

## KEEP THIS BOOKLET AS A HELPFUL REMINDER

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

## 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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <http://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Side effects should also be reported to Neuraxpharm UK Ltd by:

**Email:** [pv-uk@neuraxpharm.com](mailto:pv-uk@neuraxpharm.com)

**Phone number:** +44 330 128 0919

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

# GUIDE FOR PAEDIATRIC PATIENTS AND THEIR CAREGIVERS

Important information  
about safe use and handling of  
Sodium oxybate 500 mg/ml oral solution

**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:

- When taking Sodium oxybate 500 mg/ml oral solution, your child should not drink alcohol or take other medicines 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 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.

- Patients usually fall asleep in about 5 to 15 minutes, although some patients have reported falling asleep more quickly (without first feeling drowsy) and others take more time. The time that it takes to fall asleep might be different from night to night. You should give each dose of Sodium oxybate 500 mg/ml oral solution while your child is sitting up in bed and have your child lie down immediately after.
- The first dose should be given at bedtime and the second should be given at the time prescribed by your healthcare professional, 2.5 to 4 hours after the first dose. You may need to set an alarm to awaken to give the second dose.

For children who sleep longer than 8 hours but less than 12 hours, the first dose may be given after the child has been sleeping for 1 to 2 hours. If in doubt about administration of a dose, do not re-administer the dose to reduce the risk of overdose.

- 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.

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 affects him or her.

- Keep Sodium oxybate 500 mg/ml oral solution out of the sight and reach of children and pets. Get emergency medical help right away if a child who has not been prescribed Sodium oxybate drinks this medicine.

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

**Any questions? Please call your child's doctor**

## 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.

## TABLE OF CONTENTS

### PREPARATION AND ADMINISTRATION OF SODIUM OXYBATE 500 mg/ml ORAL SOLUTION 5

What will I get with my child's Sodium oxybate 500 mg/ml oral solution prescription? 5

How do I prepare my child's doses? 5

How do I give my child's doses? 8

What do I do if my child misses a dose? 9

How soon will we see a change in symptoms? 9

What are the possible side effects of Sodium oxybate 500 mg/ml oral solution? 10

Are there any precautions my child or I should take while on Sodium oxybate 500 mg/ml oral solution? 10

### STORAGE AND SAFETY TIPS AT HOME 11

How do I store Sodium oxybate 500 mg/ml oral solution? 11

### IMPORTANT INFORMATION YOUR CHILD MUST KNOW ABOUT TAKING SODIUM OXYBATE 500 MG/ML ORAL SOLUTION 12

What should my child know about taking Sodium oxybate 500 mg/ml oral solution? 12-13

### INCLUDING YOUR CHILD IN HIS OR HER CARE 12-15

How can I prepare my child to be able to carry out one or more safe use activities? 12-15

## 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 healthcare professional. Your pharmacist will dispense Sodium oxybate 500 mg/ml oral solution upon presentation of the prescription.

### 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 specific measuring syringe for drawing up your child's Sodium oxybate dose, 2 empty dosing cups with child resistant caps, a press-in-bottle adapter and a printed Product Information Leaflet.

### How do I prepare my child's doses?

Always take this medicine exactly as your child's doctor or pharmacist has told you. Check with your child's doctor or Pharmacist if you are not sure.

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

#### STEP 1

Remove the bottle cap by pushing down while turning the cap anti-clockwise (to the left). After removing the cap, set the bottle upright on a table-top.

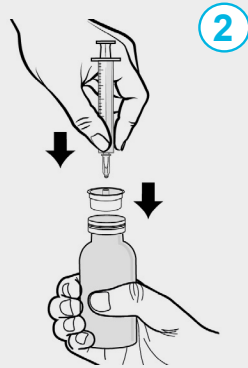
While holding the bottle in its upright position, insert the press-in bottle adaptor into the neck of the bottle. This needs only to be done the first time that the bottle is opened. The adaptor can then be left in the bottle for all subsequent uses.



**Any questions? Please call your child's doctor**

## STEP 2

Take the measuring syringe and insert the tip of the syringe into the centre opening of the bottle adaptor and press down firmly.



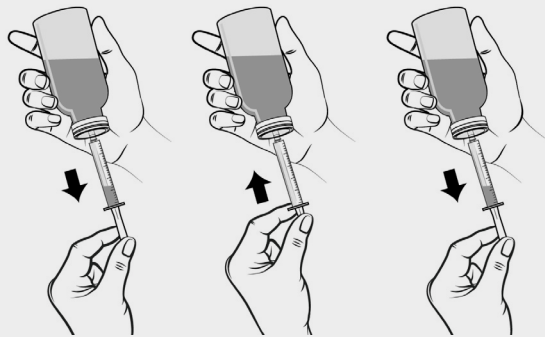
## STEP 3

Turn the bottle upside down.



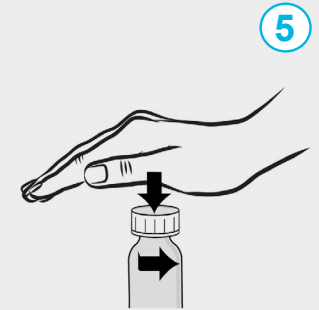
## STEP 4

Fill the measuring syringe with a small amount of solution by pulling the piston down, then push the piston upward in order to remove any possible bubbles. Finally, pull the piston down to the graduation mark corresponding to the quantity in grams (g) prescribed by your doctor.



## STEP 5

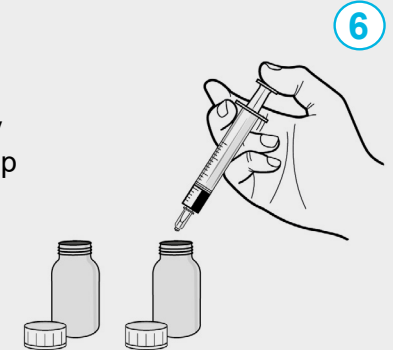
Turn the bottle the right way up before removing the measuring syringe from the adaptor. Remove the cap from the first dosing cup by pressing down on the child resistant locking tab and turning the cap anticlockwise (to the left).



## STEP 6

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).

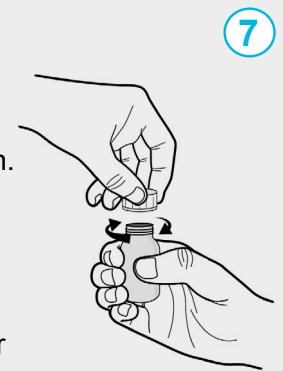


## STEP 7

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

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

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



**Any questions? Please call your child's doctor**

## How do I give my child's doses?

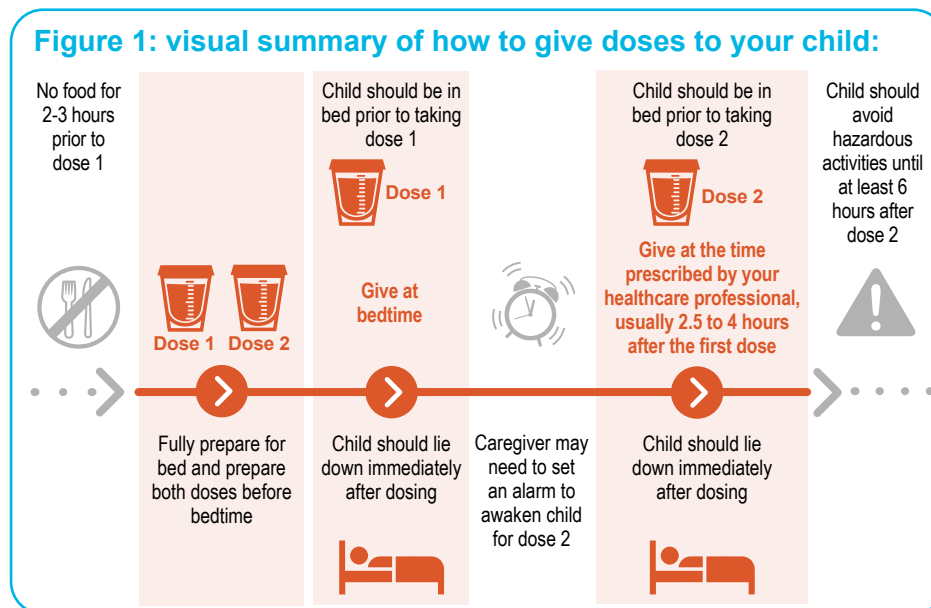
Food will lower the amount of Sodium oxybate 500 mg/ml oral solution that passes into your child's body. You should allow 2-3 hours after your child eats a meal before giving the first dose of Sodium oxybate 500 mg/ml oral solution.

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 (please refer to page 2-3 for further information).

Give the second dose at the time prescribed by your healthcare professional (2.5 to 4 hours after the first dose). Ensure that all Sodium oxybate 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 (Figure 1).



## 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 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 healthcare professional how to dispose of medicines you no longer use. These measures will help to protect the environment.

**Any questions? Please call your child's doctor**

### **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 healthcare professional often when your child first starts taking Sodium oxybate 500 mg/ml oral solution.

Tell your child's healthcare professional 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 healthcare provider right away.

If your child has had or is having upsetting feelings, particularly if he/she is feeling very sad or has lost interest in life, it is important that you talk with your child's doctor or healthcare professional.

The most common side effects with Sodium oxybate 500 mg/ml oral solution in paediatric patients are bedwetting, nausea, vomiting, and weight loss. Side effects may increase with higher doses. Tell your child's doctor straight away if he/she experiences any of these side effects.

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 with Sodium oxybate 500 mg/ml oral solution, talk with your child's doctor or healthcare professional.

### **Are there any additional precautions my child or I should take while on Sodium oxybate 500 mg/ml oral solution?**

- Before starting Sodium oxybate 500 mg/ml oral solution, tell your child's healthcare professional if your child is pregnant, or plans to become pregnant, or is breastfeeding. Sodium oxybate passes into breast milk.
- 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.
- While taking Sodium oxybate 500 mg/ml oral solution, your child should not drink alcohol or take medicines that causes sleepiness.
- 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 or healthcare professional 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.

**Any questions? Please call your child's doctor**

## STORAGE AND SAFETY TIPS AT HOME

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

- 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 sight and reach of children. Get emergency medical help right away if a child not prescribed Sodium oxybate drinks Sodium oxybate 500 mg/ml oral solution.

### Other safety tips

- 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 the following 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.**

**Any questions? Please call your child's doctor**

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.
- Finish your bedtime routine before you get in bed and drink your Sodium oxybate.



### → *Stay in Bed*

- Drink your Sodium oxybate 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.
- It may take a while, or you may fall asleep quickly after taking Sodium oxybate.



Any questions? Please call your child's doctor



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.

➔ **Be careful**

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



➔ **Always Remember!**

- Don't share your Sodium oxybate with anyone else
  - This medicine is only for you!
- Don't drink too much Sodium oxybate
  - Never drink more than one cup of your Sodium oxybate at a time
  - Only drink Sodium oxybate from your Sodium oxybate 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.



**Any questions? Please call your child's doctor**

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**Any questions? Please call your child’s doctor**