



**Keep the focus
on school,
not seizures**



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 an immediate-use intranasal diazepam spray that 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 2 years of age and older.¹

2. What is an episode of frequent seizures?

An episode of frequent seizures 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 an immediate-use seizure medication for students who experience episodes of frequent seizures that are 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 2 years of age and older.¹ Episodes of frequent seizures 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.^{2,3} VALTOCO may be given at any time during an episode of frequent seizures.

5. Can my students carry VALTOCO with them?

Yes, it is important for students to have VALTOCO readily available when an episode of frequent seizures occurs. VALTOCO packaging is small, portable, discreet, and intended to be carried.⁴ Students should not remove VALTOCO from the blister pack until ready to use. You may request that at least 2 doses be stored in the original pharmacy carton in the nurse's office. Please refer to your school's guidelines on storing prescription medications for students.

6. Who can administer VALTOCO?

VALTOCO is designed for prompt administration by anyone—school nurse, teacher, coach, or others.⁴ Please read the Instructions for Use and refer to local and state guidelines on medication administration delegation.

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

7. How soon after a seizure starts can VALTOCO® (diazepam nasal spray) be administered?

VALTOCO may be administered at any point during a seizure, including as soon as onset occurs.^{4,5}

8. How is VALTOCO 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



	5 mg	10 mg	15 mg	20 mg
2-5 years (0.5 mg/kg)	6-11 kg (13-24 lb)	12-22 kg (25-49 lb)	23-33 kg (50-73 lb)	
6-11 years (0.3 mg/kg)	10-18 kg (22-40 lb)	19-37 kg (41-81 lb)	38-55 kg (82-121 lb)	56-74 kg (122-163 lb)
12+ years (0.2 mg/kg)	14-27 kg (30-60 lb)	28-50 kg (61-111 lb)	51-75 kg (112-166 lb)	76 kg and up (167 lb and up)

The 20 mg dose was not clinically evaluated in 2- to 5-year-old children.

Dose based on patient weight

Each box contains 5 doses.

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

Do not use more than 2 doses of VALTOCO to treat a single episode. A second dose, when required, may be administered at least 4 hours after the initial dose. Do not use VALTOCO to treat more than 1 episode every 5 days or more than 5 episodes per month.¹

9. Will my student stop breathing after administering VALTOCO?

In clinical studies of patients 2 through 65 years of age, there were no treatment-related reports of respiratory depression.^{6,7,*}

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

Data from a study of subjects 6 to 65 years of age have shown that VALTOCO still works despite allergies or nasal congestion.^{8,†}

*Data pooled from 2 open-label, repeat-dose safety studies in patients with epilepsy aged 2 to 5 years (N=35) and 6 to 65 years (N=175); of 210 enrolled patients, 198 received ≥1 dose of VALTOCO, representing a total of 4,080 seizure episodes treated.^{6,7}

†Interim analysis of a phase 3, open-label, repeat-dose safety study in patients aged 6 to 65 years. Of 175 enrolled, 158 received ≥1 dose of VALTOCO, including 62 with a history of seasonal allergies (1,561 treated seizure episodes) and 96 with no history (1,836 treated seizure episodes).⁸

11. Do I need to call EMS after administering VALTOCO® (diazepam nasal spray)?

It is not necessary to call EMS after administration of VALTOCO. Call for emergency help if any of the following happen:

- Seizure behavior in the person is different from that of other episodes.
- You are alarmed by how often the seizures happen, by how severe the seizure is, by how long the seizure lasts, or by the color or breathing of the person.

In a clinical study of subjects 6 to 65 years of age, 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.^{10,‡}

12. How can I get a demo device?

You can order a demo kit at [VALTOCOHCP.com](https://www.valtochohcp.com).

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

13. Do you have resources for my students with episodes of frequent seizures and their families?

Resources, including a patient brochure, Instructions for Use videos, and more, can be found at [VALTOCO.com](https://www.valtochohcp.com). myNEURELIS is also available to provide personalized support for students and their care partners. Services include checking VALTOCO 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](tel:1-866-696-3873)) or visit [myNEURELIS.com](https://www.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](https://www.valtochohcp.com).

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

[‡]Phase 1, open-label, pharmacokinetic and safety study of VALTOCO in patients with epilepsy (N=57) 6 to 59 years of age during seizure and nonseizure states. Sedation was assessed using a 6-point scale. Sedation scores indicated small increases in sedation overall. These small increases generally appeared to be higher during ictal/peri-ictal administration, were transient, and were not dose dependent.¹⁰

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 2 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.



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 “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](tel:1-866-696-3873) or FDA at [1-800-FDA-1088](tel:1-800-FDA-1088) (www.fda.gov/medwatch).

Please see full [Prescribing Information](#), including **Boxed Warning**.

References: **1.** Valtoco. Prescribing Information. Neurelis, Inc. <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.** Haut SR. Seizure clusters: characteristics and treatment. *Curr Opin Neurol.* 2015;28(2):143-150. doi:10.1097/WCO.0000000000000177; **4.** Valtoco. Instructions for Use. Neurelis, Inc. https://www.valtoco.com/sites/default/files/pdf/Instructions_For_Use.pdf; **5.** Misra SN, Jarrar R, Stern JM, Becker DA, Carrazana E, Rabinowicz AL. Rapid rescue treatment with diazepam nasal spray leads to faster seizure cluster termination in epilepsy: an exploratory post hoc cohort analysis. *Neurol Ther.* 2024;13(1):221-231. doi:10.1007/s40120-023-00568-4; **6.** 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; **7.** Segal EB, Wheless JW, Zafar M, et al; DIAZ.001.008 Study Group. Pharmacokinetics and 180-day safety of diazepam nasal spray in pediatric patients with epilepsy aged 2-5 years. *Epilepsia.* 2025;66(9):3231-3241. doi:10.1111/epi.18473; **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; **10.** Hogan RE, Tarquinio D, Sperling MR, et al. Pharmacokinetics and safety of VALTOCO (NRL-1; diazepam nasal spray) in patients with epilepsy during seizure (ictal/peri-ictal) and nonseizure (interictal) conditions: a phase 1, open-label study. *Epilepsia.* 2020;61(5):935-943. doi:10.1111/epi.16506