

Important risk minimisation information for Patients: How to take Xyrem® (sodium oxybate) Brochure.

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, website: <http://yellowcard.mhra.gov.uk/> You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Please also report to UCB Pharma Ltd at UCBCares: +44(0) 1753 777100;
Email: UCBCares.UK@ucb.com (UK) or +353 1463 2371;
Email: UCBCares.IE@ucb.com (Ireland)

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

Your Xyrem® box contains one bottle of this product, a press-in-bottle-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.



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

If you have any additional questions or concerns about Xyrem®, be sure to contact your physician.

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This information is part of the Risk Management Program requested by the EMA 04-Dec-2014.



Preparing Xyrem®

You will need to prepare both doses for bedtime.

Step 1 (Figure 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. There is a plastic covered foil seal on the top of the bottle, which must be removed before using the bottle for the first time. 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.

Figure 1



Step 2 (Figure 2)

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

Figure 2



Step 3 (Figure 3)

While holding the bottle and syringe with one hand, 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 upright position.

Figure 3



Step 4 (Figure 4)

Remove the syringe from the centre opening of the bottle. Empty the medicine from the syringe into one of the dosing cups 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 4



Step 5 (Figure 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. Rinse out the syringe with water.

Figure 5



Step 6 (Figure 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, and then lie down right away.

Figure 6



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.

For more details about the information contained in this guide, please consult the Patient Information Leaflet in the Xyrem® box and contact your physician or pharmacist.