

Valtoco[®] (diazepam) – Expanded indication

- On April 16, 2025, [Neurelis announced](#) the FDA approval of [Valtoco \(diazepam\)](#), 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 years of age and older**.
 - Valtoco was previously approved for this indication in patients 6 years of age and older.
- The use of Valtoco in this age group is supported by evidence from adequate and well-controlled studies of diazepam rectal gel in adult and pediatric patients, adult bioavailability studies comparing Valtoco with diazepam rectal gel, patient pharmacokinetic data, and open-label safety studies of Valtoco including patients 2 years to 16 years of age.
- Valtoco carries a boxed warning for risks from concomitant use with opioids; abuse, misuse, and addiction; and dependence and withdrawal reactions.
- The recommended dose of Valtoco nasal spray is 0.2 mg/kg to 0.5 mg/kg, depending on the patient's age and weight. Refer to the drug label for specific recommendations.



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