



# TEAM UP

with VALTOCO® (diazepam nasal spray)



## Together, we can change the seizure cluster rescue experience at school

**VALTOCO is the ONLY nasal seizure rescue medication for students 6 years and older with episodes of frequent seizures<sup>1</sup>**

- ◆ **DISCREET** and **EASY TO USE** at a moment's notice<sup>1,2</sup>—head can be in any position, no clothing removal required
- ◆ Designed for **PROMPT** administration by anyone, anywhere—from the classroom to the playground\*
- ◆ **EMPOWERS** nurses like you, teachers, and other staff members to administer VALTOCO confidently

### A 12-month, open-label, repeat-dose safety study found:

**Rapid**



**4-minute median time** from administration to seizure cessation<sup>3,†,‡</sup>

- ◆ Seizures treated in the first 5 minutes with VALTOCO stopped within a median of 2 minutes<sup>4</sup>

**Reliable**



87% of seizure episodes used a **single dose** over a 24-hour period<sup>5,†</sup>

- ◆ 89% of seizure episodes in patients aged 6 to 17 years<sup>6</sup>

**Ready**



A majority of patients returned to their usual selves **within 1 hour** of administration<sup>7§</sup>

- ◆ Treatment-related somnolence was reported in 1.8% of patients<sup>5</sup>

\*Patients and care partners should read the Instructions for Use before using VALTOCO.

†This was an exploratory analysis; the study did not have prespecified efficacy endpoints.<sup>5</sup>

‡Median time to seizure cessation of 4 minutes (range, -1-1151 minutes).<sup>3</sup>

§59% of patients returned to their usual selves within 60 minutes of administration of VALTOCO as recorded in patient and caregiver surveys.<sup>7</sup>

To learn more about advocating for **THE COMPASSIONATE CHOICE** for your students this school year, scan the QR code or visit [VALTOCOHCP.com](http://VALTOCOHCP.com)



#### Indication

VALTOCO® (diazepam nasal spray) is indicated 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 6 years of age and older.

#### IMPORTANT SAFETY INFORMATION

**WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS**

**-Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.**

Please see reverse for continued Boxed Warning and additional important safety information, and read full Prescribing Information.



## Flexible support for you

Through myNEURELIS®, you can connect with a registered nurse educator for one-on-one instruction. myNEURELIS nurse educators can:

- ◆ Provide virtual training on how to give VALTOCO® (diazepam nasal spray)
- ◆ Answer VALTOCO-related questions
- ◆ Send you a demo device

Personalized support is also available for your students and their care partners.

For more information about myNEURELIS, scan the QR code or call  
1-866-myNEURELIS (1-866-696-3873)



### IMPORTANT SAFETY INFORMATION (CONT'D)

#### **WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS (CONT'D)**

- **The use of benzodiazepines, including VALTOCO, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing VALTOCO and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.**
- **The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although VALTOCO is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of VALTOCO may precipitate acute withdrawal reactions, which can be life-threatening. For patients using VALTOCO more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue VALTOCO.**

**Contraindications:** VALTOCO is contraindicated in patients with:

- Hypersensitivity to diazepam
- Acute narrow-angle glaucoma

#### **Central Nervous System (CNS) Depression**

Benzodiazepines, including VALTOCO, may produce CNS depression. Caution patients against engaging in hazardous activities requiring mental alertness, such as operating machinery, driving a motor vehicle, or riding a bicycle, until the effects of the drug, such as drowsiness, have subsided, and as their medical condition permits.

The potential for a synergistic CNS-depressant effect when VALTOCO is used with alcohol or other CNS depressants must be considered, and appropriate recommendations made to the patient and/or care partner.

#### **Suicidal Behavior and Ideation**

Antiepileptic drugs (AEDs), including VALTOCO, increase the risk of suicidal ideation and behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or unusual changes in mood or behavior.

#### **Glaucoma**

Benzodiazepines, including VALTOCO, can increase intraocular pressure in patients with glaucoma. VALTOCO may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. VALTOCO is contraindicated in patients with narrow-angle glaucoma.

#### **Neonatal Sedation and Withdrawal Syndrome**

Use of VALTOCO late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Monitor neonates exposed to VALTOCO during pregnancy or labor for signs of sedation and monitor neonates exposed to VALTOCO during pregnancy for signs of withdrawal; manage these neonates accordingly.

#### **Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preservative**

VALTOCO is not approved for use in neonates or infants. Serious and fatal adverse reactions, including "gasping syndrome," can occur in neonates and low-birth-weight infants treated with benzyl alcohol-preserved drugs, including VALTOCO. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known.

#### **Adverse Reactions**

The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort.

#### **Diazepam, the active ingredient in VALTOCO, is a Schedule IV controlled substance.**

To report SUSPECTED ADVERSE REACTIONS, contact Neurelis, Inc. at 1-866-696-3873 or FDA at 1-800-FDA-1088 ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

#### **Please see full Prescribing Information, including Boxed Warning.**

**References:** 1. Valtoco. Prescribing Information. Neurelis Inc; 2022. Accessed January 5, 2023. <https://www.valtoco.com/PI/>; 2. Valtoco. Instructions for Use. Neurelis Inc; 2022. Accessed January 5, 2023. [https://www.valtoco.com/sites/default/files/pdf/Instructions\\_For\\_Use.pdf](https://www.valtoco.com/sites/default/files/pdf/Instructions_For_Use.pdf); 3. Data on file. REF-01245. Neurelis Inc; 4. Data on file. REF-01288. Neurelis Inc; 5. Wheless JW, Miller I, Hogan RE, et al; DIAZ.001.05 Study Group. Final results from a phase 3, long-term, open-label, repeat-dose safety study of diazepam nasal spray for seizure clusters in patients with epilepsy. *Epilepsia*. 2021;62(10):2485-2495. doi:10.1111/epi.17041; 6. Tarquinio D, Dlugos D, Wheless JW, et al. Safety of Valtoco® (diazepam nasal spray) in children and adolescents with epilepsy: final subgroup results from a phase 3, long-term, open-label, repeat-dose safety study. Poster presented at: Child Neurology Society 50th Annual Meeting, September 29 – October 2, 2021, Boston, MA; 7. Penovich P, Wheless JW, Hogan RE, et al. Examining the patient and caregiver experience with diazepam nasal spray for seizure clusters: results from an exit survey of a phase 3, open-label, repeat-dose safety study. *Epilepsy Behav*. 2021;121(pt A):108013. doi:10.1016/j.yebeh.2021.108013