



Dear School Nurse,

The classroom can present unique challenges for your students with epilepsy who have episodes of frequent seizure activity. But together, we can change the seizure rescue experience at school.

Did you know there's a non-rectal treatment option available for them called VALTOCO® (diazepam nasal spray)? It's the **only** nasal spray seizure rescue medication for students **6 years of age and older**.¹

VALTOCO is a DISCREET nasal spray seizure rescue medication that empowers nurses like you, teachers, and other staff to confidently administer treatment to students¹:

- Designed for **PROMPT** administration by anyone, anywhere—from the classroom to the playground^{1,*}
- **EASY TO USE** and **READY** at a moment's notice with no assembly required^{1,2}
- **TRUSTED** and **RELIABLE** active ingredient (diazepam) has been safely used by nonmedical care partners for more than 20 years^{1,3-5}

Also, VALTOCO aligns with the National Association of School Nurses (NASN) guidelines for treating students with epilepsy, which calls for the **“least restrictive medication choice (buccal or nasal vs. rectal) in the child’s environment.”**⁶

You can be an advocate for the **COMPASSIONATE CHOICE** this school year.⁷ It all starts by clicking [here](#)[†] for a range of tools, including a demo kit with training device.

*Before using VALTOCO, please read the Instructions for Use that come with the medication.

[†]VALTOCOHCP.com/resources#for-school-nurses

Please see the full [Prescribing Information](#) and Important Safety Information on the next page.

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

Please see the complete Boxed Warning and Important Safety Information on the next page.

Best Regards,

Neurelis, Inc.



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.

Please see additional Important Safety Information continued on the next page.

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.**
- **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 only be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. VALTOCO is contraindicated in patients with narrow-angle glaucoma.

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 “gaspings syndrome”, can occur in neonates and low-birth-weight infants treated with benzyl alcohol-preserved drugs, including VALTOCO. The “gaspings 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).

Please read full [Prescribing Information](#), including [Boxed Warning](#), for additional Important Safety Information.

References: 1. VALTOCO® (diazepam nasal spray) Prescribing Information. Neurelis, Inc. 2. VALTOCO® (diazepam nasal spray) Instructions for Use. Neurelis, Inc. 3. Sánchez Fernández I, Gainza-Lein M, Loddenkemper T. Nonintravenous rescue medications for pediatric status epilepticus: a cost-effectiveness analysis. *Epilepsia*. 2017;58(8):1349-1359. doi:10.1111/epi.13812. 4. Parsonage MJ, Norris JW. Use of diazepam in treatment of severe convulsive status epilepticus. *Br Med J*. 1967;3(5557):85-88. doi:10.1136/bmj.3.5557.85. 5. Drugs@FDA: FDA approved drug products. Approval dates, history, and labels; reviews for NDA 020648. Original approvals. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210046>. Accessed June 16, 2021. 6. National Association of School Nurses. School nursing evidence-based practice clinical guideline: students with seizures and epilepsy. 2019:1-36. Silver Spring, MD. 7. Woodcock J; on behalf of Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER). Petition Response Letter from FDA CDER to Arent Fox LLP. Docket No. FDA-2019-P-5121. <https://www.regulations.gov/document?D=FDA-2019-P-5121-0011>. Published January 10, 2020. Accessed June 15, 2021.

This letter is intended for US Healthcare Professionals only.