Dosing information

VALTOCO® (diazepam nasal spray) CIV

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 patients with epilepsy 6 years of age and older.[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

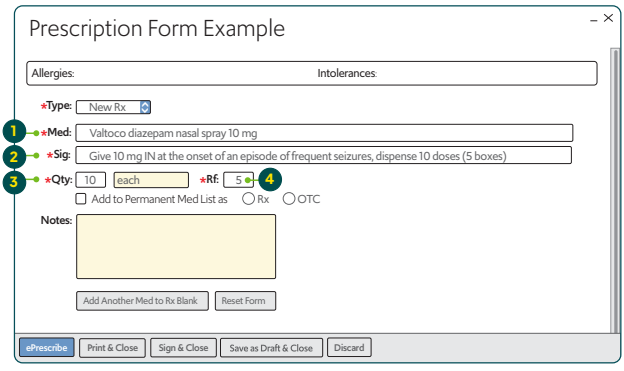
Dose based on patient age and weight[1]

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

Please see reverse for important safety information, including Boxed Warning.

How to prescribe VALTOCO

When prescribing VALTOCO® (diazepam nasal spray) electronically, follow the steps below to save time for office staff while ensuring the pharmacy provides exactly what you prescribed.



1. **Specify the dose**
   5 mg, 10 mg, 15 mg, or 20 mg
2. **Indicate the number of doses in the sig field**
   Each box contains 2 doses
3. **Indicate quantity in doses (or "each")**
   So your patients get the quantity you intend
4. **Specify the number of refills**

Please see reverse for important safety information, including Boxed Warning.

- If needed, a second dose of VALTOCO may be given at least 4 hours after the initial dose[1]
- Patients should not use more than 2 doses of VALTOCO to treat a single episode[1]
- Be sure to identify the dose, number of refills, and number of boxes when prescribing VALTOCO so your patients get exactly what you intend

Visit VALTOCOHCP.com or scan the QR code for more information

Please see reverse for important safety information, including Boxed Warning.

VALTOCO® (diazepam nasal spray) CIV

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.**

IMPORTANT SAFETY INFORMATION (CONT'D)

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 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.

IMPORTANT SAFETY INFORMATION (CONT'D)

Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preservative

VALTOCO® (diazepam nasal spray) 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.

Reference: 1. Valtoco. Prescribing Information. Neurelis Inc; 2023. Accessed August 14, 2024. https://www.valtoco.com/PI

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