

MEDICATION GUIDE
Sodium Oxybate
Oral Solution, CIII

Read this Medication Guide carefully before you start or your child starts taking Sodium Oxybate Oral Solution and each time you get or your child gets a refill. There may be new information. This information does not take the place of talking to your doctor about your or your child's 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 or your child 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, or your child is, 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 or your child has 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 or your child.
- 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 central pharmacy in the XYWAV and XYREM REMS. You or your child must be enrolled in the XYWAV and XYREM REMS to receive Sodium Oxybate Oral Solution. For information on how to receive Sodium Oxybate Oral Solution visit www.XYWAVXYREMREMS.COM. Before you receive or your child receives 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 XYWAV and XYREM REMS at 1-866-997-3688.

What is Sodium Oxybate Oral Solution?

Sodium Oxybate Oral Solution is a prescription medicine used to treat the following symptoms in people 7 years of age or older 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 or your child:

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

Before taking Sodium Oxybate Oral Solution, tell your doctor about all medical conditions, including if you or your child:

- have a history of drug abuse.
- have short periods of not breathing while sleeping (sleep apnea)
- has trouble breathing or has lung problems. You or your child may have a higher chance of having serious breathing problems when taking Sodium Oxybate Oral Solution.
- have or had depression or has tried to harm yourself or themselves. You or your child 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 or your child.
- 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 Oral Solution passes into breast milk. You and your doctor should decide if you or your child will take Sodium Oxybate Oral Solution or breastfeed.

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

Especially, tell your doctor if you take or your child takes other medicines to help you or your child sleep (sedatives). Know the medicines you take or your child takes. Keep a list of them to show your doctor and pharmacist when you get or your child gets 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.
 - **Children:** Give the first Sodium Oxybate Oral Solution dose at bedtime or after an initial period of sleep, while your child is in bed and have them lie down immediately. Give 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 give the second Sodium Oxybate Oral Solution dose. Your child should remain in bed after taking the first and second doses of Sodium Oxybate Oral Solution.
- If you miss or your child misses 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 or your child takes 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 or your child has symptoms of mental health problems, or a change in weight or appetite.
- **sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you start or your child starts sleepwalking. Your doctor should check you or your child.

The most common side effects of Sodium Oxybate Oral Solution in adults include:

- | | |
|--------------|--------------|
| • nausea | • vomiting |
| • sleepiness | • bedwetting |
| • dizziness | • tremor |

The most common side effects of Sodium Oxybate Oral Solution in children include:

- | | |
|--------------|----------------------|
| • nausea | • weight decreased |
| • bedwetting | • decreased appetite |
| • vomiting | • dizziness |
| • headache | • sleepwalking |

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

Distributed By:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

For more information, go to www.XYWAVXYREMREMS.com or call the XYWAV and XYREM REMS at 1-866-997-3688.

This Medication Guide has been approved by the U.S. Food and Drug Administration

Issued: 9/2020

Instructions for Use Sodium Oxybate Oral Solution, CIII

Read this Instructions for Use carefully before you (or your child) start taking Sodium Oxybate Oral Solution and each time you (or your child) get a refill. There may be new information. This information does not take the place of talking to your doctor about your (or your child's) medical condition or treatment.

Important Information:

- You will need to split your (or your child's) 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 or give your child 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 (or giving your child) Sodium Oxybate Oral Solution. See Figure A:

- Bottle of Sodium Oxybate Oral Solution medicine
- Dosing syringe for measuring and dispensing the Sodium Oxybate Oral Solution dose
- Measuring cup that is able to measure about $\frac{1}{4}$ 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

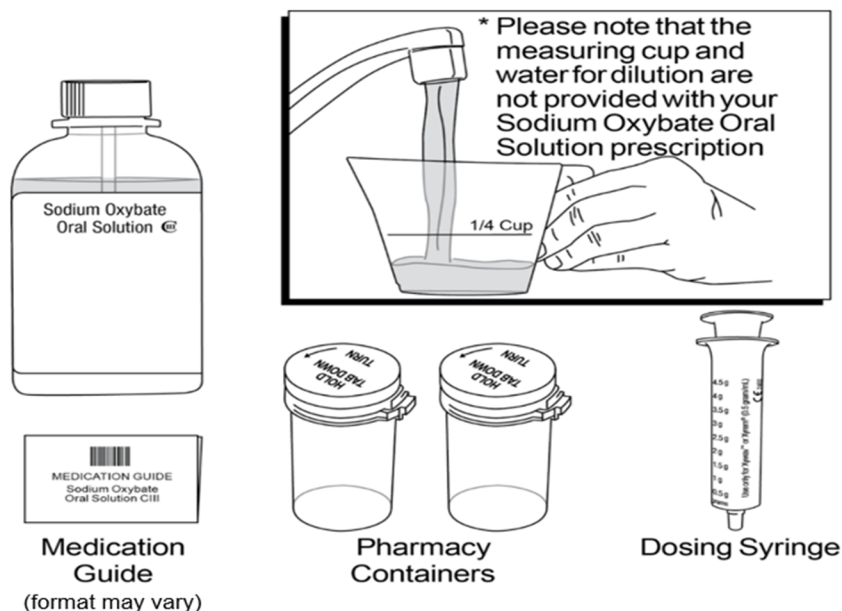


Figure A

Step 1: Setup

- Take the Sodium Oxybate Oral Solution bottle, 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 $\frac{1}{4}$ 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.

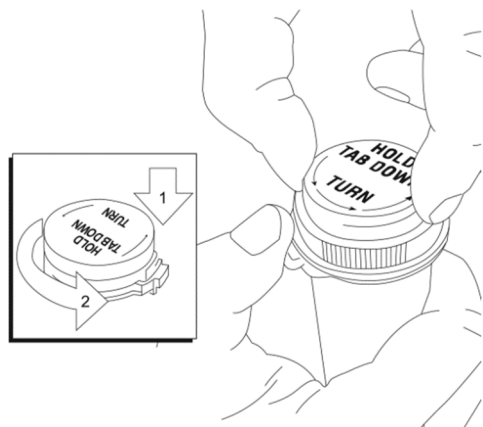


Figure B

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.

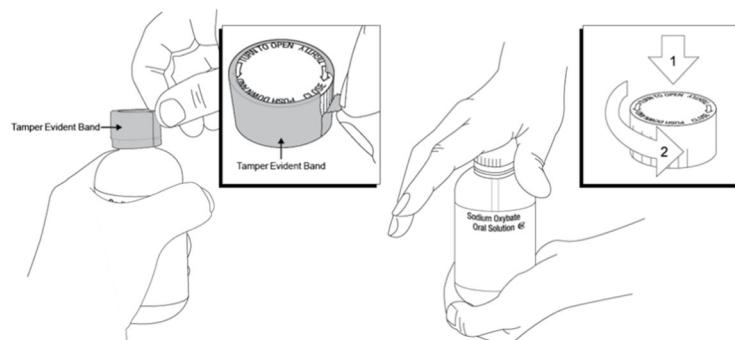


Figure C

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 D.

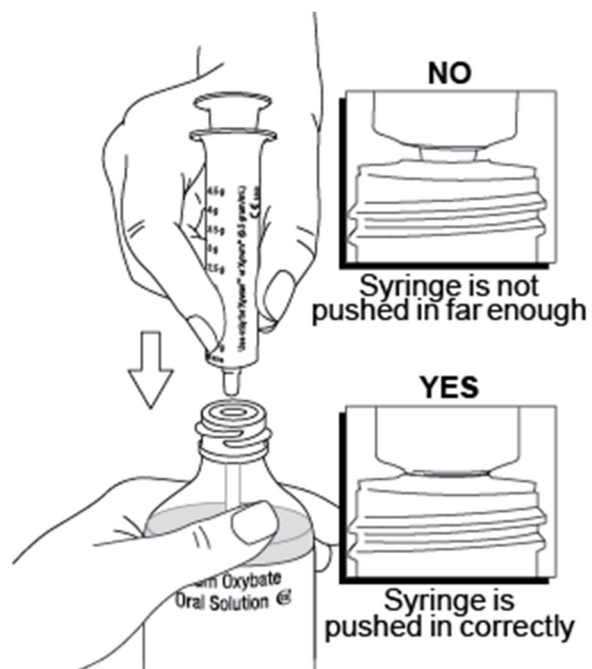


Figure D

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 you or your child's dose. See Figure E.

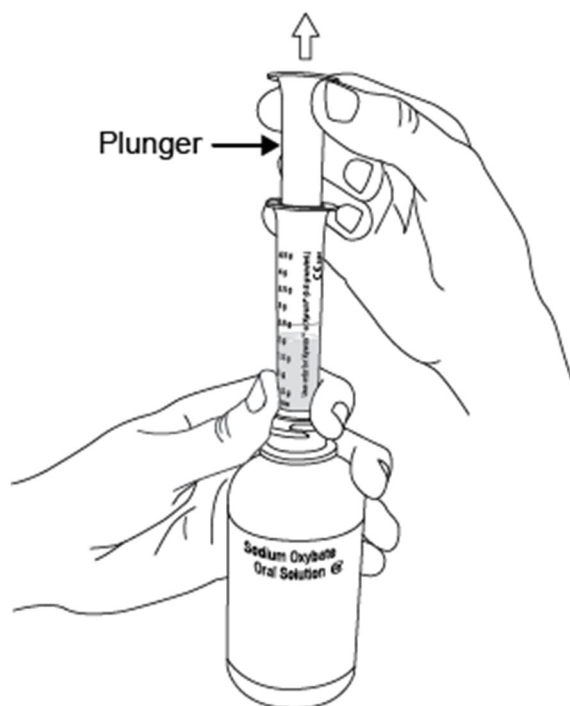


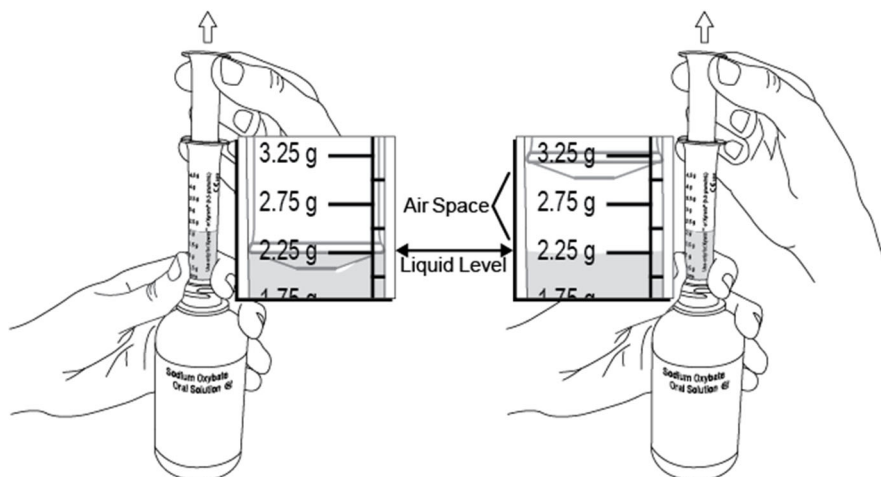
Figure E

Note: The Sodium Oxybate Oral Solution medicine will not flow into the syringe unless you keep the bottle upright.

Figure F shows an example of drawing up a Sodium Oxybate Oral Solution dose of 2.25 g. Figure G shows an example if an air space forms when drawing up the dose.

Figure F

Figure G



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 or your child's dose. See Figure G 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 H.

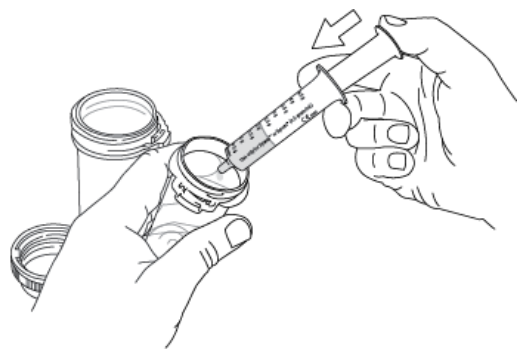


Figure H

- Using a measuring cup, pour about $\frac{1}{4}$ 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 I.
- Caution: the pharmacy container cap is reversible with a non-child resistant side. See Figure J. 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.

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

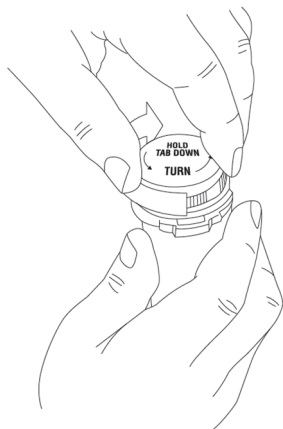


Figure I



Figure J

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 (or your child's) second dose:
 - emptying the syringe into the second pharmacy container
 - adding about $\frac{1}{4}$ 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 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 $2\frac{1}{2}$ 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 (or have your child 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 (or have your child lie down to sleep).
- You (or your child) 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 (or your child) 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 (or your child's) second dose of Sodium Oxybate Oral Solution, take the cap off the second pharmacy container.
- If you (or your child) 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 (or give your child) the second Sodium Oxybate Oral Solution dose.
- Drink (or have your child 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 (or have your child 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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