VALTOCO® (diazepam nasal spray) CIV

Frequently Asked Questions

about VALTOCO

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

2. How is VALTOCO dosed?

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

(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 age and 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. Patients should not use more than 2 doses of VALTOCO to treat a single seizure.[1]

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

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

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

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4. How quickly after administering VALTOCO will my patient return to their usual self?

In a clinical study, a majority (59%) of patients returned to their usual selves within 1 hour of administration of VALTOCO.[2]

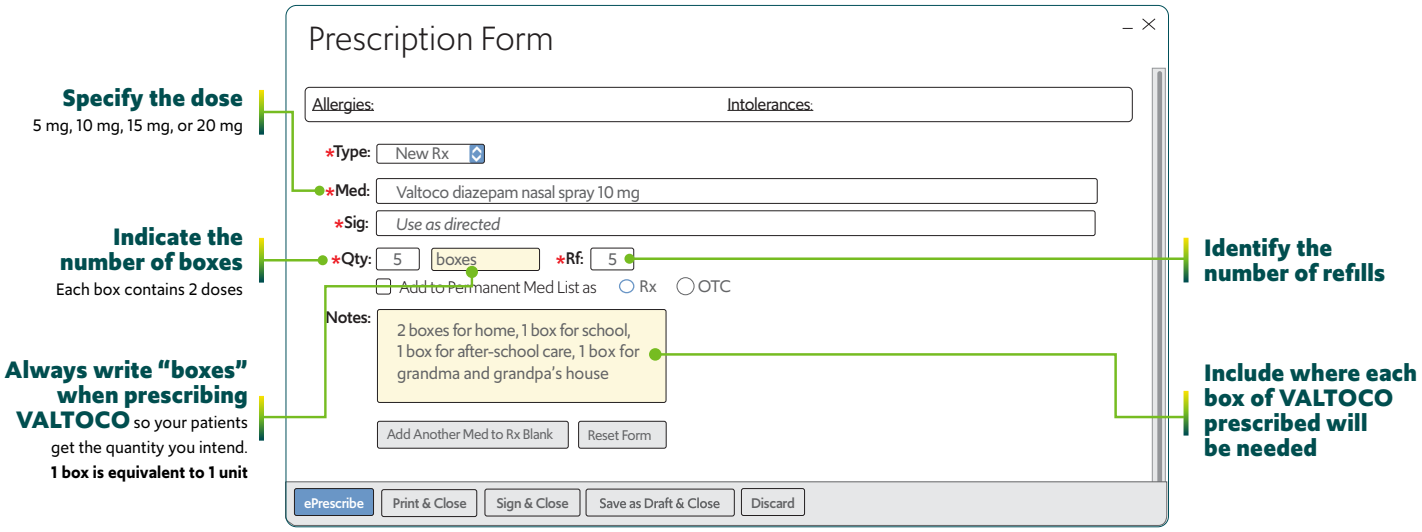
5. Can VALTOCO be used for patients under 6 years old?

VALTOCO is not approved for use in patients younger than 6.

6. Can my patients carry VALTOCO with them?

Yes. VALTOCO's small, portable, and discreet packaging is intended for patients to carry with them in their pocket or purse—anytime, anywhere. In a patient survey, 85% of patients reported being "extremely comfortable" or "very comfortable" carrying VALTOCO with them.[2] It does not need to be refrigerated and is designed for prompt administration by anyone.[1,3]

7. How do I write a VALTOCO prescription?



8. What is the shelf life of VALTOCO?

The shelf life of a box of VALTOCO is 27 months.

9. Is there a copay savings program?

Eligible patients may pay as little as $20 with the VALTOCO copay card. It may even help lower their deductible. To find out more about the program and how to get a copay card, patients can call 1-866-629-6779.

10. How can I get more information about VALTOCO?

To learn more about VALTOCO or to request a visit from your local Neurelis representative, go to VALTOCOHCP.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.

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

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IMPORTANT SAFETY INFORMATION (CONT'D)

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).

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.** 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; **3.** Valtoco. Instructions for Use. Neurelis Inc; 2022. Accessed January 5, 2023. https://www.valtoco.com/sites/default/files/pdf/Instructions_For_Use.pdf

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