

Libervant[™] (diazepam) – New drug approval

- On April 26, 2024, the FDA approved Aquestive Therapeutics' [Libervant \(diazepam\)](#) buccal film, for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age.
- Libervant is the first FDA approved orally-administered rescue product for the treatment of seizure clusters.
 - Diazepam is available in several other formulations, including a nasal spray, oral solution, tablet, rectal gel, and injection.
- The efficacy of Libervant was supported by evidence from adequate and well-controlled studies of diazepam rectal gel in adult and pediatric patients, adult bioavailability studies comparing Libervant with diazepam rectal gel, adult and pediatric Libervant pharmacokinetic data, and an open-label safety study of Libervant including patients 2 years to 5 years of age.
- Libervant carries a boxed warning for risks from concomitant use with opioids; abuse, misuse, and addiction; and dependence and withdrawal reactions.
- Libervant is contraindicated in patients with:
 - Hypersensitivity to diazepam
 - Acute narrow-angle glaucoma.
- Additional warnings and precautions for Libervant include central nervous system depression; suicidal behavior and ideation; glaucoma; neonatal sedation and withdrawal syndrome; and risk of serious adverse reactions in infants due to benzyl alcohol preservative.
- The most common adverse reactions (> 4%) with Libervant use were somnolence and headache.
- The recommended dose of Libervant is 5 mg to 15 mg orally, dependent on the patient's weight. A second dose, when required, may be administered at least 4 hours after the first dose.
 - More than 2 doses of Libervant should not be used to treat a single episode.
 - More than one episode should not be treated with Libervant every five days or more than five episodes per month.
- Aquestive Therapeutics' launch plans for Libervant are pending. Libervant will be available as 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg buccal films.