

## IMPORTANT RISK MINIMISATION INFORMATION FOR PATIENTS: HOW TO TAKE SODIUM OXYBATE 500 MG/ML ORAL SOLUTION (SODIUM OXYBATE) BROCHURE.

Your Sodium Oxybate 500 mg/ml oral solution box contains one bottle of Sodium Oxybate 500mg/ml oral solution, an adaptor, a measuring syringe, two dosing cups with child resistant 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 Sodium Oxybate 500 mg/ml oral solution.

Please read the Patient Information Leaflet for additional important information before taking your first doses of Sodium Oxybate 500mg/ml oral solution. Always take Sodium Oxybate 500mg/ml oral solution exactly as your doctor has told you.

If you have any additional questions or concerns about Sodium Oxybate 500mg/ml oral solution, be sure to contact your physician.

### Preparing Sodium Oxybate 500mg/ml oral solution

You will need to prepare both doses for bedtime.

#### Step 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.

#### Step 2 (Figure 1)

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

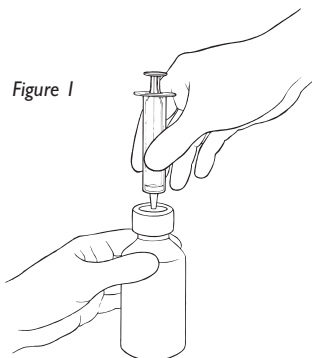


Figure 1

#### Step 3 (Figure 2)

While holding the bottle and syringe with each 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.**

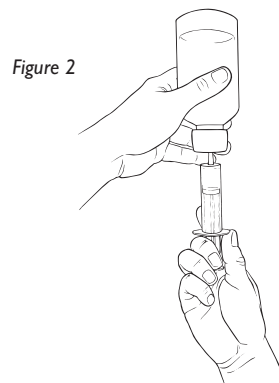


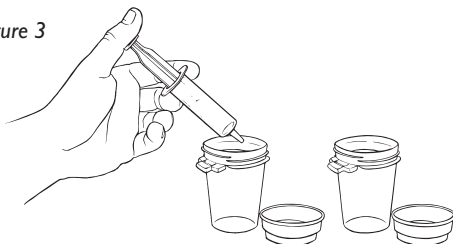
Figure 2



### Step 4 (Figure 3)

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



### Step 5 (Figure 4)

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. Rinse out the syringe with water.

Figure 4



### Step 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 the entire first dose while sitting in bed, recap the cup ensuring that the cap is turned clockwise (to the right) until it clicks and locks into the child-resistant position, and then lie down right away.

### Step 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 ensuring that the cap is turned clockwise (to the right) until it clicks and locks into the child-resistant position.

For more details about the information contained in this guide, please consult the Patient Information Leaflet in the Sodium Oxybate 500 mg/ml oral solution box and contact your physician or pharmacist.

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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. 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](http://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](mailto:pharmacovigilance@reigjofre.com); +34 934806710 (Spain) [Medinfouk@reigjofre.com](mailto:Medinfouk@reigjofre.com) (UK)

Laboratorio Reig Jofre, S.A. Instructions for patients on how to take Sodium Oxybate 500mg/ml oral solution, v2.0 May 2023.