

XYWAV ORAL SOLUTION (calcium, magnesium, potassium, and sodium oxybates)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xywav is a central nervous system (CNS) depressant. Xywav is a mixture of calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate (gamma-hydroxybutyrate). Gamma-hydroxybutyrate is an endogenous compound and metabolite of the neurotransmitter GABA. Xywav is thought to exert its therapeutic effects through GABA_B actions during sleep at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons (1).

Regulatory Status

FDA-approved indications: Xywav is a central nervous system depressant indicated for the treatment of: (1)

1. Cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
2. Idiopathic Hypersomnia (IH) in adults.

Xywav includes a boxed warning regarding central nervous system depression and misuse and abuse. Because of the risks of CNS depression, abuse, and misuse, Xywav is available only through a restricted distribution program called the Xywav and Xyrem REMS program, using a centralized pharmacy. Prescribers and patients must enroll in the program (1).

Xywav is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency and in combination with sedative hypnotics or alcohol (1).

Safety and effectiveness of Xywav for the treatment of cataplexy or EDS in pediatric patients less than 7 years of age have not been established. Safety and effectiveness of Xywav for the treatment of idiopathic hypersomnia in pediatric patients have not been established (1).

Summary

Xywav is indicated for use in patients with cataplexy or EDS in narcolepsy and in patients with idiopathic hypersomnia. Due to the potential for abuse and misuse, Xywav is only available through the Xywav and Xyrem REMS program. Safety and effectiveness of Xywav for the treatment of



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Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Xywav while maintaining optimal therapeutic outcomes.

References

1. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.