

GUIDE FOR PAEDIATRIC PATIENTS AND THEIR CAREGIVERS

Any questions? Please call your child's doctor

KEEP THIS BOOKLET AS A HELPFUL REMINDER

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

**IMPORTANT INFORMATION ABOUT
SAFE USE AND HANDLING OF XYREM®**

Guide For Paediatric Patients and Their Caregivers. v1.0 - GL-N-XR-NAR-2000007.

© Copyright UCB Biopharma SRL 2020 - All Rights Reserved.

This information is part of the Risk Management Programme requested
by the European Medicines Agency

IE-N-XR-NAR-2300001

**WARNING: XYREM® can cause serious side effects.
Your child should not drink alcohol or
take other medicines that cause sleepiness**

Xyrem® 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 XYREM® INCLUDES THE FOLLOWING:

- When taking Xyrem®, 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.
- Xyrem® 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.
- Xyrem® has the potential for abuse and dependence. When Xyrem® 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 Xyrem® 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 Xyrem®.

When your child first starts taking Xyrem®, or when the dose has been increased, you and your child will need to be careful until you know how Xyrem® affects him or her.

- Keep Xyrem® out of the reach of children and pets. Get emergency medical help right away if a child who has not been prescribed Xyrem® drinks Xyrem®.

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 Xyrem® properly, how to store it safely, and how to get your child's Xyrem®. It also gives you important information about Xyrem®.

TABLE OF CONTENTS

PREPARATION AND ADMINISTRATION OF XYREM®	6
What will I get with my child's Xyrem® prescription?	6
How do I prepare my child's doses?	7
How do I give my child's doses?	12
What do I do if my child misses a dose?	13
How soon will we see a change in symptoms?	14
What are the possible side effects of Xyrem®?	15
Are there any precautions my child or I should take while on Xyrem®?	16
STORAGE AND SAFETY TIPS AT HOME	17
How do I store Xyrem®?	17
IMPORTANT INFORMATION YOUR CHILD MUST KNOW ABOUT TAKING XYREM®	18
What should my child know about taking Xyrem®?	18-19
INCLUDING YOUR CHILD IN HIS OR HER CARE	18-21
How can I prepare my child to be able to carry out one or more safe use activities?	18-21

PREPARATION AND ADMINISTRATION OF XYREM®

Xyrem® should be prepared and taken only as prescribed by your healthcare professional. Your pharmacist will dispense Xyrem® upon presentation of the prescription.

WHAT WILL I GET WITH MY CHILD'S XYREM® PRESCRIPTION?

With each prescription, you will get 1 or more bottles of Xyrem®, a Xyrem®-specific dosing syringe for drawing up your child's Xyrem® dose, 2 empty dosing cups with child-resistant caps, a press-in-bottle-adaptor and a printed Product Information Leaflet (Figure 1).



Figure 1

Any questions? Please call your child's doctor

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 Xyrem®. The Xyrem® syringe has two different measurement scales, one scale may be more helpful when preparing your child's dose than the other depending on which dose your child's doctor has prescribed. By looking at each scale you will see which one provides the exact mark for your child's dose.

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 (See figure 2).



Figure 2

Next, insert the tip of the measuring syringe into the centre opening of the bottle and press down firmly (See figure 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 (See Figure 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 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 (See figure 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 (See Figure 6).



Figure 6

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?

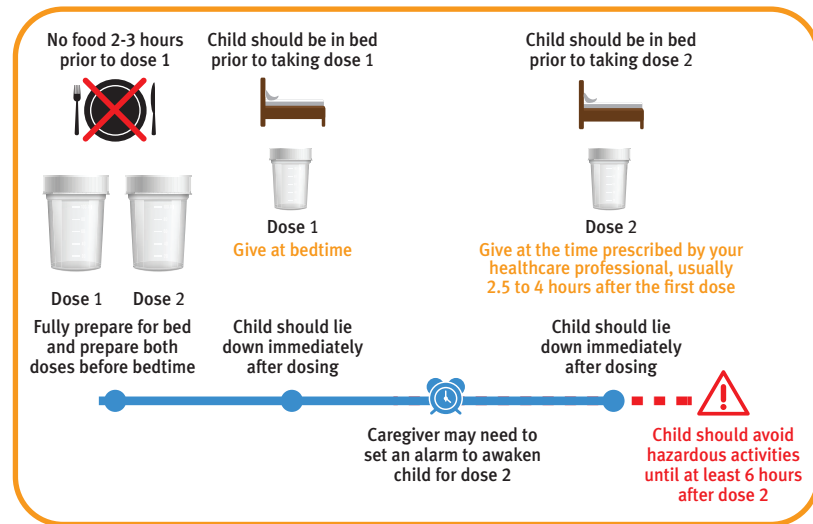
Food will lower the amount of Xyrem® that passes into your child's body. You should allow 2-3 hours after your child eats a meal before giving the first dose of Xyrem®.

Xyrem® 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 Xyrem® (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 Xyrem® 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 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 Xyrem® doses are kept in a safe place until given.

Figure 7



WHAT DO I DO IF MY CHILD MISSES A DOSE?

- It is very important to give both doses of Xyrem® 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 Xyrem® again until the next night
- Never give your child both Xyrem® doses at once

- Any unused Xyrem® 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.

HOW SOON WILL WE SEE A CHANGE IN SYMPTOMS?

After starting Xyrem®, 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 Xyrem®.

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

WHAT ARE THE POSSIBLE SIDE EFFECTS OF XYREM®?

Xyrem® 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 Xyrem® in paediatric patients are bedwetting, nausea, vomiting, weight loss, decreased appetite, headache, dizziness, suicidal thoughts and feeling mentally unwell. 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 Xyrem®. If you or your child are worried about any possible side effects with Xyrem®, talk with your child's doctor or health care professional.

ARE THERE ANY ADDITIONAL PRECAUTIONS MY CHILD OR I SHOULD TAKE WHILE ON XYREM®?

- Before starting Xyrem®, tell your child's healthcare professional if your child is pregnant, or plans to become pregnant, or is breastfeeding. Xyrem® passes into breast milk.
- 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 Xyrem®. 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 Xyrem® before your child starts or changes any medications.

STORAGE AND SAFETY TIPS AT HOME

HOW DO I STORE XYREM®?

- Always store Xyrem® in its original bottle.
- Store Xyrem® at room temperature. Do not refrigerate Xyrem®.
- Keep Xyrem® in a safe place, out of the reach of children. Get emergency medical help right away if a child not prescribed Xyrem® drinks Xyrem®.

You can use these pages to help teach your young child what he or she needs to know about taking his or her Xyrem®.

IMPORTANT INFORMATION YOUR CHILD MUST KNOW ABOUT TAKING XYREM®

Get Ready

- Get ready for bed before you drink your Xyrem®
- Finish your bedtime routine before you get in bed and drink your Xyrem®



Any questions? Please call your child's doctor



Stay in Bed

- Drink your Xyrem® 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 Xyrem®
- It may take a while, or you may fall asleep quickly after taking Xyrem®

You can use these pages to help teach your young child what he or she needs to know about taking his or her Xyrem®.

You can use these pages to help teach your young child what he or she needs to know about taking his or her Xyrem®.

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



NOTES

[illegible][illegible]