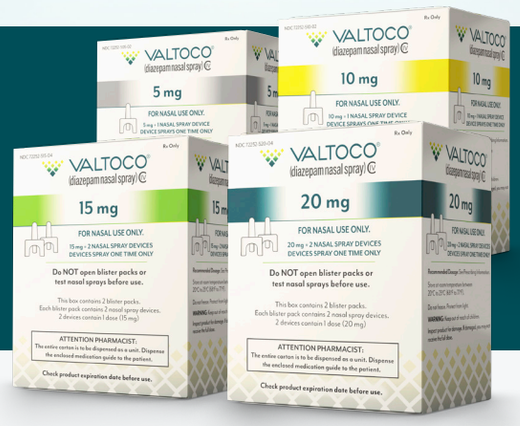
VALTOCO®
(diazepam nasal spray) CIV

Reliable on-hand rescue treatment for episodes of frequent seizure activity[1]

For pharmacists looking to place orders for VALTOCO® (diazepam nasal spray), here's what you need to know.



Please contact your wholesaler to place orders for VALTOCO

Dose	NDC Number	What's Included	Pkg. Size / Pkg. Quantity	Box Dimensions / Weight
5 mg	72252-505-02	This box contains two (2) individual blister packs. Each blister pack contains 1 VALTOCO nasal spray device. Each VALTOCO nasal spray device contains 5 mg diazepam in 0.1 mL solution. The entire carton is to be dispensed as a unit.	1 / 2	3.457" x 2.552" x 4.214" / 0.134 lb
10 mg	72252-510-02	This box contains two (2) individual blister packs. Each blister pack contains 1 VALTOCO nasal spray device. Each VALTOCO nasal spray device contains 10 mg diazepam in 0.1 mL solution. The entire carton is to be dispensed as a unit.	1 / 2	3.457" x 2.552" x 4.214" / 0.134 lb
15 mg	72252-515-04	This box contains two (2) individual blister packs. Each blister pack contains 2 VALTOCO nasal spray devices. Each VALTOCO nasal spray device contains 7.5 mg diazepam in 0.1 mL solution. Use both nasal spray devices for a full 15 mg dose. The entire carton is to be dispensed as a unit.	1 / 2	3.457" x 2.552" x 4.214" / 0.163 lb
20 mg	72252-520-04	This box contains two (2) individual blister packs. Each blister pack contains 2 VALTOCO nasal spray devices. Each VALTOCO nasal spray device contains 10 mg diazepam in 0.1 mL solution. Use both nasal spray devices for a full 20 mg dose. The entire carton is to be dispensed as a unit.	1 / 2	3.457" x 2.552" x 4.214" / 0.163 lb

Store at room temperature between 68°F and 77°F (20°C to 25°C). Do not freeze. Protect from light.[1]

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.

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.**

How to administer VALTOCO[2]

Remove VALTOCO from the blister pack.

1. HOLD

HOLD VALTOCO with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

DO NOT test or prime; each device sprays only one time.

2. INSERT

INSERT the tip of the nozzle into 1 nostril until your fingers, on either side of the nozzle, are against the bottom of the person's nose.

For nasal use only.

3. PRESS

PRESS the bottom of the plunger firmly with your thumb to give VALTOCO.

Throw away nasal spray device(s) after use.

If giving the **15 mg or 20 mg dose**, repeat the steps using the second device **in the other nostril** to give the full dose of VALTOCO.

Remember: If needed, a second dose may be given at least 4 hours after initial dose. Patients should not use more than 2 doses of VALTOCO to treat a single episode.[1] These are not the full Instructions for Use. Please see the complete Instructions for Use at VALTOCOHCP.com.

Please see full Important Safety Information on the back, and read the accompanying full Prescribing Information, including complete Boxed Warning.

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Sample package of 1 dosing option.

Frequently Asked Questions About VALTOCO® (diazepam nasal spray)

1. How frequently can VALTOCO be dosed?

It's recommended that VALTOCO be used to treat no more than 1 episode every 5 days and no more than 5 episodes per month. If needed, a second dose may be given at least 4 hours after initial dose. Patients should not use more than 2 doses of VALTOCO to treat a single episode.[1]

2. What is the most important information I should know about VALTOCO?

VALTOCO is a benzodiazepine medicine. Benzodiazepines have warnings for risks from concomitant use with opioids; abuse, misuse, and addiction; and dependence and withdrawal reactions.[1]

3. Does VALTOCO need to be primed?

No. Patients or their care partners SHOULD NOT test or prime VALTOCO. Each device sprays only one time.[2]

4. Can patients carry VALTOCO with them?

Yes. With the small, portable, and discreet packaging of VALTOCO, patients can carry it with them in their backpack or purse—whenever, wherever. It does not need to be refrigerated and is designed for prompt administration by anyone.[1]

5. 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**.

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.

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 see accompanying full Prescribing Information, including Boxed Warning.

References: 1. VALTOCO® (diazepam nasal spray) Prescribing Information. Neurelis, Inc. **2.** VALTOCO® (diazepam nasal spray) Instructions for Use. Neurelis, Inc.

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OUR PASSION IS PROGRESS