891-04-2026
SODIUM OXYBATE ORAL SOLUTION ©

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

SODIUM OXYBATE oral solution, CIII

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 (5.1, 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, 9.2)**

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).

----------DOSAGE AND ADMINISTRATION----------

Dosage for Adult Patients
- Initiate dosage at 4.5 g per night orally, divided into two doses (2.1).
- Titrate to effect in increments of 1.5 g per night at weekly intervals (0.75 g at bedtime and 0.75 g taken 2.5 to 4 hours later) (2.1).
- Recommended dosage range: 6 g to 9 g per night orally (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 ¼ cup of water in pharmacy-provided containers (2.3).
- Allow 2 hours after eating before dosing (2.3).
- 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).

----------DOSAGE 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) (3)

----------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 them adversely (5.1).
- Depression and suicidality: Monitor patients for emergent or increased depression and suicidality (5.5).
- Confusion/Anxiety: Monitor for impaired motor/cognitive function (5.6).
- Parasomnias: Evaluate episodes of sleepwalking (5.7).
- High sodium 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 (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Camber Pharmaceuticals, Inc. at 1-866-495-8330, 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, 7.2).

----------USE IN SPECIFIC POPULATIONS----------
- Pregnancy: Based on animal data, may cause fetal harm (8.1).
- Geriatric patients: Monitor for impaired motor and/or cognitive function when taking sodium oxybate oral solution (8.5).

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.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 04/2026

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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)]*. Many patients who received sodium oxybate oral solution during clinical trials in narcolepsy were receiving central nervous system stimulants *[see Clinical Trials (14)]*.**

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, decreases in the level of 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 under a Risk Evaluation and Mitigation Strategy (REMS) called the Sodium Oxybate REMS Program *[see Warnings and Precautions (5.3)]*.**

1 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 DOSAGE AND ADMINISTRATION

2.1 Adult Dosing Information

The recommended starting dosage is 4.5 grams (g) per night administered orally, divided into two doses: 2.25 g at bedtime and 2.25 g taken 2.5 to 4 hours later (see Table 1). Increase the dosage by 1.5 g per night at weekly intervals (additional 0.75 g at bedtime and 0.75 g taken 2.5 to 4 hours later) to the effective dosage range of 6 g to 9 g per night orally. 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.

Table 1: Recommended Adult Sodium oxybate oral solution Dose Regimen (g = grams)

If a Patient's Total Nightly Dose is:	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

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.

2.3 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 prior to bedtime. Prior to ingestion, each dose of sodium oxybate oral solution should be diluted with approximately ¼ 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 Clinical Pharmacology (12.3)]*. 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 may cause patients to fall asleep abruptly without first feeling drowsy *[see Adverse Reactions (6.2)]*. Patients will often fall asleep within 5 minutes of taking sodium oxybate oral solution, and will usually fall asleep within 15 minutes, though the time it takes any individual patient to fall asleep may vary from night to night. Patients may need to set an alarm to awaken for the second dose. Rarely, patients may take up to 2 hours to fall asleep.

If the second dose is missed, that dose should be skipped and sodium oxybate oral solution should not be taken again until the next night. Both sodium oxybate oral solution doses should never be taken at one time.

2.4 Dosage Modification in Patients with Hepatic Impairment

The recommended starting dosage in patients with hepatic impairment is one-half of the original dosage per night, administered orally divided into two doses *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]*.

2.5 Dosage Adjustment with Co-administration of Divalproex Sodium

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 Drug Interactions (7.2) and Clinical Pharmacology (12.3)]*. When initiating sodium oxybate oral solution in patients already taking divalproex sodium, a lower starting dosage of sodium oxybate oral solution is recommended. Subsequently, the dosage of sodium oxybate oral solution can be adjusted based on individual clinical response and tolerability.

3 DOSAGE FORMS AND STRENGTHS

Sodium oxybate oral solution is a clear to slightly opalescent oral solution, in a concentration of 0.5 g per mL (0.5 g/mL of sodium oxybate equivalent to 0.413 g/mL of oxybate).

4 CONTRAINDICATIONS

Sodium oxybate oral solution is contraindicated for use in:
- combination with sedative hypnotics *[see Warnings and Precautions (5.1)]*.
- combination with alcohol *[see Warnings and Precautions (5.1)]*.
- patients with succinic semialdehyde dehydrogenase deficiency *[see Clinical Pharmacology (12.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Central Nervous System Depression

Sodium oxybate is a central nervous system (CNS) depressant. In adult clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in patients treated with sodium oxybate oral solution. Sodium oxybate oral solution is contraindicated in combination with alcohol and sedative hypnotics. The concurrent use of sodium oxybate oral solution with other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating anti-epileptic drugs, general anesthetics, muscle relaxants, and/or illicit CNS depressants, may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death. If use of these CNS depressants in combination with sodium oxybate oral solution is required, dose reduction or discontinuation of one or more CNS depressants (including sodium oxybate oral solution) should be considered. In addition, if short-term use of an opioid (e.g., post- or perioperative) is required, interruption of treatment with sodium oxybate oral solution should be considered.

Healthcare providers should caution patients about operating hazardous machinery, including automobiles or airplanes, until they are reasonably certain that sodium oxybate oral solution does not affect them adversely (e.g., impair judgment, thinking, or motor skills). Patients should not engage in hazardous occupations or activities requiring complete mental alertness or motor coordination, such as operating machinery or a motor vehicle or flying an airplane, for at least 6 hours after taking sodium oxybate oral solution. Patients should be queried about CNS depression-related events upon initiation of sodium oxybate oral solution therapy and periodically thereafter.

Sodium oxybate oral solution is available only through a restricted program under a REMS *[see Warnings and Precautions (5.3)]*.

5.2 Abuse and Misuse

Sodium oxybate oral solution is a Schedule III controlled substance. The active ingredient of sodium oxybate oral solution, sodium oxybate or gamma-hydroxybutyrate (GHB), is a Schedule I controlled substance. Abuse 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. The rapid onset of sedation, coupled with the amnestic features of sodium oxybate oral solution, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (e.g., assault victim). Because illicit use and abuse of GHB have been reported, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse of GHB (e.g., increase in size or frequency of dosing, drug-seeking behavior, feigned cataplexy) *[see Drug Abuse and Dependence (9.2)]*.

Sodium oxybate oral solution is available only through a restricted program under a REMS *[see Warnings and Precautions (5.3)]*.

5.3 Sodium Oxybate REMS Program

Sodium oxybate oral solution is available only through a restricted distribution program called the Sodium Oxybate REMS Program because of the risks of central nervous system depression and abuse and misuse *[see Warnings and Precautions (5.1, 5.2)]*.

Notable requirements of the Sodium Oxybate REMS Program include the following:
- Healthcare Providers who prescribe sodium oxybate are specially certified
- Sodium oxybate oral solution will be dispensed only by the certified pharmacy that is specially certified
- Sodium oxybate oral solution will be dispensed and shipped only to patients who are enrolled in the Sodium Oxybate REMS Program with documentation of safe use

Further information is available at www.SOXREMSProgram.com or 1-833-769-7367 (1-833-SOX-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 overdoses, life-threatening respiratory depression has been reported *[see Overdosage (10)]*.

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 worsening of the apnea/hypopnea index during treatment.

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 (≤ 55%) 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 PSG measures in adult patients with narcolepsy, 40 of 477 patients were included with a baseline apnea/hypopnea 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 g 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 not 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. In most cases, no change in sodium oxybate oral solution treatment was required.

In a controlled adult trial, with patients randomized to fixed doses of 3 g, 6 g, or 9 g per night sodium oxybate oral solution or placebo, there was a single event of depression at the 3 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%), 2 (3.2%), and 2 (3.6%) 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 a 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 6 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 at the 9 g per night dose. In the majority of cases in all adult clinical trials in patients with narcolepsy, confusion resolved either soon after termination of dosing or with continued treatment.

Anxiety 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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5.7 Parasomnias

Sleepwalking, defined as confused behavior occurring at night and at times associated with wandering, was reported in 6% of 781 patients with narcolepsy treated with sodium oxybate oral solution in adult controlled trials and long-term open-label studies, with < 1% of patients discontinuing due to sleepwalking. Rates of sleepwalking were similar for patients taking placebo and patients taking sodium oxybate oral solution in controlled trials. It is unclear if some or all of the reported sleepwalking episodes correspond to true somnambulism, which is a parasomnia occurring during non-REM sleep, or to any other specific medical disorder. Five instances of sleepwalking with potential injury or significant injury were reported during a clinical trial of sodium oxybate oral solution in patients with narcolepsy.

Parasomnias, including sleepwalking, also have been reported in postmarketing experience with sodium oxybate oral solution. Therefore, episodes of sleepwalking should be fully evaluated and appropriate interventions considered.

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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), consider the amount of daily sodium intake in each dose of sodium oxybate oral solution. Table 3 provides the approximate sodium content per sodium oxybate oral solution dose.

Table 3
Approximate Sodium Content per Total Nightly Dose of Sodium oxybate oral solution (g = grams)

Sodium oxybate oral solution Dose	Sodium Content/Total Nightly Exposure
3 g per night	550 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 Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adult Patients

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 (398 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 trials (N1, N3, N4) in patients with narcolepsy.

Adverse Reactions Leading to Treatment Discontinuation:

Of the 398 patients with narcolepsy treated with sodium oxybate oral solution, 10.3% of patients discontinued because of adverse reactions compared with 2.8% of patients receiving placebo. The most common adverse reaction leading to discontinuation was nausea (2.8%). 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.

Adverse Reactions Occurring at an Incidence of 2% or Greater:

Table 4 lists adverse reactions that occurred at a frequency of 2% or more in any treatment group for three controlled trials and were more frequent in any sodium oxybate oral solution treatment group than with placebo. Adverse reactions are summarized by dose at onset. Nearly all patients in these studies initiated treatment at 4.5 g per night. In patients who remained on treatment, adverse reactions tended to occur early and to diminish over 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 at Onset

Adverse Reaction	Placebo (n=213) %	Sodium oxybate oral solution 4.5g (n=185) %	Sodium oxybate oral solution 6g (n=258) %	Sodium oxybate oral solution 9g (n=178) %
ANY ADVERSE REACTION	62	45	55	70
GASTROINTESTINAL DISORDERS				
Nausea	3	8	13	20
Vomiting	1	2	4	11
Diarrhea	2	4	3	4
Abdominal pain upper	2	3	1	2
Dry mouth	2	1	2	1
GENERAL DISORDERS AND ADMINISTRATIVE SITE CONDITIONS				
Pain	1	1	<1	3
Feeling drunk	1	0	<1	3
Edema peripheral	1	3	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
Cataplexy	1	1	1	2
Muscle spasms	2	2	<1	2
Pain in extremity	1	3	1	1
NERVOUS SYSTEM DISORDERS				
Dizziness	4	9	11	15
Somnolence	4	1	3	8
Tremor	0	0	2	5
Disturbance in attention	0	1	0	4
Paresthesia	1	2	1	3
Sleep paralysis	1	0	1	3
PSYCHIATRIC DISORDERS				
Disorientation	1	1	2	3
Irritability	1	0	<1	3
Sleep walking	0	0	0	3
Anxiety	1	1	1	2
RENAL AND URINARY DISORDERS				
Enuresis	1	3	3	7
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
Hyperhidrosis	0	1	1	3

Dose-Response Information

In clinical trials in narcolepsy, a dose-response relationship was observed for nausea, vomiting, paresthesia, disorientation, irritability, disturbance in attention, feeling drunk, sleepwalking, and enuresis. The incidence of all these reactions was notably higher at 9 g per night.

In controlled trials in narcolepsy, discontinuations of treatment due to adverse reactions were greater at higher doses of sodium oxybate oral solution.

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6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of sodium oxybate oral solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

arthralgia, decreased appetite, fall*, fluid retention, hangover, headache, hypersensitivity, hypertension, memory impairment, nocturia, panic attack, vision blurred, and weight decreased.

*The sudden onset of sleep in patients taking sodium oxybate, including in a standing position or while rising from bed, has led to falls complicated by injuries, in some cases requiring hospitalization.

7 DRUG INTERACTIONS

7.1 Alcohol, Sedative Hypnotics, and CNS Depressants

Sodium oxybate oral solution is contraindicated for use in combination with alcohol or sedative hypnotics. Use of other CNS depressants may potentiate the CNS-depressant effects of sodium oxybate oral solution *[see Warnings and Precautions (5.1)]*.

7.2 Divalproex Sodium

Concomitant use of sodium oxybate oral solution with divalproex sodium results in an increase in systemic exposure to GHB, which was shown to cause a greater impairment on some tests of attention and working memory in a clinical study *[see Clinical Pharmacology (12.3)]*. An initial dose reduction of sodium oxybate oral solution is recommended when used concomitantly with divalproex sodium *[see Dosage and Administration (2.5)]*. Prescribers are advised to monitor patient response closely and adjust dose accordingly if concomitant use of sodium oxybate oral solution and divalproex sodium is warranted.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of sodium oxybate in pregnant women. Oral administration of sodium oxybate to pregnant rats (150, 350, or 1,000 mg/kg/day) or rabbits (300, 600, or 1,200 mg/kg/day) throughout organogenesis produced no clear evidence of developmental toxicity; however, oral administration to rats throughout pregnancy and lactation resulted in increased stillbirths and decreased offspring postnatal viability and growth, at a clinically relevant dose *[see Data]*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Clinical Considerations

Labor or Delivery

Sodium oxybate oral solution has not been studied in labor or delivery. In obstetric anesthesia using an injectable formulation of sodium oxybate, newborns had stable cardiovascular and respiratory measures but were very sleepy, causing a slight decrease in Apgar scores. There was a fall in the rate of uterine contractions 20 minutes after injection. Placental transfer is rapid and gamma-hydroxybutyrate (GHB) has been detected in newborns at delivery after intravenous administration of GHB to mothers. Subsequent effects of sodium oxybate on later growth, development, and maturation in humans are unknown.

Data

Animal Data

Oral administration of sodium oxybate to pregnant rats (150, 350, or 1,000 mg/kg/day) or rabbits (300, 600, or 1,200 mg/kg/day) throughout organogenesis produced no clear evidence of developmental toxicity. The highest doses tested in rats and rabbits were approximately 1 and 3 times, respectively, the maximum recommended human dose (MRHD) of 9 g per night on a body surface area (mg/m^2) basis.

Oral administration of sodium oxybate (150, 350, or 1,000 mg/kg/day) to rats throughout pregnancy and lactation resulted in increased stillbirths and decreased offspring postnatal viability and body weight gain at the highest dose tested. The no-effect dose for pre- and post-natal developmental toxicity in rats is less than the MRHD on a mg/m^2 basis.

8.2 Lactation

Risk Summary

GHB is excreted in human milk after oral administration of sodium oxybate. There is insufficient information on the risk to a breastfed infant, and there is insufficient information on milk production in nursing mothers. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for sodium oxybate oral solution and any potential adverse effects on the breastfed infant from sodium oxybate oral solution or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of sodium oxybate oral solution in pediatric patients below the age of 7 years have not been established.

Juvenile Animal Toxicity Data

In a study in which sodium oxybate (0, 100, 300, or 900 mg/kg/day) was orally administered to rats during the juvenile period of development (postnatal days 21 through 90), mortality was observed at the two highest doses tested. Deaths occurred during the first week of dosing and were associated with clinical signs (including decreased activity and respiratory rate) consistent with the pharmacological effects of the drug. Reduced body weight gain in males and females and delayed sexual maturation in males were observed at the highest dose tested. The no-effect dose for adverse effects in juvenile rats is associated with plasma exposures (AUC) less than that at the maximum recommended human dose (9 g/night).

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.

8.5 Geriatric Use

Clinical studies of sodium oxybate oral solution in patients with narcolepsy did not include sufficient numbers of subjects age 65 years and older to determine whether they respond differently from younger subjects. In controlled trials in another population, 39 (5%) of 874 patients were 65 years or older. Discontinuations of treatment due to adverse reactions were increased in the elderly compared to younger adults (21% vs. 19%). Frequency of headaches was markedly increased in the elderly (39% vs. 19%). The most common adverse reactions were similar in both age categories. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

8.6 Hepatic Impairment

Because of an increase in exposure to sodium oxybate oral solution, the starting dose should be reduced by half in patients with hepatic impairment *[see Dosage and Administration (2.4) and Clinical Pharmacology (12.3)]*.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Sodium oxybate oral solution is a Schedule III controlled substance under the Federal Controlled Substances Act. Non-medical use of sodium oxybate oral solution could lead to penalties assessed under the higher Schedule I controls.

9.2 Abuse

Sodium oxybate oral solution, the sodium salt of GHB, produces dose-dependent central nervous system effects, including hypnotic and positive subjective reinforcing effects. The onset of effect is rapid, enhancing its potential for abuse or misuse.

Drug abuse is the intentional non-therapeutic use of a drug product or substance, even once, for its desirable psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug misuse and abuse may occur with or without progression to addiction. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence.

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 (e.g., assault victim).

Illicit GHB is abused in social settings primarily by young adults. Some of the doses estimated to be abused are in a similar dosage range to that used for treatment of patients with cataplexy. GHB has some commonalities with ethanol over a limited dose range, and some cross tolerance with ethanol has been reported as well. Cases of severe dependence and craving for GHB have been reported when the drug is taken around the clock. Patterns of abuse indicative of dependence include: 1) the use of increasingly large doses, 2) increased frequency of use, and 3) continued use despite adverse consequences.

Because illicit use and abuse of GHB have been reported, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse of GHB (e.g., increase in size or frequency of dosing, drug-seeking behavior, feigned cataplexy). Dispose of sodium oxybate oral solution according to state and federal regulations. It is safe to dispose of sodium oxybate oral solution down the sanitary sewer.

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 or a significant dose reduction of a drug. There have been case reports of withdrawal, ranging from mild to severe, following discontinuation of illicit use of GHB at frequent repeated doses (18 g to 250 g per day) in excess of the recommended dosage range. Signs and symptoms of GHB withdrawal following abrupt discontinuation included insomnia, restlessness, anxiety, psychosis, lethargy, nausea, tremor, sweating, 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 generally abated in 3 to 14 days. 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.

Tolerance

Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose). Tolerance to sodium oxybate oral solution has not been systematically studied in controlled clinical trials. There have been some case reports of symptoms of tolerance developing after illicit use at dosages far in excess of the recommended sodium oxybate oral solution dosage regimen. Clinical studies of sodium oxybate in the treatment of alcohol withd

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SODIUM OXYBATE ORAL SOLUTION C

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

Manufactured by:
Ascent Pharmaceuticals, Inc.
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

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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

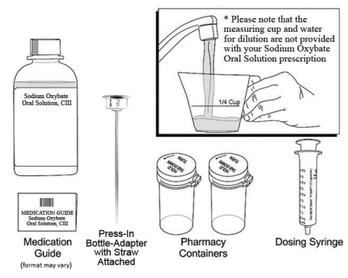

Figure A
Step 1: Setup

- 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.

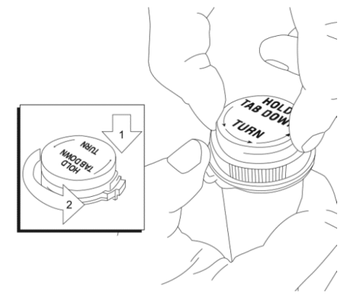

Figure B
Remove the tamper evident band by pulling at the perforations and then remove the bottle cap from the sodium oxybate oral solution bottle by pushing down while turning the cap counterclockwise. See Figure C.

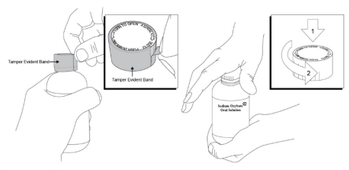

Figure C

- The press-in-bottle-adaptor may already be put in place by the pharmacy. If it is not already in place, you will have to do it yourself. After removing the cap from the sodium oxybate oral solution bottle, set the bottle upright on a tabletop.
- 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.

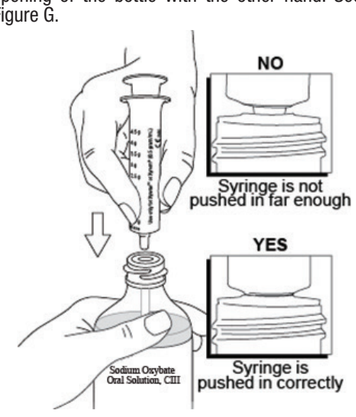

Figure G
Pull back on the plunger until the medicine flows into the syringe and the liquid level is lined up with the marking on the syringe that matches your dose. See Figure H.

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.

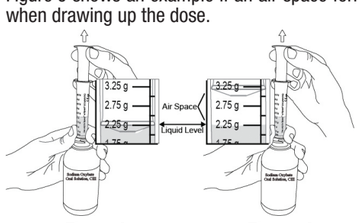

Figure I **Figure J**

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.

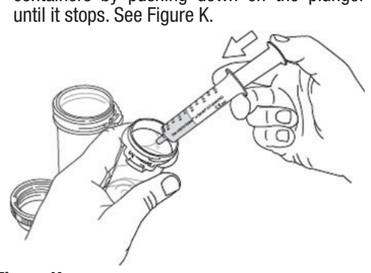

Figure K

- 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.

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 store 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.**

Manufactured by:
Ascent Pharmaceuticals Inc.
Central Islip, NY 11722

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

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