Lumryz™ (sodium oxybate) – Expanded indication

- On October 17, 2024, Avadel Pharmaceuticals announced the FDA approval of Lumryz (sodium oxybate) extended-release oral suspension, for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
    - Lumryz was previously approved in adults only.
- The effectiveness of Lumryz in pediatric patients is based upon a clinical study in patients treated with immediate-release sodium oxybate.
- Lumryz carries a boxed warning for central nervous system depression and abuse and misuse.
- The most common adverse reactions (≥ 5%) with immediate-release sodium oxybate use in pediatric patients were nausea, enuresis, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking.
- The recommended starting dosage of Lumryz in pediatric patients 7 years and older weighing at least 45 kg is 4.5 g once per night administered orally. The dosage should be increased by 1.5 g per night at weekly intervals to the maximum recommended dosage of 9 g once per night orally. The dosage may be gradually titrated based on efficacy and tolerability.
- Because the recommended starting dosage in pediatric patients 7 years and older weighing less than 45 kg cannot be achieved with the available strengths of Lumryz, another sodium oxybate product should be used to initiate treatment. Refer to the drug labels of other sodium oxybate products for the recommended dosage for those products. The maximum recommended dosage for patients 7 years and older weighing 20 kg to < 30 kg is 6 g once per night orally, and the maximum recommended dosage for patients 7 years and older weighing 30 kg to < 45 kg is 7.5 g once per night orally.
    - There is insufficient information to provide specific dosing recommendations for patients 7 years and older who weigh less than 20 kg.
- Refer to the Lumryz drug label for adult dosing.