VALTOCO® (diazepam nasal spray) CIV

School Nurse Frequently Asked Questions

About VALTOCO® (diazepam nasal spray)

Visit **www.VALTOCOHCP.com** to learn more

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, or episode of frequent seizure activity, is often defined as 2 or more seizures in a 24-hour period.[1,2]

3. Is VALTOCO a replacement for anti-seizure medications (ASMs)?

No. Students still need to take their ASMs; VALTOCO is intended as a rescue medication for students who experience episodes of frequent seizure activity 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] Episodes of frequent seizure activity 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 can be given at any time during episodes of seizure activity.[5]

5. How is VALTOCO dosed?

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

6-11 years (0.3 mg/kg | 0.66 mg/lb)

Weight (kg)	Weight (lb)	Dose (mg)	Given As
10-18	22.0-39.7	5	One **5 mg** nasal spray device in one nostril
19-37	41.9-81.6	10	One **10 mg** nasal spray device in one nostril
38-55	83.8-121.3	15	Two **7.5 mg** nasal spray devices, one in each nostril
56-74	123.5-163.1	20	Two **10 mg** nasal spray devices, one in each nostril

12+ years (0.2 mg/kg | 0.44 mg/lb)

Weight (kg)	Weight (lb)	Dose (mg)	Given As
14-27	30.9-59.5	5	One **5 mg** nasal spray device in one nostril
28-50	61.7-110.2	10	One **10 mg** nasal spray device in one nostril
51-75	112.4-165.3	15	Two **7.5 mg** nasal spray devices, one in each nostril
76 and up	167.6 and up	20	Two **10 mg** nasal spray devices, one in each nostril

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

6. Can my students carry VALTOCO with them?

Yes, it is important for students to have VALTOCO readily available when an episode of frequent seizure activity occurs. VALTOCO packaging is small, portable, discreet, and intended to be carried.[1] Students should not remove VALTOCO from blister pack until ready to use. Please refer to your school's guidelines on whether a student may keep VALTOCO on hand.

Please see full Important Safety Information on the last page and full Prescribing Information, including Boxed Warning.

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7. Who can administer VALTOCO?

VALTOCO is designed for prompt administration by anyone—school nurse, teacher, coach, or others.[1] Please read the Instructions for Use and refer to local and state guidelines on medication administration delegation.

8. How is VALTOCO supplied?

VALTOCO is currently available in 4 treatment doses (5 mg, 10 mg, 15 mg, 20 mg).[1]

9. What is contained in a VALTOCO box?

Each box of VALTOCO contains 2 blister packs with Instructions for Use and the full Prescribing Information with Medication Guide. Each box contains 2 doses.

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.

10. How can I get a training device?

You can order a demo kit at VALTOCOHCP.com.

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

11. Is VALTOCO covered by insurance plans, including Medicaid?

VALTOCO has strong coverage across various plans, including state Medicaid programs. Out-of-pocket costs will vary depending on an individual's insurance plan and benefit design. In some cases a prior authorization may be required. VALTOCO has a Copay Assistance Program for patients with commercial insurance and a Patient Assistance Program for those who qualify.

12. How can I get more information about VALTOCO?

To learn more about VALTOCO, 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.

13. Do you have resources for my students with episodes of frequent seizure activity 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 coverage, savings for those who qualify, and providing virtual training on how to give VALTOCO. Families can call myNEURELIS™ at 1-866-myNEURELIS (1-866-696-3873) or visit myNEURELIS.com.

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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.

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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 "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 read full Prescribing Information, including Boxed Warning, for additional important safety information.

References: 1. VALTOCO® (diazepam nasal spray) Prescribing Information. Neurelis, Inc. **2.** Fisher RS, Bartfeld E, Cramer JA. Use of an online epilepsy diary to characterize repetitive seizures. *Epilepsy Behav.* 2015;47:66-71. **3.** Epilepsy Foundation. Types of seizures. https://www.epilepsy.com/learn/types-seizures. Accessed September 30, 2020. **4.** Haut SR. Seizure clusters: characteristics and treatments. *Curr Opin Neurol.* 2015;28(2):143-150. **5.** VALTOCO® (diazepam nasal spray) Instructions for Use. Neurelis, Inc.

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