Generic Name:
Sodium oxybate
Trade Name:
Xyrem
Company:
Jazz Pharmaceuticals
Notes:

FDA approved sodium oxybate for treatment of cataplexy and excessive daytime sleepiness in pediatric patients (aged 7?17 y) with narcolepsy.

Sodium oxybate is a central nervous system (CNS) depressant approved in 2002 for treatment of cataplexy in adult patients with narcolepsy. Cataplexy is a sudden and transient episode of muscle weakness accompanied by full conscious awareness, typically triggered by emotions such as laughing, crying, or terror.

Sodium oxybate either alone or in combination with other CNS depressants may be associated with adverse reactions that include seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Rapid onset of sedation, coupled with amnesia, particularly when combined with alcohol, has posed risks for voluntary and involuntary users (e.g., assault victims).

The agent is contraindicated in patients being treated with sedative hypnotic agents and in patients with succinic semialdehyde dehydrogenase deficiency. In addition, patients should not drink alcohol when using Sodium oxybate. Succinic semialdehyde deficiency is a rare inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia.

The most common adverse reactions in pediatric patients were bed-wetting, nausea, headache, vomiting, weight decrease, decreased appetite, and dizziness.

The following adverse reactions have been identified during postapproval use of sodium oxybate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: joint pain, decreased appetite, fall, fluid retention, hangover, headache, hypersensitivity, hypertension, memory impairment, nocturia, panic attack, vision blurred and weight decreased.

Because of the risk of serious outcomes resulting from inappropriate prescribing, misuse, abuse and diversion, sodium oxybate is only available through a risk evaluation mitigation strategy (REMS) programs.

Medication Monitor Categories:
Supplemental Approvals