Talk About Cataplexy and Excessive Daytime Sleepiness (EDS) in Narcolepsy

Everybody with narcolepsy has EDS, but did you know that about 70% of people with narcolepsy also have cataplexy? Here’s a little more information about these 2 common symptoms of narcolepsy.

• What is EDS?
  EDS is characterized by the inability to stay awake and alert during the day, which causes an uncontrollable need for sleep or makes you feel very drowsy. It is the main symptom of narcolepsy.

• What is cataplexy?
  Cataplexy is characterized by suddenly weak or paralyzed muscles triggered by strong emotions. It can happen during positive or negative emotions, such as laughing out loud or feeling angry or stressed.

Also, did you know there are 2 types of narcolepsy? Based on your symptoms, your doctor determines which type of narcolepsy you have—narcolepsy type 1 (narcolepsy with cataplexy) or narcolepsy type 2 (narcolepsy without cataplexy).

XYREM® (sodium oxybate) oral solution, 0.5 g/mL is a prescription medicine used to treat the following symptoms in people 7 years of age or older with narcolepsy:
  • sudden onset of weak or paralyzed muscles (cataplexy)
  • excessive daytime sleepiness (EDS)

Important Safety Information

WARNING: Taking XYREM with other Central Nervous System (CNS) depressants such as medicines used to make you or your child fall asleep, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol, or street drugs, may cause serious medical problems, including trouble breathing (respiratory depression), low blood pressure (hypotension), changes in alertness (drowsiness), fainting (syncope), and death.

The active ingredient of XYREM is a form of gamma hydroxybutyrate (GHB). Abuse or misuse of illegal GHB alone or with other CNS depressants (drugs that cause changes in alertness or consciousness) have caused serious side effects. These effects include seizures, trouble breathing (respiratory depression), changes in alertness (drowsiness), coma, and death. Call your doctor right away if you or your child has any of these serious side effects.

Because of these risks, you have to go through the XYWAV and XYREM REMS. You or your child must be enrolled in the XYWAV and XYREM REMS to receive XYREM.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED Warning, and Medication Guide.
Talk About Your ESS and SNS Scores

The Epworth Sleepiness Scale (ESS) and Swiss Narcolepsy Scale (SNS) are 2 questionnaires that can help your healthcare provider assess your symptoms. So share your scores at your visit. You can get your scores by taking the ESS and SNS questionnaires here.

• What do ESS scores mean?
  Higher ESS scores are associated with more daytime sleepiness.

• What do SNS scores mean?
  Negative SNS scores (ie, less than 0) are associated with a greater possibility of narcolepsy with cataplexy.

Talk About XYREM as a Treatment Option

XYREM is approved by the US Food and Drug Administration (FDA) for treating both cataplexy and EDS in narcolepsy.

• Approved by the FDA in 2002 for treating cataplexy in narcolepsy in adults, in 2005 for treating EDS in narcolepsy in adults, and in 2018 for treating cataplexy and EDS in narcolepsy in patients ages 7 years and older
• Prescribed to more than 64,000 patients as of 2018

Please see the list of questions below to help facilitate a more informed conversation with your healthcare provider. Some important information is provided here, but your healthcare provider may be able to give you more in-depth and personalized answers.

• What does my narcolepsy diagnosis mean?
  The diagnosis of narcolepsy type 1 (with cataplexy) or narcolepsy type 2 (without cataplexy) can only be made by a healthcare provider.

• Is XYREM effective for the symptoms I have?
  XYREM is FDA-approved for the treatment of cataplexy and EDS in narcolepsy. In clinical studies, XYREM significantly reduced the frequency of cataplexy attacks compared with placebo at 4 weeks of treatment. It also significantly reduced EDS as measured by ESS score at 8 weeks of treatment.

• How will I know if XYREM is working for me?
  To see if XYREM is working for you, consult with your healthcare provider. Together you can determine the best way to track your progress over time. You can compare your ESS scores from before and during treatment, you can evaluate any reduction in cataplexy events, or you can watch for personal benchmarks, like not falling asleep during a meeting or a movie.

Important Safety Information

Do not take XYREM if you take or your child takes other sleep medicines or sedatives (medicines that cause sleepiness), drink alcohol, or have a rare problem called succinic semialdehyde dehydrogenase deficiency.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED Warning, and Medication Guide.
Talk About XYREM as a Treatment Option (continued)

- **What are the most common side effects of XYREM?**

  The most common side effects of XYREM in adults include nausea, sleepiness, dizziness, vomiting, bedwetting, and tremor. The most common side effects of XYREM in children include, nausea, bedwetting, vomiting, headache, weight decreased, decreased appetite, dizziness and sleepwalking. Your side effects may increase when you take higher doses of XYREM. XYREM can cause physical dependence and craving for the medicine when it is not taken as directed. These are not all the possible side effects of XYREM. See Important Safety Information for more about possible side effects.

- **How frequently do I need to take XYREM?**

  XYREM is a liquid that is taken at night divided into 2 doses. You take your first dose once you are in bed for the night and at least 2 hours after eating. Then, 2½ to 4 hours later, you take your second dose, while still in bed. Never take both XYREM doses at the same time. See the Medication Guide for more about taking XYREM.

- **Are there any medical or lifestyle restrictions when taking XYREM?**

  Do not drink alcohol or take other medicines that help you sleep or cause drowsiness at any time during XYREM treatment. Doing so may result in very severe sleepiness and trouble breathing. Also, do not drive, operate heavy machinery, or do any other activity that requires you to be fully awake or is dangerous for at least 6 hours after taking XYREM. Make a list of any medications you take and share it with your healthcare provider, so he or she can advise you on taking or stopping them.

- **What else do I need to know about XYREM?**

  This will give your healthcare provider the opportunity to share any additional information or advice he or she thinks is important based on your medical history.

- **Is there any support for people taking XYREM?**

  A range of support options is available for XYREM patients. JazzCares® for XYREM offers access to information, resources, and support programs, including the chance to connect with a fellow XYREM patient to learn more about treatment. Nurse Case Managers at the Certified Pharmacy are another resource for XYREM information. Also, Jazz Pharmaceuticals is committed to making sure that those who may benefit from XYREM can affordably get it. Several different options are available for qualified patients. Ask your healthcare provider and visit XYREM.com to find the support you need.

**Important Safety Information**

Keep XYREM in a safe place to prevent abuse and misuse. Selling or giving away XYREM may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Anyone who takes XYREM should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery, or flying an airplane, for at least 6 hours after taking XYREM. Those activities should not be done until you know how XYREM affects you or your child.

Falling asleep quickly, including while standing or while getting up from the bed, has led to falls with injuries that have required some people to be hospitalized.

**XYREM can cause serious side effects, including the following:**

- **Breathing problems, including** slower breathing, trouble breathing, and/or short periods of not breathing while sleeping (sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they take XYREM.

- **Mental health problems, including** confusion, seeing or hearing things that are not real (hallucinations), unusual or disturbing thoughts (abnormal thinking), feeling anxious or upset, depression, thoughts...
of killing yourself or trying to kill yourself, increased tiredness, feelings of guilt or worthlessness, and difficulty concentrating. Tell your doctor if you or your child have or had depression or have tried to harm yourself or themselves. **Call your doctor right away if you have or your child has symptoms of mental health problems or a change in weight or appetite.**

- **Sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you or your child starts sleepwalking. Your doctor should check you or your child.

Tell your doctor if you are or your child is on a salt-restricted diet or if you have or your child has high blood pressure, heart failure, or kidney problems. XYREM contains a lot of sodium (salt) and may not be right for you or your child.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.