

Xyrem® (sodium oxybate) – First-Time Generic

- On January 17, 2017, the [FDA announced](#) the [approval](#) of an [AA-rated](#) generic version of Jazz Pharmaceuticals' [Xyrem \(sodium oxybate\)](#) oral solution for the treatment of cataplexy in narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in narcolepsy.
 - The launch of generic Xyrem oral solution is delayed due to ongoing patent litigations and is based on court decisions.
 - Roxane/West-Ward Pharmaceuticals has been granted 180-days of exclusivity.
- Xyrem carries a boxed warning for central nervous system depression and misuse and abuse.
- The use of Xyrem has been associated with serious side effects including seizures, trouble breathing, changes in alertness, coma, and death. Additionally, sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB). GHB has not been approved for any medical use and has the potential for abuse, such as in cases of sexual assault.
 - GHB is a Schedule I controlled substance while sodium oxybate is a Schedule III controlled substance.
- The FDA's approval of generic sodium oxybate is subject to a [Risk Evaluation and Mitigation Strategy \(REMS\)](#) with strict safety controls that are comparable to those currently required for brand Xyrem.
- Specifically, under both the Xyrem REMS and the generic sodium oxybate REMS, sodium oxybate can be prescribed only by a certified prescriber, and dispensed only to an enrolled patient by a certified pharmacy. Only a certified pharmacy that ships directly to patients can dispense sodium oxybate. Sodium oxybate will not be available in retail pharmacies.
- There are some differences in the operational aspects of the brand Xyrem and the generic sodium oxybate REMS.
 - The Xyrem REMS uses a single pharmacy and a single database to verify the safe use conditions required prior to dispensing the drug.
 - The generic sodium oxybate REMS uses multiple certified pharmacies and multiple databases that are connected via an electronic telecommunication verification mechanism known as a "switch system," which verifies in real-time the same safe use conditions as the Xyrem REMS prior to dispensing the drug.
- The generic sodium oxybate REMS will require the certified pharmacy to contact the Xyrem REMS program to verify that the patient has no other active prescriptions for Xyrem that overlap with the prescription to be filled, and to identify any patient and prescriber dis-enrollments from the Xyrem REMS for suspected abuse, misuse or diversion.

- A certified pharmacy in the generic sodium oxybate REMS also will provide corresponding information to the Xyrem REMS program, so that the Xyrem REMS certified pharmacy can include that information in its central database and verify prescriptions and enrollment status against the generic sodium oxybate REMS system.



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