

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

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

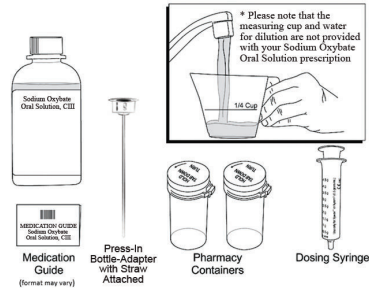


Figure A

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.

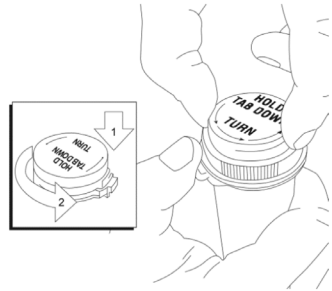


Figure B

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.

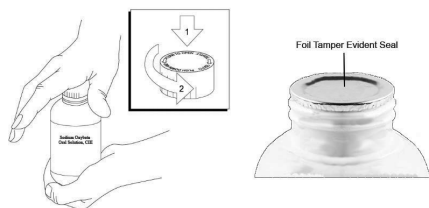


Figure C

- 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.

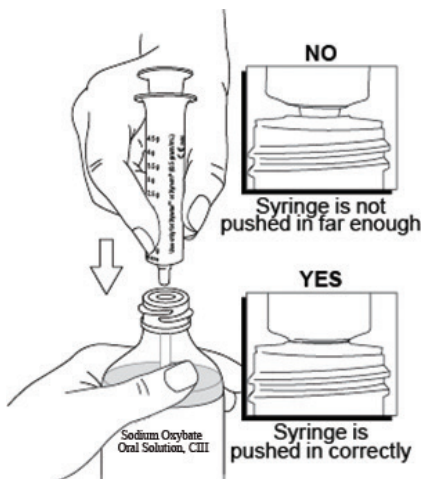


Figure G

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.

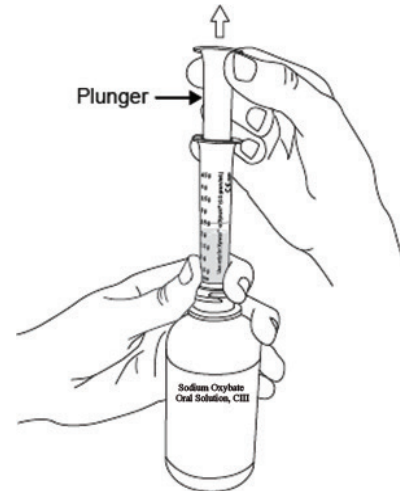


Figure H

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.

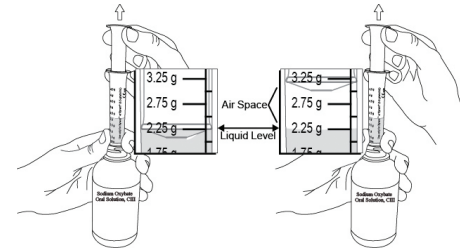


Figure I

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.

- 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.

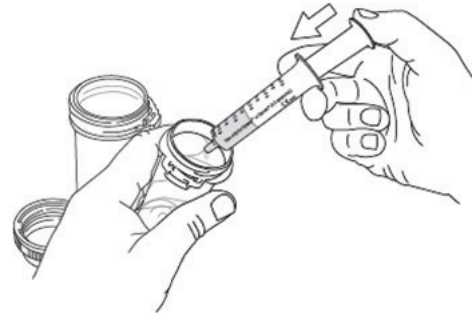


Figure K

- 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.

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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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