



GUIDE FOR PAEDIATRIC PATIENTS AND THEIR CAREGIVERS

IMPORTANT INFORMATION ABOUT SAFE USE AND HANDLING OF SODIUM OXYBATE 500 MG/ML ORAL SOLUTION (SODIUM OXYBATE)

KEEP THIS BOOKLET AS A HELPFUL REMINDER

If you have questions or need information, please call your child's doctor or healthcare professional.

WARNING: Sodium Oxybate 500 mg/ml oral solution can cause serious side effects. Your child should not drink alcohol or take other medicines that cause sleepiness.

Sodium Oxybate 500 mg/ml oral solution is a prescription medicine used to treat the following symptoms in people who fall asleep frequently during the day, often at unexpected times:

- Excessive daytime sleepiness (narcolepsy).
- Suddenly weak or paralyzed muscles when they feel strong emotions (cataplexy).

Important information about Sodium Oxybate 500 mg/ml oral solution includes the following:

- When taking Sodium Oxybate 500 mg/ml oral solution, your child should not drink alcohol or take other medicine that may slow his or her breathing or mental activity or make him or her sleepy. Your child could have serious side effects.

- Sodium Oxybate 500 mg/ml oral solution can cause serious side effects, including slow breathing or changes in alertness. Call your child's doctor right away if your child has any of these serious side effects.
- Sodium Oxybate 500 mg/ml oral solution has the potential for abuse and dependence. When Sodium Oxybate 500 mg/ml oral solution is stopped, especially when it is stopped suddenly, withdrawal symptoms can develop, such as insomnia, headache, anxiety, dizziness, sleep disorder, sleepiness, hallucination, and abnormal thinking.
- Whilst the doctor is adjusting the dose which may take a number of weeks, parent/caregivers should carefully monitor the child's breath during the first 2 hours after sodium



oxybate intake to assess if there is any abnormality in breathing, for example stoppage of breathing for short periods while sleeping, noisy breathing and bluish colour of the lips and face.

If abnormality in breathing is observed medical support should be sought and the doctor should be informed as soon as possible.

If any abnormality is noted after the first dose, the second dose should not be administered. If no abnormality is noted the second dose can be administered. The second dose should not be given earlier than 2.5 hours or later than 4 hours after the first dose.

- Your child should not do anything that requires him or her to be fully alert for at least the first 6 hours after taking Sodium Oxybate 500 mg/ml oral solution.
- Keep Sodium Oxybate 500 mg/ml oral solution out of the reach of children and pets. Get emergency medical help right away if a child who has not been prescribed Sodium Oxybate 500 mg/ml oral solution drinks Sodium Oxybate 500 mg/ml oral solution.

Report all side effects to your child's healthcare professional, including behavior changes, especially in school.

What will you find in this guide?

This guide answers important questions about how to use Sodium Oxybate 500 mg/ml oral solution properly, how to

store it safely, and how to get your child's Sodium Oxybate 500 mg/ml oral solution. It also gives you important information about Sodium Oxybate 500 mg/ml oral solution.

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PREPARATION AND ADMINISTRATION OF SODIUM OXYBATE 500 MG/ML ORAL SOLUTION

Sodium Oxybate 500 mg/ml oral solution should be prepared and taken only as prescribed by your doctor and pharmacist.

What will I get with my child's Sodium Oxybate 500 mg/ml oral solution prescription?

With each prescription, you will get 1 or more bottles of Sodium Oxybate 500 mg/ml oral solution, a Sodium Oxybate 500 mg/ml oral solution -specific dosing syringe for drawing up your child's Sodium Oxybate 500 mg/ml oral solution dose, 2 empty dosing cups with child-resistant caps, a press-in-bottle-adaptor and a printed Product Information Leaflet.

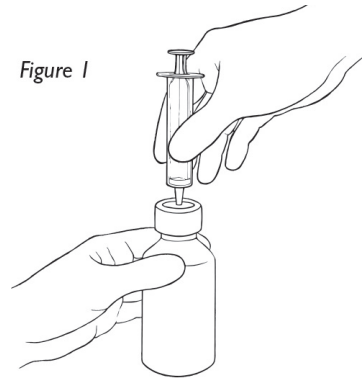
How do I prepare my child's doses?

It is important that you only use the syringe provided in the box when preparing doses of Sodium Oxybate 500 mg/ml oral solution.

Remove the bottle cap by pushing down while turning the cap anticlockwise (to the left). After removing the cap, set the bottle upright on a table-top. While holding the bottle in its upright position, insert the press-in-bottle-adaptor into the neck of the bottle. This needs only to be done the first time that the bottle is opened. The adaptor can then be left in the bottle for all subsequent uses

Next, insert the tip of the measuring syringe into the centre opening of the bottle and press down firmly (Figure 1).

Figure 1



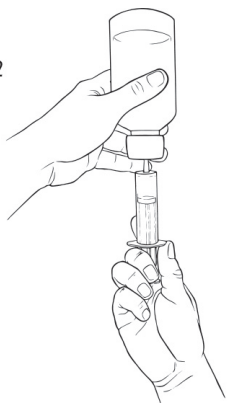
While holding the bottle and syringe with one hand, turn the bottle upside down. Fill the syringe with the prescribed dose by pulling the plunger back slowly to the correct line on the syringe. If air bubbles appear in the solution of the syringe, fill the syringe to a slight excess of the prescribed dose and remove all air bubbles from the syringe by tapping the syringe and pushing the plunger back into





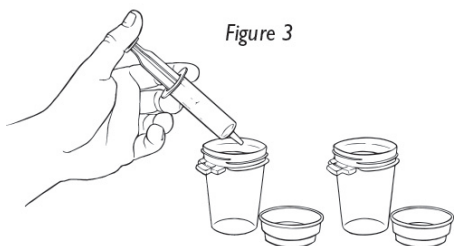
the syringe. Then, fill the syringe to the prescribed dose once air bubbles have been removed. **NOTE: Medicine will not flow into the syringe unless you keep the bottle in its upside-down position (Figure 2).**

Figure 2



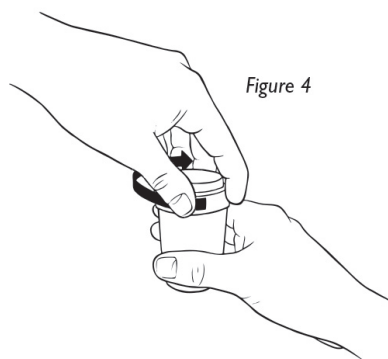
Put the bottle back in an upright position. Remove the syringe from the centre opening of the bottle. Empty the medicine from the syringe into one of the dosing cups provided by pushing on the plunger. Repeat this step for the second dosing cup. Then add about 60 ml of water to each dosing cup - 60 ml is about 4 tablespoons (Figure 3).

Figure 3



Place the caps provided on the dosing cups and turn each cap clockwise (to the right) until it clicks and locks into its child-resistant position (Figure 4).

Figure 4



Then put the 2 prepared doses in a safe place, out of the reach of children and pets until each is needed.

Rinse out the syringe and dosing cups with water after each use.

How do I give my child's doses?

Food will lower the amount of Sodium Oxybate 500 mg/ml oral solution that passes into your child's body. You should allow at least 2 hours after your child drinks or eats a meal before giving the first dose of Sodium Oxybate 500 mg/ml oral solution.

Sodium Oxybate 500 mg/ml oral solution is a medicine that can make your child sleepy quickly; therefore, give your child's doses while he or she is sitting up in bed and have your child lie down immediately after dosing and remain in bed. Ensure your child is fully prepared for bed prior to taking the first nightly dose of Sodium Oxybate 500 mg/ml oral solution (for example, has brushed teeth, gone to the bathroom).

Give the first dose at bedtime. Monitor the child's breathing during the first 2 hours after Sodium Oxybate 500 mg/ml





oral solution intake to assess if there is any abnormality in breathing, for example stoppage of breathing for short periods while sleeping, noisy breathing and bluish colour of the lips and face.

Give the second dose at the time prescribed by your doctor (2.5 to 4 hours after the first dose). Ensure that all Sodium Oxybate 500 mg/ml oral solution doses are kept in a safe place until given.

As with any medicine that causes sleepiness, if your child continues evening activities after taking his or her dose, such as watching television or walking around, your child may experience light-headedness, dizziness, nausea, confusion, or other unpleasant feelings. Have the child lie down immediately after dosing and remain in bed.

What do I do if my child misses a dose?

- It is very important to give both doses of Sodium Oxybate 500 mg/ml oral solution each night as prescribed.

If you forget to give your child the first dose, give it as soon as you remember and then continue as before.

If the second dose is missed, skip that dose.

- Do not give your child Sodium Oxybate 500 mg/ml oral solution again until the next night.
- Never give your child both Sodium Oxybate 500 mg/ml oral solution doses at once.

Any unused Sodium Oxybate 500 mg/ml oral solution doses that you prepared but

didn't give to your child must be safely stored and thrown away within 24 hours from the time you first prepared your child's doses if not used. Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

How soon will we see a change in symptoms?

After starting Sodium Oxybate 500 mg/ml oral solution, it may take a few weeks or longer to see your child's symptoms improve. It may also take time to find the right dose that works for your child.

During this time, when your child's doctor adjusts the dose, inform the doctor about any significant body weight change. If there are breathing troubles, lethargy or sedation tell your child's doctor straight away.

It is important that you talk with your child's doctor often when your child first starts taking Sodium Oxybate 500 mg/ml oral solution.

Tell your child's doctor if you or your child do not see any improvements.

What are the possible side effects of Sodium Oxybate 500 mg/ml oral solution?

Sodium Oxybate 500 mg/ml oral solution can cause serious side effects, including breathing problems (slower breathing, trouble breathing, and short periods of no breathing while asleep), mental health problems (confusion, seeing or hearing things that are not real, unusual



or disturbing thoughts, feeling anxious or upset, depression, thoughts of suicide), and sleepwalking. If your child has any of these side effects, call your child's doctor right away.

The most common side effects with Sodium Oxybate 500 mg/ml oral solution in paediatric patients are bedwetting, nausea, throwing up, and weight loss. Side effects may increase with higher doses.

These are not the only possible side effects with Sodium Oxybate 500 mg/ml oral solution. If you or your child are worried about any possible side effects Sodium Oxybate 500 mg/ml oral solution, talk with your child's doctor.

Are there any other precautions my child or I should take while on Sodium Oxybate 500 mg/ml oral solution?

- While taking Sodium Oxybate 500 mg/ml oral solution, your child should not drink alcohol or take medicines that cause sleepiness.
- When your child first starts taking Sodium Oxybate 500 mg/ml oral solution, or when the dose has been increased, you and your child will need to be careful until you know how Sodium Oxybate 500 mg/ml oral solution affects him or her.
- Before starting Sodium Oxybate 500 mg/ml oral solution, tell your child's doctor if your child is pregnant, at risk of becoming pregnant, or is breastfeeding.

Monitor the child's breath during the first 2 hours after Sodium Oxybate 500

mg/ml oral solution.

- Keep Sodium Oxybate 500 mg/ml oral solution in a safe place, out of the reach of children.
- Tell your child's doctor and pharmacist about any other medicines he or she is taking, including if your child begins a new medicine while taking Sodium Oxybate 500 mg/ml oral solution. This would include prescription and non-prescription medicines, vitamins, and supplements.
- It is also important to tell other healthcare professionals that your child is taking Sodium Oxybate 500 mg/ml oral solution before your child starts or changes any medications.

How often should my child's doctor check on my child's progress on Sodium Oxybate 500 mg/ml oral solution?

When your child first starts taking Sodium Oxybate 500 mg/ml oral solution, you may need to talk to his or her doctor often until he or she has determined the best dose for your child. You can expect that your child's dose may need to be adjusted. After your child's dose has been established, his or her doctor should check on your child at his/her discretion while taking Sodium Oxybate 500 mg/ml oral solution.

STORAGE AND SAFETY TIPS AT HOME

How do I store Sodium Oxybate 500 mg/ml oral solution?

Any questions? Please call your child's doctor





- Always store Sodium Oxybate 500 mg/ml oral solution in its original bottle.
- Store Sodium Oxybate 500 mg/ml oral solution at room temperature. Do not refrigerate Sodium Oxybate 500 mg/ml oral solution.
- Keep Sodium Oxybate 500 mg/ml oral solution in a safe place, out of the reach of children. Get emergency medical help right away if a child not prescribed Sodium Oxybate 500 mg/ml oral solution drinks Sodium Oxybate 500 mg/ml oral solution.

How do I properly dispose of Sodium Oxybate 500 mg/ml oral solution?

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

What if I have concerns about having Sodium Oxybate 500 mg/ml oral solution in my home?

- If your child's Sodium Oxybate 500 mg/ml oral solution is lost or stolen, report the incident right away to the local police and to the Pharmacy.
- Give Sodium Oxybate 500 mg/ml oral solution only as your child's doctor tells you. Remember that use of your child's Sodium Oxybate 500 mg/ml oral solution by others is illegal. If you have any questions or concerns, or if you need advice about Sodium Oxybate

500 mg/ml oral solution, call your child's doctor or the Pharmacy.

You can use these pages to help teach your young child what he or she needs to know about taking his or her Sodium Oxybate 500 mg/ml oral solution.

IMPORTANT INFORMATION YOUR CHILD MUST KNOW ABOUT TAKING SODIUM OXYBATE 500 MG/ML ORAL SOLUTION

Get Ready

- Get ready for bed before you drink your Sodium Oxybate 500 mg/ml oral solution.
- Finish your bedtime routine before you get in bed and drink your Sodium Oxybate 500 mg/ml oral solution.

Stay in Bed

- Drink your Sodium Oxybate 500 mg/ml oral solution while sitting up in bed. Lie down right away after you drink it and stay in bed.
- Call for a grown-up if you want to get out of bed after taking Sodium Oxybate 500 mg/ml oral solution.
- It may take a while, or you may fall asleep quickly after taking Sodium Oxybate 500 mg/ml oral solution.



Be Careful

- Be careful in the morning.
- Call for a grown-up to help you if you still feel sleepy in the morning.

Always Remember!

- Don't share your Sodium Oxybate 500 mg/ml oral solution with anyone else.
 - This medicine is only for you!
- Don't drink too much Sodium Oxybate 500 mg/ml oral solution.
 - Never drink more than one of your Sodium Oxybate 500 mg/ml oral solution cups at a time.
 - Only drink Sodium Oxybate 500 mg/ml oral solution from your Sodium Oxybate 500 mg/ml oral solution cup.
- Tell a grown-up how you are feeling and about any changes in how you are feeling.
- Tell a grown-up if you feel differently in school, if it is harder to learn or play with friends.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting side effects, you can help provide more information on the safety of this medicine.

Please also report to Laboratorio Reig Jofre, S.A. at:
pharmacovigilance@reigjofre.com; +34 934806710 (Spain)
Medinfouk@reigjofre.com (UK)

REIG  JOFRE

Laboratorio Reig Jofre, S.A. Guide for paediatric patients and their caregivers - Important information about safe use and handling of Sodium Oxybate 500 mg/ml oral solution, v1 May 2023.

