TEAM UP

with VALTOCO® (diazepam nasal spray)

Frequently asked questions for school nurses

Please ensure you are following your institution's guidelines and the student's seizure action plan.

1. What is VALTOCO?

VALTOCO 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 student's usual seizure pattern in those with epilepsy 6 years of age and older.[1]

2. What is a seizure cluster?

A seizure cluster is often defined as 2 or more seizures in a 24-hour period.[2]

3. Is VALTOCO a replacement for antiseizure medications (ASMs)?

No. Students still need to take their ASMs; VALTOCO is intended as a rescue medication for students who experience seizure clusters distinct from their usual seizure pattern.[1]

4. Can VALTOCO be used to treat prolonged seizures or status epilepticus?

VALTOCO 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 student's usual seizure pattern in those with epilepsy 6 years of age and older.[1] Seizure clusters may present differently from one student to another in terms of seizure type (eg, tonic-clonic, focal onset, absence, etc), number of seizures, severity, or length of seizure.[2-4] VALTOCO may be given at any time during a seizure cluster.

5. Can my students carry VALTOCO with them?

Yes, it is important for students to have VALTOCO readily available when a seizure cluster occurs. VALTOCO packaging is small, portable, discreet, and intended to be carried.[5] Students should not remove VALTOCO from the blister pack until ready to use. Please refer to your school's guidelines on whether a student may keep VALTOCO on hand.

6. Who can administer VALTOCO?

VALTOCO is designed for prompt administration by anyone—school nurse, teacher, coach, or others.[5] Please read the Instructions for Use and refer to local and state guidelines on medication administration delegation.

7. How soon after a seizure starts can VALTOCO be administered?

VALTOCO may be administered at any point during a seizure, including as soon as onset occurs.[6]

Please see full important safety information on the last 2 pages and read full Prescribing Information, including Boxed Warning.

VALTOCO® (diazepam nasal spray) IV

8. How is VALTOCO® (diazepam nasal spray) dosed?

VALTOCO has specific, individualized dosing based on age and weight.[1]

- For 5 mg or 10 mg, each blister pack contains 1 VALTOCO nasal spray device, which is 1 full dose of VALTOCO
- For 15 mg or 20 mg, each blister pack contains 2 nasal spray devices. Both devices must be used for 1 full dose

(2) doses of (1) 5 mg sprayer

(2) doses of (1) 10 mg sprayer

(2) doses of (2) 7.5 mg sprayers

(2) doses of (2) 10 mg sprayers

	5 mg	10 mg	15 mg	20 mg
6-11 years (0.3 mg/kg)	**10-18 kg**	**19-37 kg**	**38-55 kg**	**56-74 kg**
12+ years (0.2 mg/kg)	**14-27 kg**	**28-50 kg**	**51-75 kg**	**76 kg and up**

Dose based on patient weight

1 blister pack = 1 complete dose and includes Instructions for Use

If needed, a second dose may be given at least 4 hours after the initial dose. Students should not use more than 2 doses of VALTOCO to treat a single seizure.[1]

9. Will my student stop breathing after administering VALTOCO?

In a clinical study, no clinically relevant changes in respiratory rate were observed.[7]

10. If my student has allergies or nasal congestion, will VALTOCO still work?

Data have shown that VALTOCO still works despite allergies or nasal congestion.[8]

11. Do I need to call EMS after administering VALTOCO?

It is not necessary to call EMS after administration of VALTOCO. In a clinical study, a majority (59%) of patients returned to their usual selves within 1 hour of administration.[9] Overall mean sedation levels were low, mild, transient, and not considered clinically relevant.[7]

12. How can I get a demo device?

You can order a demo kit at VALTOCOHCP.com.

If you are interested in ordering more than one demo device, please contact myNEURELIS® at 1-866-myNEURELIS (1-866-696-3873).

Please see full important safety information on the last 2 pages and read full Prescribing Information, including Boxed Warning.

VALTOCO® (diazepam nasal spray) CIV

13. Do you have resources for my students with seizure clusters and their families?

Resources, including a patient brochure, Instructions for Use videos, and more, can be found at VALTOCO.com. myNEURELIS is also available to provide personalized support for students and their care partners. Services include checking VALTOCO® (diazepam nasal spray) coverage, savings for those who qualify, and virtual training on how to give VALTOCO. Families can call myNEURELIS at 1-866-myNEURELIS (1-866-696-3873) or visit myNEURELIS.com.

14. How can I get more information about VALTOCO?

To learn more about VALTOCO and access resources and tools for school nurses, please visit VALTOCOHCP.com.

You can also contact myNEURELIS at 1-866-myNEURELIS (1-866-696-3873) for training on how to give VALTOCO and to order training devices.

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.**
- **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.

Please see next page for additional important safety information and read full Prescribing Information, including Boxed Warning.

VALTOCO® (diazepam nasal spray) CIV

IMPORTANT SAFETY INFORMATION (CONT'D)

Glaucoma

Benzodiazepines, including VALTOCO® (diazepam nasal spray), 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).

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.** Fisher RS, Bartfeld E, Cramer JA. Use of an online epilepsy diary to characterize repetitive seizures. *Epilepsy Behav.* 2015;47:66-71. doi:10.1016/j.yebeh.2015.04.022; **3.** Types of seizures. Epilepsy Foundation. Accessed January 5, 2023. https://www.epilepsy.com/learn/types-seizures; **4.** Haut SR. Seizure clusters: characteristics and treatment. *Curr Opin Neurol.* 2015;28(2):143-150. doi:10.1097/WCO.0000000000000177; **5.** Valtoco. Instructions for Use. Neurelis Inc; 2022. Accessed January 5, 2023. https://www.valtoco.com/sites/default/files/pdf/Instructions_For_Use.pdf; **6.** Data on file. REF-01288. Neurelis Inc; **7.** 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; **8.** Vazquez B, Wheless J, Desai J, Rabinowicz AL, Carrazana E. Lack of observed impact of history or concomitant treatment of seasonal allergies or rhinitis on repeated doses of diazepam nasal spray administered per seizure episode in a day, safety, and tolerability: interim results from a phase 3, open-label, 12-month repeat-dose safety study. *Epilepsy Behav.* 2021;118:107898. doi:10.1016/j.yebeh.2021.107898; **9.** 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

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