

PVC Drug Safety Communication: FDA Warning against use of Xyrem (sodium oxybate) with alcohol or drugs causing respiratory depression
20 Dec 2012

Pharmacy, Patient Safety, Neurology and Internal Medicine communities:

Please share with pharmacists and providers at your MTFs and regions.

The FDA issued a reminder to healthcare professionals and patients that the combined use of Xyrem (sodium oxybate) with alcohol or central nervous system (CNS) depressant drugs can markedly impair consciousness and may lead to severe breathing problems (respiratory depression). The use of alcohol with Xyrem is a new contraindication added to the Xyrem label, which already contraindicates its use with insomnia drugs. The use of Xyrem with other CNS depressant drugs (drugs that affect the CNS and may lead to breathing problems) such as opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, general anesthetics, and muscle relaxants should generally be avoided. The use of Xyrem along with these products or other CNS depressants increases the risk of breathing problems that may lead to loss of consciousness, coma, and death.

BACKGROUND: Xyrem (sodium oxybate) is FDA-approved to reduce attacks of muscle weakness (cataplexy) and treat daytime sleepiness in patients with narcolepsy. Sodium oxybate, the active ingredient of Xyrem, is also known as gamma-hydroxybutyrate (GHB). GHB is a known drug of abuse that has been associated with central nervous system (CNS) adverse events, including death. Even at recommended doses, Xyrem can cause confusion, depression, and other neuropsychiatric events.

XYREM USE IN DOD: Overall, use of Xyrem in the DOD is very low. There were approximately 1,100 patients who received a prescription for Xyrem or sodium oxybate in the 6-year period (FY06--FY11), approximately 400 individuals annually.

RECOMMENDATION: Healthcare professionals are urged to follow the dosing recommendations, contraindications, and boxed warning in the updated Xyrem drug label and to avoid drug combinations that raise the risk of respiratory depression and death. Patients taking Xyrem should not drink alcohol or take insomnia drugs. The entire FDA Drug Safety Communication is available at:

<http://www.fda.gov/Drugs/DrugSafety/ucm332029.htm>

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

www.fda.gov/MedWatch/report.htm

QUESTIONS OR ADDITIONAL INFORMATION: Send requests for additional information regarding this alert or the analysis conducted by the Pharmacovigilance Center (PVC) to: otsg.pvc@amedd.army.mil