION

Key highlights do not include all the information needed to use SODIUM OXYBATE (XR) safely and effectively. See full prescribing information for SODIUM OXYBATE ORAL SOLUTION.

SODIUM OXYBATE Oral Solution, CII
Initial U.S. Approval: 2002

WARNING: CENTRAL NERVOUS SYSTEM (CNS) DEPRESSION AND ABUSE AND MISUSE

See full prescribing information for complete boxed warning.

Central Nervous System Depression

Sodium oxybate oral solution is a CNS depressant, and respiratory depression can occur with sodium oxybate oral solution use (1.5, 5.4).

Abuse and Misuse
Sodium oxybate oral solution is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB is associated with CNS adverse reactions, including seizure, respiratory depression, decreased consciousness, coma, and death (5.2).

Sodium oxybate oral solution is available only through a restricted program called the Sodium Oxybate REMS Program (5.3).

INDICATIONS AND USAGE

Sodium oxybate oral solution is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients with narcolepsy (1).

DOSEAGE AND ADMINISTRATION

Initial dosage at 4.5 g per night, divided into two doses (2.1).

Increase the dosage by 1.5 g per night at weekly intervals (0.75 g at bedtime and 0.75 g at night) until (2.1).

Recommended dosage range: 6 to 9 g per night (2.1).

Total Nightly Dose	Take at Bedtime	Take 2.5 to 4 Hours Later
4.5 g per night	2.25 g	2.25 g
6 g per night	3 g	3 g
7.5 g per night	3.75 g	3.75 g
9 g per night	4.5 g	4.5 g

Important Administration Information

Prepare both doses prior to bedtime; dilute each dose with approximately 1/4 cup (60 mL) of water (2.3).

Allow 2 hours after eating before dosing (2.3).

FULL PRESCRIBING INFORMATION: CONTENTS

WARNING: CENTRAL NERVOUS SYSTEM (CNS) DEPRESSION AND ABUSE AND MISUSE

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

9 DRUG ABUSE AND DEPENDENCE

10 HOW SUPPLIED/STORAGE AND HANDLING

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

13 NONCLINICAL TOXICOLOGY

14 CLINICAL STUDIES

15 HOW SUPPLIED/STORAGE AND HANDLING

16 DESCRIPTION

17 PATIENT COUNSELING INFORMATION

18 FULL PRESCRIBING INFORMATION

WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION AND ABUSE AND MISUSE

Central Nervous System Depression

Sodium oxybate is a CNS depressant. In clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in adult patients treated with sodium oxybate oral solution (see **Warnings and Precautions (5.1)**).

Abuse and Misuse
Sodium oxybate is the sodium salt of 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, decreased consciousness, coma, and death (see **Warnings and Precautions (5.2)**).

Because of the risks of CNS depression and abuse and misuse, sodium oxybate oral solution is available only through a restricted program called the Sodium Oxybate REMS Program (see **Warnings and Precautions (5.3)**).

INDICATIONS AND USAGE

Sodium oxybate oral solution is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients with narcolepsy.

Pediatric use information is approved for Jazz Pharmaceuticals Inc.'s XYREM (sodium oxybate) Oral Solution. However, due to Jazz Pharmaceuticals Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

2.1 Adult Dosage and Administration

The recommended starting dosage is 4.5 grams (g) per night administered orally, divided into two doses: 2.25 g (0.75 g at bedtime and 0.75 g at night) at weekly intervals (additional 0.75 g at bedtime and 0.75 g at night) until the effective dosage range (6 to 9 g per night) is reached. The dosage may be gradually titrated based on efficacy and tolerability. Doses higher than 9 g per night have not been studied and should not ordinarily be administered.

2.2 Dosage Modification in Patients with Hepatic Impairment

When initiating divalproex sodium in patients taking a stable dosage of sodium oxybate oral solution, a reduction of the sodium oxybate oral solution dosage by at least 20% is recommended with initial concomitant use (see **Dose Adjustments (2.5)**).

2.3 Important Administration Instructions for All Patients

The total nightly dosage of sodium oxybate oral solution is divided into two doses. Prepare both doses of sodium oxybate oral solution to be diluted with approximately 1/4 cup (approximately 60 mL) of water in the empty pharmacy containers provided.

Take the first nightly dose of sodium oxybate oral solution at least 2 hours after eating (see **Warnings and Precautions (5.3)**).

Take the second nightly dose 2.5 to 4 hours after the first dose.

Patients should take both doses of sodium oxybate oral solution while in bed and lie down immediately after dosing, and remain in bed following ingestion of each dose. Sodium oxybate oral solution should be diluted with water without first filtering through a strainer (see **Warnings and Precautions (5.4)**).

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Take each dose while in bed and lie down after dosing (2.3).

Patients with Hepatic Impairment
Recommended starting dosage is one-half of the original dosage per night administered orally, divided into two doses (2.4).

DOSEAGE FORMS AND STRENGTHS
Oral solution, 0.5 g per mL (0.5 g/mL of sodium oxybate equivalent to 0.413 g/mL of oxybate) (2.1).

CONTRAINDICATIONS
In combination with sedative hypnotics or alcohol (4).
Succinic semialdehyde dehydrogenase deficiency (4).

WARNINGS AND PRECAUTIONS
CNS depression: Use caution when considering the concurrent use of sodium oxybate oral solution with other CNS depressants (5.1).
Caution patients against hazardous activities requiring complete mental alertness or motor coordination within the first 6 hours of dosing or after first initiating treatment until certain that sodium oxybate oral solution does not affect adversely (5.1).
Depression and suicidality: Monitor patients for emergent or increased depression and suicidality (5.5).
Confusion/drowsiness: Monitor for impaired motor/cognitive function (5.6).
Parasomnias: Evaluate episodes of sleepwalking (5.7).
High cardiac content in sodium oxybate oral solution: Monitor patients with heart failure, hypertension, or impaired renal function (5.8).

ADVERSE REACTIONS
Most common adverse reactions in adults (≥5% and at least twice the incidence with placebo) were nausea, dizziness, vomiting, somnolence, enuresis, and tremor (6).

USE IN SPECIFIC POPULATIONS
To report SUSPECTED ADVERSE REACTIONS, contact Camber Pharmaceuticals, Inc. at 1-800-465-8330, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
Concomitant use with divalproex sodium: An initial reduction in sodium oxybate oral solution dose of at least 20% is recommended (2.5, 7.1).

PREGNANCY: Based on animal data, may cause fetal harm (8.1).
GERIATRIC PATIENTS: Monitor for impaired motor or cognitive function when taking sodium oxybate oral solution (8.5).

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17 PATIENT COUNSELING INFORMATION and Medication Guide

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide. Revised: 04/2026

8.4 Pediatric Use

8.5 Geriatric Use
8.6 Hepatic Impairment

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance
9.2 Abuse
9.3 Dependence

10 HOW SUPPLIED/STORAGE AND HANDLING

10.1 Human Experience
10.2 Signs and Symptoms
10.3 Recommended Treatment of Overdose

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES

14.1 Category in Adult Narcolepsy
14.2 Excessive Daytime Sleepiness in Adult Narcolepsy

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied
16.2 Storage
16.3 Handling and Disposal

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

Further information is available at www.SODIUMREMS.com or 1-833-769-7377 (1-833-SOD-REMS).

5.4 Respiratory Depression and Sleep-Disordered Breathing

Sodium oxybate oral solution may impair respiratory drive, especially in patients with compromised respiratory function. In overdose, life-threatening respiratory depression has been reported (see **Warnings and Precautions (5.1)**).

In an adult study assessing the respiratory-depressant effects of sodium oxybate oral solution at doses up to 9 g per night in 21 patients with narcolepsy, no dose-related changes in oxygen saturation were demonstrated in the group as a whole. One of the four patients with preexisting, moderate-to-severe sleep apnea had significant hypoxemia during treatment. None of the 40 patients had a clinically significant episode of desaturation.

In an adult study assessing the effects of sodium oxybate oral solution 9 g per night in 50 patients with obstructive sleep apnea, sodium oxybate oral solution did not increase the severity of sleep-disordered breathing and did not adversely affect the average duration and severity of oxygen desaturation overall. However, there was a significant increase in the number of central apneas in patients taking sodium oxybate oral solution, and clinically significant oxygen desaturation (≥5%) was measured in three patients (6%) after sodium oxybate oral solution administration, with one patient withdrawing from the study and two continuing after single brief instances of desaturation.

Prescribers should be aware that increased central apneas and clinically relevant desaturation events have been observed with sodium oxybate oral solution administration in adult patients.

In adult clinical trials in 128 patients with narcolepsy, two subjects had profound CNS depression, which resolved after supportive respiratory intervention. Two other patients discontinued sodium oxybate because of severe difficulty breathing and an increase in obstructive sleep apnea. In two controlled trials assessing PDS measures in adult patients with narcolepsy, 40 of 477 patients were included with a baseline apnea-hypoxemia index of 16 to 67 events per hour, indicative of mild to severe sleep-disordered breathing. None of the 40 patients had a clinically significant worsening of respiratory function as measured by apnea/hypopnea index and pulse oximetry at doses of 4.5 to 9 g per night.

Prescribers should be aware that sleep-related breathing disorders tend to be more prevalent in obese patients, in men, in postmenopausal women than on hormone replacement therapy and among patients with narcolepsy.

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5.5 Depression and Suicidality

In adult clinical trials in patients with narcolepsy (n=781), there were two suicides and two attempted suicides in patients treated with sodium oxybate oral solution, including three patients with a previous history of depressive psychiatric disorder. Of the two suicides, one patient used sodium oxybate oral solution in conjunction with other drugs. Sodium oxybate oral solution was not involved in the second suicide. Adverse reactions of depression were reported by 7% of 781 patients treated with sodium oxybate oral solution, with four patients (~1%) discontinuing because of depression. None of the 40 patients had a clinically significant episode of depression in most cases, no change in suicide risk with sodium oxybate oral solution treatment was reported.

In a controlled adult trial, with patients randomized to fixed doses of 3, 6 g, or 9 g per night sodium oxybate oral solution or placebo, there was a single event of suicidal ideation in 3 of 9 patients in the 9 g per night dose. In another adult controlled trial, with patients titrated from an initial 4.5 g per night starting dose, the incidences of depression were 1 (1.7%), 1 (1.5%), and 2 (2.6%) for the placebo, 4.5 g, 6 g, and 9 g per night doses, respectively.

The emergence of depression in patients treated with sodium oxybate oral solution requires careful and immediate evaluation. Patients with a previous history of depressive illness and/or suicide attempt should be monitored carefully for the emergence of depressive symptoms while taking sodium oxybate oral solution.

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5.6 Other Behavioral or Psychiatric Adverse Reactions

During adult clinical trials in patients with narcolepsy, 3% of 781 patients treated with sodium oxybate oral solution experienced confusion, with incidence generally increasing with dose.

Less than 1% of patients discontinued the drug because of confusion. Confusion was reported at all recommended doses from 0 g to 9 g per night. In a controlled trial in adults where patients were randomized to fixed total daily doses of 3 g, 6 g, or 9 g per night or placebo, a dose-response relationship for confusion was demonstrated, with 17% of patients at 9 g per night experiencing confusion, in all cases in that controlled trial, the confusion resolved soon after termination of treatment. In Trial 3 where sodium oxybate was titrated from an initial 4.5 g per night dose, there was a single event of confusion in one patient on the 9 g per night dose. In the majority of cases in adult clinical trials in patients with narcolepsy, confusion resolved either soon after termination of dosing or with continued treatment.

Another event occurred in 5.8% of the 874 patients receiving sodium oxybate oral solution in adult clinical trials in another population.

Other neuropsychiatric reactions reported in adult clinical trials in patients with narcolepsy and the post-marketing setting included hallucinations, paranoia, psychosis, aggression, and agitation.

The emergence or increase in the occurrence of behavioral or psychiatric events in adult patients taking sodium oxybate oral solution should be carefully monitored.

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5.8 Use in Patients Sensitive to High Sodium Intake

Sodium oxybate oral solution has a high salt content. In patients sensitive to salt intake (e.g., those with heart failure, hypertension, or renal impairment), the amount of daily sodium intake in each dose of sodium oxybate oral solution, together with the approximate sodium content per sodium oxybate oral solution dose, should be considered.

Table 3 Approximate Sodium Content per Total Nightly Dose of Sodium oxybate Oral Solution (CII) (g = grams)

Sodium oxybate oral solution (CII) Dose	Sodium Content/Total Nightly Exposure Dose
3 g per night	500 mg
4.5 g per night	820 mg
6 g per night	1100 mg
7.5 g per night	1400 mg
9 g per night	1640 mg

6 ADVERSE REACTIONS

The following clinically significant adverse reactions appear in other sections of the labeling:

CNS depression (see **Warnings and Precautions (5.1)**)
Abuse and Misuse (see **Warnings and Precautions (5.2)**)
Respiratory Depression and Sleep-Disordered Breathing (see **Warnings and Precautions (5.4)**)
Depression and Suicidality (see **Warnings and Precautions (5.5)**)
Other Behavioral or Psychiatric Adverse Reactions (see **Warnings and Precautions (5.6)**)
Parasomnias (see **Warnings and Precautions (5.7)**)
Use in Patients Sensitive to High Sodium Intake (see **Warnings and Precautions (5.8)**)

6.1 Clinical Trials

Sodium oxybate oral solution was studied in three placebo-controlled clinical trials (Trials N1, N3, and N4) described in Sections 14.1 and 14.2. In 611 patients with narcolepsy (388 subjects treated with sodium oxybate oral solution, and 213 with placebo). A total of 781 patients with narcolepsy were treated with sodium oxybate oral solution in controlled and uncontrolled clinical trials.

Section 6.1 and Table 4 present adverse reactions from three pooled, controlled studies.

Trials N1, N3, and N4) in patients with narcolepsy.

Adverse Reactions Leading to Treatment Discontinuation:
Of the 611 patients with narcolepsy treated with sodium oxybate oral solution, 10.3% of patients discontinued because of adverse reactions compared with 2.0% of patients receiving placebo. The most common adverse reaction leading to discontinuation was nausea (2.9%). The majority of adverse reactions leading to discontinuation began during the first few weeks of treatment.

Commonly Observed Adverse Reactions in Controlled Clinical Trials:
The most common adverse reactions (incidence ≥5% and twice the rate seen with placebo) in patients treated with sodium oxybate oral solution were nausea, dizziness, vomiting, somnolence, enuresis, and tremor.

9.3 Dependence
Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation of a significant dose reduction of a drug. There have been case reports of withdrawal, ranging from mild to severe, following discontinuation of the use of GHB at frequent repeated doses (18 to 250 g daily) in excess of the recommended dosage range. Signs and symptoms of GHB withdrawal following abrupt discontinuation included insomnia, restlessness, anxiety, irritability, muscle cramps, tachycardia, muscle cramps, tachycardia, headache, dizziness, rebound fatigue and sleepiness, confusion, and, particularly in the case of severe withdrawal, visual hallucinations, agitation, and delirium. These symptoms occurred in 14 of 14 patients. In cases of severe withdrawal, hospitalization may be required. The discontinuation effects of sodium oxybate oral solution have not been systematically evaluated in controlled clinical trials. In the clinical trial experience with sodium oxybate oral solution in narcolepsy/cataplexy patients at recommended doses, two patients reported anxiety and one reported insomnia following abrupt discontinuation at the termination of the clinical trial in the two patients with anxiety, the frequency of cataplexy had increased markedly at the same time.

**Table 4
Adverse Reactions Occurring in ≥2% of Adult Patients and More Frequently with Sodium oxybate oral solution than Placebo in Three Controlled Trials (N1, N3, N4) by Body System and Dose**

MEDICATION GUIDE
Sodium oxybate (SO dee um OX i bate)
oral solution, CIII

Read this Medication Guide carefully before you start taking sodium oxybate oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about sodium oxybate oral solution?

- Sodium oxybate oral solution is a central nervous system (CNS) depressant. Taking sodium oxybate oral solution with other 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)
 - death

Ask your doctor if you are not sure if you are taking a medicine listed above.

- Sodium oxybate oral solution is a federal controlled substance (CIII). The active ingredient of sodium oxybate oral solution is a form of gamma-hydroxybutyrate (GHB) that is also a federal controlled substance (CI). Abuse of illegal GHB, either alone or with other CNS depressants may cause serious medical problems, including:
 - seizure
 - trouble breathing (respiratory depression)
 - changes in alertness (drowsiness)
 - coma
 - death

Call your doctor right away if you have any of these serious side effects.

- Anyone who takes sodium oxybate oral solution 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 oral solution. Those activities should not be done until you know how sodium oxybate oral solution affects you.

- Keep sodium oxybate oral solution in a safe place to prevent abuse and misuse. Selling or giving away sodium oxybate oral solution 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 oral solution is available only by prescription, and filled through the certified pharmacy in the Sodium Oxybate REMS Program. You must be enrolled in the Sodium Oxybate REMS Program to receive sodium oxybate oral solution. For information on how to receive sodium oxybate oral solution visit www.SOXREMSProgram.com. Before you receive sodium oxybate oral solution, your doctor or pharmacist will make sure that you understand how to take sodium oxybate oral solution safely and effectively. If you have any questions about sodium oxybate oral solution, ask your doctor or call the Sodium Oxybate REMS Program at 1-833-769-7367 (1-833-SOX-REMS).

What is sodium oxybate oral solution?

Sodium oxybate oral solution is a prescription medicine used to treat the following symptoms in people with narcolepsy:

- sudden onset of weak or paralyzed muscles (cataplexy), or
- excessive daytime sleepiness (EDS)

It is not known if sodium oxybate oral solution is safe and effective in children less than 7 years of age.

Do not take sodium oxybate oral solution if you:

- 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 oral solution, tell your doctor about all medical conditions, including if you:

- have a history of drug abuse.
- have short periods of not breathing while sleeping (sleep apnea)
- has trouble breathing or has lung problems. You may have a higher chance of having serious breathing problems when taking sodium oxybate oral solution.
- have or had depression or has tried to harm yourself or themselves. You should be watched carefully for new symptoms of depression.
- has or had behavior or other psychiatric problems such as:

○ anxiety	○ seeing or hearing things that are not real (hallucinations)
○ feeling more suspicious (paranoia)	○ being out of touch with reality (psychosis)
○ acting aggressive	○ agitation

- have liver problems
- are on a salt-restricted diet. Sodium oxybate oral solution contains a lot of sodium (salt) and may not be right for you.
- have high blood pressure
- have heart failure
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if sodium oxybate oral solution can harm your unborn baby.

- are breastfeeding or plan to breastfeed. Sodium oxybate passes into breast milk. You and your doctor should decide if you will take sodium oxybate oral solution or breastfeed.

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). Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take or give sodium oxybate oral solution?

- Read the **Instructions for Use** at the end of this Medication Guide for detailed instructions on how to take sodium oxybate oral solution.
- Take or give sodium oxybate oral solution exactly as your doctor tells you to take or give it.

- Sodium oxybate oral solution can cause physical dependence and craving for the medicine when it is not taken as directed.
- Never change the sodium oxybate oral solution dose without talking to your doctor.

- Sodium oxybate oral solution can cause sleep very quickly without feeling drowsy. Some people fall asleep within 5 minutes and most fall asleep within 15 minutes. The time it takes to fall asleep might be different from night to night.

- 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.

- Sodium oxybate oral solution is taken at night divided into 2 doses.

- Adults:** Take the first sodium oxybate oral solution dose at bedtime while you are in bed and lie down immediately. Take the second sodium oxybate oral solution dose 2½ to 4 hours after the first sodium oxybate oral solution dose. You may want to set an alarm clock to make sure you wake up to take the second sodium oxybate oral solution dose. You should remain in bed after taking the first and second doses of sodium oxybate oral solution.

- If you miss the second sodium oxybate oral solution dose, skip that dose and do not take or give sodium oxybate oral solution again until the next night. Never take or give 2 sodium oxybate oral solution doses at 1 time.

- Wait at least 2 hours after eating before taking sodium oxybate oral solution.

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

What are the possible side effects of sodium oxybate oral solution?

Sodium oxybate oral solution can cause serious side effects, including:

- See **“What is the most important information I should know about sodium oxybate oral solution?”**

- breathing problems, including:**
 - slower breathing
 - trouble breathing
 - 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 take sodium oxybate oral solution.

- 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
 - difficulty concentrating

- Call your doctor right away if you have symptoms of mental health problems, or a change in weight or appetite.**
- sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you start sleepwalking. Your doctor should check you.

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

- nausea
- vomiting
- sleepiness
- bedwetting
- dizziness
- tremor

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

These are not all the possible side effects of sodium oxybate oral solution. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sodium oxybate oral solution?

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

- Store sodium oxybate oral solution at room temperature between 68°F to 77°F (20°C to 25°C).

- Sodium oxybate oral solution prepared after mixing with water should be taken within 24 hours.

- When you have finished using a sodium oxybate oral solution bottle:
 - empty any unused sodium oxybate oral solution down the sink drain
 - cross out the label on the sodium oxybate oral solution bottle with a marker
 - place the empty sodium oxybate oral solution bottle in the trash

Sodium oxybate oral solution comes in a child-resistant package. **Keep sodium oxybate oral solution and all medicines out of the reach of children and pets.**

General information about the safe and effective use of sodium oxybate oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sodium oxybate oral solution for a condition for which it was not prescribed. Do not give sodium oxybate oral solution to other people, even if they have the same symptoms. It may harm them.

You can ask your pharmacist or doctor for information about sodium oxybate oral solution that is written for health professionals.

What are the ingredients in sodium oxybate oral solution?

Active Ingredients: sodium oxybate
Inactive Ingredients: purified water and malic acid

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Central Islip, NY 11722

Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

For more information, go to www.SOXREMSProgram.com or call the Sodium Oxybate REMS Program at 1-833-769-7367 (1-833-SOX-REMS).

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 10/2025

Pediatric use information is approved for Jazz Pharmaceuticals Inc.'s XYREM (sodium oxybate) Oral Solution. However, due to Jazz Pharmaceuticals Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

Instructions for Use
Sodium Oxybate (SO dee um OX i bate)
Oral Solution, CIII

Read this Instructions for Use carefully before you start taking sodium oxybate oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

Important Information:

- You will need to split your prescribed sodium oxybate oral solution dose into 2 separate pharmacy containers for mixing.
- You will need to mix sodium oxybate oral solution with water before you take the dose.
- Safely store the prepared sodium oxybate oral solution doses and take within 24 hours after mixing. If the prepared dose was not taken within this time, throw the mixture away. See “Throwing away (disposing of) sodium oxybate oral solution” section below for instructions about how to safely throw away sodium oxybate oral solution.
- Both sodium oxybate oral solution doses should be taken while in bed.
- The pharmacy containers may be rinsed out with water and emptied into the sink drain.

Supplies you will need for mixing and taking sodium oxybate oral solution. See Figure A.

- Bottle of sodium oxybate oral solution medicine
- Press-in-bottle-adaptor with straw attached
- Dosing syringe for measuring and dispensing the sodium oxybate oral solution dose
- Measuring cup that is able to measure about ¼ cup of water (not provided with the sodium oxybate oral solution shipment)
- 2 empty pharmacy containers with child-resistant caps for mixing, storing, and taking the sodium oxybate oral solution doses
- Alarm clock (not pictured which may be included in the first shipment)
- Medication Guide

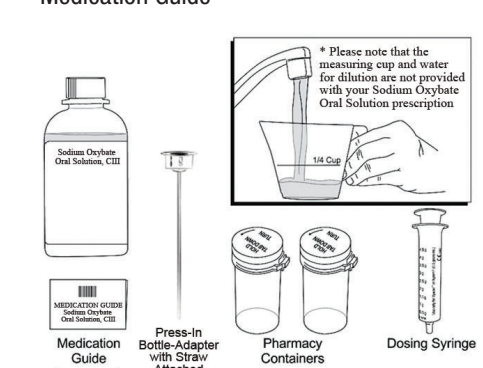


Figure A
Step 1: Setup

- Take the sodium oxybate oral solution bottle, press-in-bottle-adaptor, syringe, and pharmacy containers out of the shipping box.
- Take the syringe out of the plastic wrapper. Use only the syringe provided with the sodium oxybate oral solution prescription.
- Fill a measuring cup (not provided) with about ¼ cup of water available for mixing your dose.
- Make sure the pharmacy containers are empty.
- Open both pharmacy containers by holding the tab under the cap and turning counterclockwise (to the left). See Figure B.

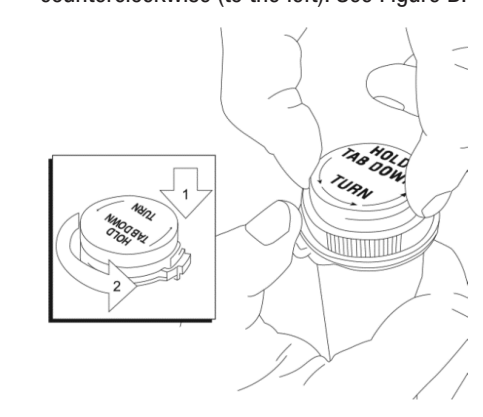
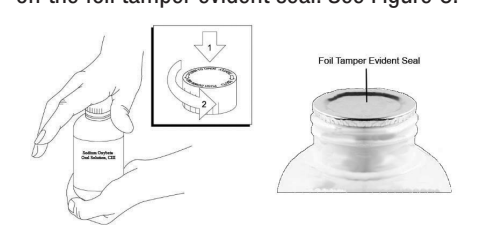


Figure B
Remove the bottle cap from the sodium oxybate oral solution bottle by pushing down while turning the cap counterclockwise and then peel off the foil tamper evident seal. See Figure C.



- While holding the sodium oxybate oral solution bottle in its upright position, insert the press-in-bottle-adaptor into the neck of the sodium oxybate oral solution bottle. See Figure D.

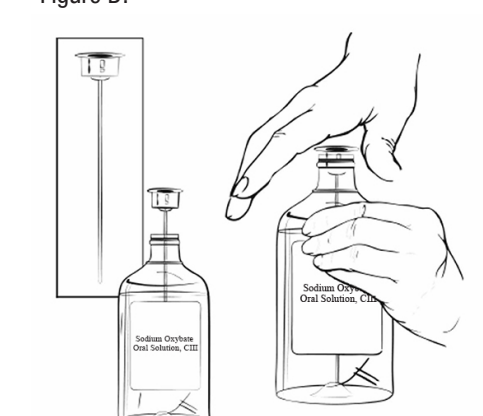


Figure D
Tilt the straw toward the edge of the bottom of the bottle to be sure you can draw out your dose of the medicine. You only need to do this the first time you open the bottle. See Figure E.

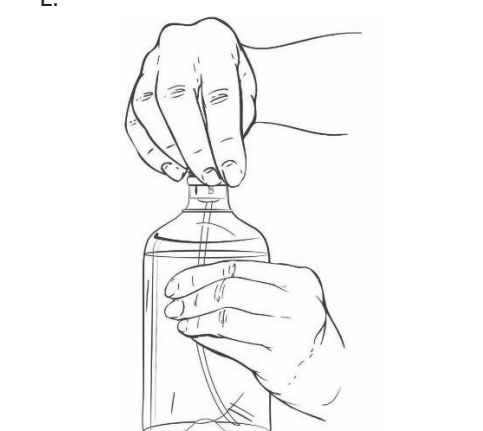


Figure E

- After you draw out your dose of the medicine, leave the adaptor in the bottle for all your future uses. See Figure F.



Figure F
Step 2. Prepare the first sodium oxybate oral solution dose (prepare before bedtime)

Place the sodium oxybate oral solution bottle on a hard, flat surface and grip the bottle with one hand and firmly press the syringe into the center opening of the bottle with the other hand. See Figure G.

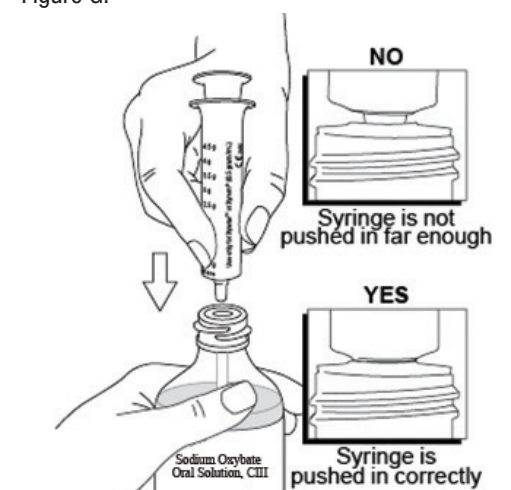


Figure G
Pull back on the plunger until the medicine flows into the syringe and the liquid level is lined up with the marking on the syringe that matches your dose. See Figure H.

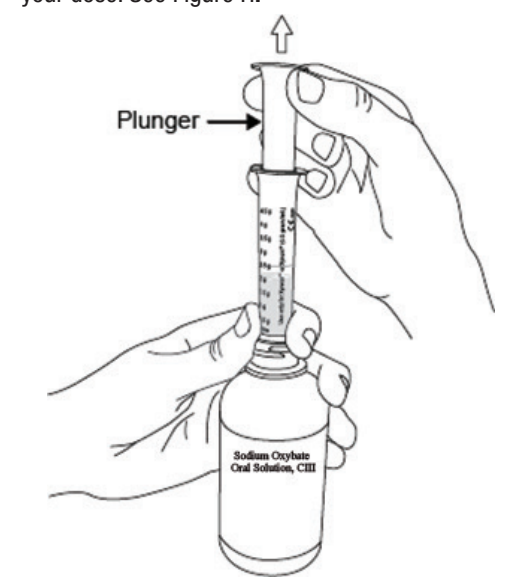


Figure H
Note: The sodium oxybate oral solution medicine will not flow into the syringe unless you keep the bottle upright.

Figure I shows an example of drawing up a sodium oxybate oral solution dose of 2.25 g. Figure J shows an example if an air space forms when drawing up the dose.

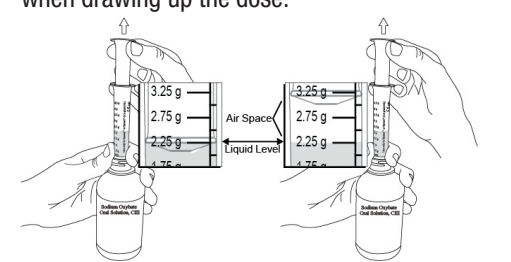


Figure I
Note: If an air space forms between the plunger and the liquid when drawing up the medicine, line up the liquid level with the marking on the syringe that matches your dose. See Figure J above.

- After you draw up the first divided sodium oxybate oral solution dose, remove the syringe from the opening of the sodium oxybate oral solution bottle.
- Empty all of the medicine from the syringe into one of the provided empty pharmacy containers by pushing down on the plunger until it stops. See Figure K.



Figure K
Using a measuring cup, pour about ¼ cup of water into the pharmacy container. Be careful to add only water to the pharmacy container and not more sodium oxybate oral solution.

- All shipped bottles of sodium oxybate oral solution contain the concentrated medicine. Water for mixing the medicine is not provided in the shipment.
- After mixing the medicine and water in the provided pharmacy container, place the child-resistant cap on the filled pharmacy container and turn the cap clockwise (to the right) until it clicks and locks into its child-resistant position. See Figure L.
- Caution: the pharmacy container cap is reversible with a non-child resistant side. See Figure M. Make sure the child-resistant side of the cap is used to prevent access to the medicine by children.



Figure L
Cap shown in child-resistant position.

Figure L
Note: Do not place the cap back on the container in a non-child resistant position as shown below.



Figure M
Step 3. Prepare the second sodium oxybate oral solution dose (prepare before bedtime)

- Repeat Step 2 drawing up the amount of medicine prescribed for your second dose:
 - emptying the syringe into the second pharmacy container
 - adding about ¼ cup of water and
 - closing the pharmacy container

Step 4. Store the prepared sodium oxybate oral solution doses

- Put the cap back on the sodium oxybate oral solution bottle and both prepared doses in a safe and secure place. Store in a locked place if needed.

- Keep the sodium oxybate oral solution bottle and both prepared sodium oxybate oral solution doses out of the reach of children and pets.
- Rinse the syringe out with water and squirt the liquid into the sink drain by pushing down on the plunger until it stops.

Step 5. Take or give the first sodium oxybate oral solution dose

- At bedtime, and before you take (or give) the first sodium oxybate oral solution dose, put the second sodium oxybate oral solution dose in a safe place. Caregivers should make sure all sodium oxybate oral solution doses are kept in a safe place until given. You may want to set an alarm clock for 2½ to 4 hours later to make sure you wake up to take (or give) the second dose.

- When it is time to take (or give) the first sodium oxybate oral solution dose, remove the cap from the pharmacy container by pressing down on the child-resistant locking tab and turning the cap counterclockwise.

- Drink all of the first sodium oxybate oral solution dose while sitting in bed. Put the cap back on the first pharmacy container and immediately lie down to sleep.

- You should fall asleep soon. Some people fall asleep within 5 minutes and most fall asleep within 15 minutes. Some patients take less time to fall asleep, and some take more time. The time it takes you to fall asleep might be different from night to night.

Step 6. Take or give the second sodium oxybate oral solution dose

- When you wake up 2½ to 4 hours later for your second dose of sodium oxybate oral solution, take the cap off the second pharmacy container.
- If you wake up before the alarm and it has been at least 2½ hours since the first sodium oxybate oral solution dose, turn off the alarm and take the second sodium oxybate oral solution dose.
- Drink all of the second sodium oxybate oral solution dose while sitting in bed. Put the cap back on the second pharmacy container and immediately lie down to continue sleeping.

How should I store sodium oxybate oral solution?

- Store sodium oxybate oral solution in the original bottle prior to mixing with water. After mixing, store sodium oxybate oral solution in the pharmacy containers provided by the pharmacy. The cap on the original bottle is child-resistant. The pharmacy container cap is child-resistant only when the child-resistant side of the cap is used.
- Store sodium oxybate oral solution at room temperature between 68°F to 77°F (20°C to 25°C).
- Sodium oxybate oral solution prepared after mixing with water should be taken within 24 hours or emptied down the sink drain.

Throwing away (disposing of) sodium oxybate oral solution

- When you have finished using a sodium oxybate oral solution bottle:
 - empty any unused sodium oxybate oral solution down the sink drain
 - cross out the label on the sodium oxybate oral solution bottle with a marker (not provided with the sodium oxybate oral solution shipment)
 - place the empty sodium oxybate oral solution bottle in the trash
- Keep sodium oxybate oral solution and all medicines out of the reach of children and pets.

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Job Specification Form - PI

Customer Name : Art #

Customer Rep :

Date Submitted :

Job Info

File Name :

Job Name :

Type :	New Design	Reprint	Manufacture by :
			Manufacture for :
Job Type :	Insert		Proof #
	Med guide		Customer item #
	Patient Guide		Rev #

Grain Direction :	Packing type :	Trays	Rubber band
Flat Size :	Flat Tolerance :		
Final Fold Size :	Fold Tolerance :		
Finishing for Padding			
Barcode Reader :	Barcode Type :		
2D Barcode : Yes No	2D Barcode Size :		
Paper Stock #	Ink Type :	Water Base	
Ink #		UV Base	

Notes :

Approved by : Date :

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