

Sodium oxybate extended-release suspension: Adis Evaluation

Clinical Considerations

- Oral ER suspension taken once at bedtime, avoiding the need for a second, middle-of-the-night dose
- First once-nightly sodium oxybate formulation approved for the treatment of narcolepsy
- Reduces cataplexy and excessive daytime sleepiness, and improves disrupted nighttime sleep compared with placebo
- Generally well tolerated

Plain Language Summary

Background and rationale

- Narcolepsy, a disorder of sleep-wake instability, is a lifelong condition characterized primarily by overwhelming and persistent daytime sleepiness. Other symptoms include sudden muscle weakness associated with strong emotions (cataplexy), disturbed nighttime sleep, sleep paralysis, and vivid hallucinations when falling asleep or when awakening
- The standard of care for patients with narcolepsy has been sodium oxybate, which requires twice-nightly dosing. Patients take their first dose at bedtime and must then awaken 2.5–4 h later to take their second dose
- A less burdensome once-nightly formulation, sodium oxybate extended-release suspension (LUMRYZ™; hereafter referred to as sodium oxybate ER), has been approved for the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy

Clinical findings

- In a clinical trial, patients treated with once-nightly sodium oxybate ER were able to stay awake longer during the day, felt less sleepy in the daytime, had fewer cataplexy attacks, and had less disruption to nighttime sleep than placebo recipients
- Sodium oxybate ER was generally well tolerated. Nausea, dizziness, bed-wetting, headache and vomiting were the most common treatment-related adverse events

Conclusion

Once-nightly sodium oxybate ER represents a promising new option for the treatment of narcolepsy.

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