

Sodium oxybate 500 mg/ml oral solution

Important risk minimisation information for Patients: How to take Sodium oxybate 500 mg/ml oral solution Brochure.

The box contains one bottle of this medicine, a measuring syringe and adaptor, two dosing cups with caps for preparing and storing your two night time doses, and the Patient Information Leaflet.

It is important that you only use the syringe provided in the box when preparing doses of your medicine.

Please read the Patient Information Leaflet for additional important information before taking your first doses of this medicine. Always take it exactly as your doctor has told you.

If you have any additional questions or concerns please contact your doctor.

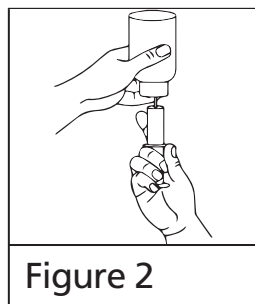
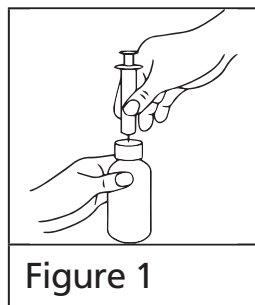
How to take Sodium Oxybate brochure, V2.0, July 2022. This information is part of the Risk Management Plan agreed with the MHRA.

Preparing Sodium oxybate 500 mg/ml oral solution

The following instructions explain how to prepare Sodium oxybate 500 mg/ml oral solution. Please read the instructions carefully and follow them step by step.

You will need to prepare both doses for bedtime.

1. 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.
2. Next, insert the tip of the measuring syringe into the centre opening of the bottle and press down firmly (See Figure 1).
3. While holding the bottle and syringe with one hand, turn the bottle upside down and draw up the prescribed dose with the other hand by pulling on the plunger. NOTE: Medicine will not flow into the syringe unless you keep the bottle in its upside down position (See Figure 2).



4. Put the bottle 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 (See Figure 3). Repeat these steps for the second dosing cup. Then add about 60 ml of water to each dosing cup (60 ml is about 4 tablespoons).

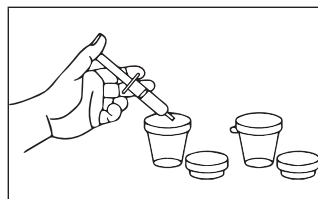


Figure 3

5. 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 (See Figure 4). Rinse out the syringe with water.

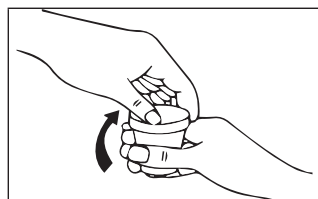


Figure 4

6. Just before going to sleep, place your second dose near your bed. You may need to set an alarm so you wake up to take your second dose no earlier than 2.5 hours and no later than 4 hours after your first dose. 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). Drink all of the first dose while sitting in bed, recap the cup, and then lie down right away.
7. When you wake up 2.5 to 4 hours later, remove the cap from the second dosing cup. While sitting in bed, drink all of the second dose right before lying down to continue sleeping. Recap the second cup.

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

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