



NOW AVAILABLE

VALTOCO—RELIABLE RESCUE FOR TREATING SEIZURE CLUSTERS



VALTOCO® (diazepam nasal spray)—a unique formulation of diazepam optimized for nasal delivery. With VALTOCO on hand, your adult and pediatric patients who experience seizure clusters have reliable rescue that's there when they need it.

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 adult and pediatric patients with epilepsy 6 years of age and older.¹

RISK FROM CONCOMITANT USE WITH OPIOIDS

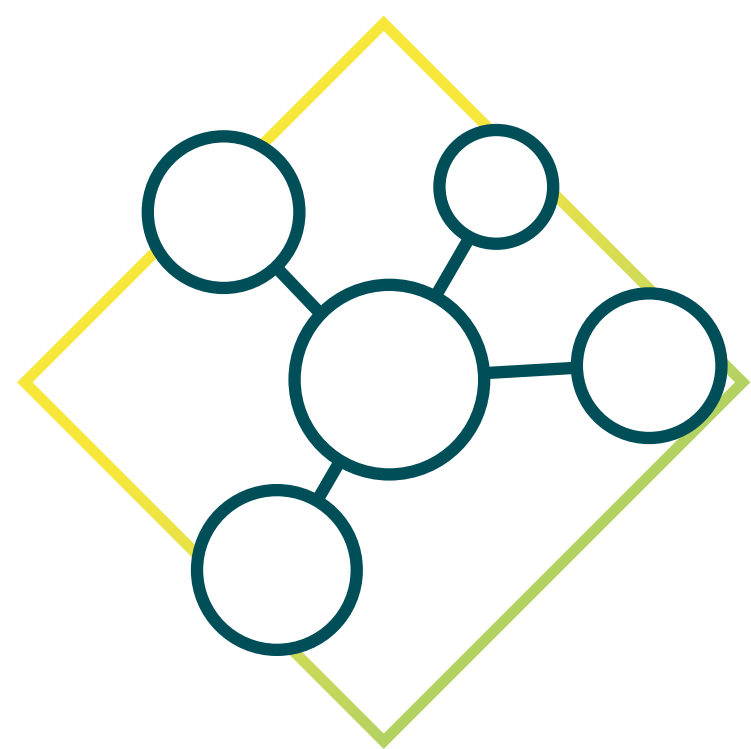
Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- **Reserve concomitant prescribing of these drugs for use in 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**

To learn more, go to **VALTOCOHCP.com**

VALTOCO—HERITAGE AND INNOVATION COME TOGETHER IN A RELIABLE NASAL SPRAY

VALTOCO combines the established history of diazepam with a novel formulation technology in a small nasal spray.¹⁻³



Diazepam

- ◆ Recognized as safe and effective seizure rescue for more than 50 years²
- ◆ Prescribed for nonmedical care partner use for more than 20 years^{4,5}



Intravail®

- ◆ Proprietary absorption enhancement technology designed to increase bioavailability and reliability of drug delivery^{6,7}



Vitamin E

- ◆ Provides adequate drug concentration in small liquid volume⁸
- ◆ Coats the nasal cavity⁹

Contraindications: VALTOCO is contraindicated in patients with:

- Known hypersensitivity to diazepam
- Acute narrow-angle glaucoma

Please see full Important Safety Information on page 11.

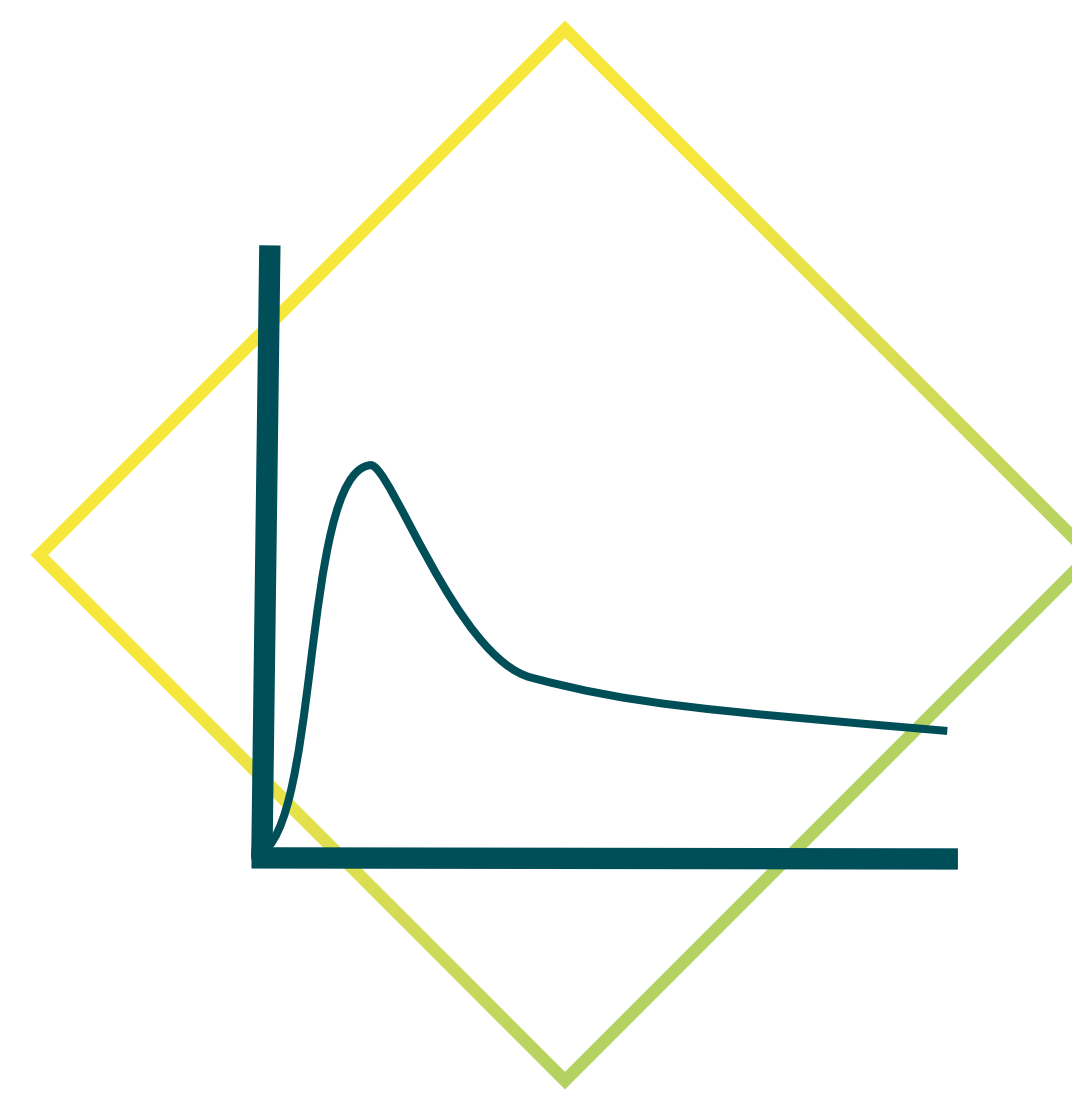
VALTOCO—RELIABLE RESCUE, THERE WHEN THEY NEED IT

Dependable absorption, with sustained plasma levels throughout the day.^{1,10,11}



NEARLY COMPLETE ABSORPTION

97% bioavailability relative to
intravenous diazepam^{1,10,11}



PREDICTABLE PHARMACOKINETICS

Low intra- and inter-patient
variability¹



SUSTAINED LEVELS

Maintained plasma levels for
over 24 hours¹

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. Please see full Important Safety Information on page 11.

VALTOCO—SPECIFIC, INDIVIDUALIZED DOSING

- ◆ Dose individualized based on age and weight¹
- ◆ Available in 4 treatment doses: 5 mg, 10 mg, 15 mg, 20 mg¹
- ◆ A second dose may be given at least 4 hours after the initial dose, if required¹
- ◆ Do not use more than 2 doses of VALTOCO to treat a seizure cluster¹
- ◆ It is recommended that VALTOCO be used to treat no more than 1 episode every 5 days and no more than 5 episodes per month¹

**Each box of
VALTOCO contains
2 blister packs¹**

**1 blister pack
equals
1 complete dose**
with Instructions for Use

6-11 years (0.3 mg/kg)

| 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)

| 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 |

Central Nervous System (CNS) Depression

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. **Please see full Important Safety Information on page 11.**

VALTOCO—SINGLE DOSE USED FOR LARGE MAJORITY

In a large majority of episodes, a single dose of VALTOCO was used over the course of 24 hours.

Percentage of seizure episodes (N=3,914) for which a single dose was used¹²

**WITH A
SINGLE
DOSE**



- ◆ Ongoing open-label, repeat-dose safety study
 - 179 patients with epilepsy, ages 6 to 65 years of age
 - 3,914 seizure episodes were treated with VALTOCO
 - Exploratory analysis. Study did not have prespecified efficacy endpoints
- ◆ 12-month treatment period
- ◆ A second dose may be given at least 4 hours after the initial dose, if required¹

Contraindications: VALTOCO is contraindicated in patients with:

- Known hypersensitivity to diazepam
- Acute narrow-angle glaucoma

Please see full Important Safety Information on page 11.

VALTOCO—PROVEN SAFETY AND TOLERABILITY¹



GENERALLY SAFE AND WELL TOLERATED

The most common local adverse reactions observed in clinical studies with epilepsy patients after administration of VALTOCO included: nasal discomfort (6%), nasal congestion (3%), epistaxis (3%), and dysgeusia (2%)¹

- ◆ The safety of VALTOCO is also supported by double-blind, placebo-controlled trials using diazepam rectal gel, using the same weight-based dosing strategy¹
 - The most frequent adverse reactions (at least 4%) were somnolence, headache, and diarrhea. Adverse events were usually mild or moderate in intensity¹

Adverse Reactions

The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort. **Please see full Important Safety Information on page 11.**

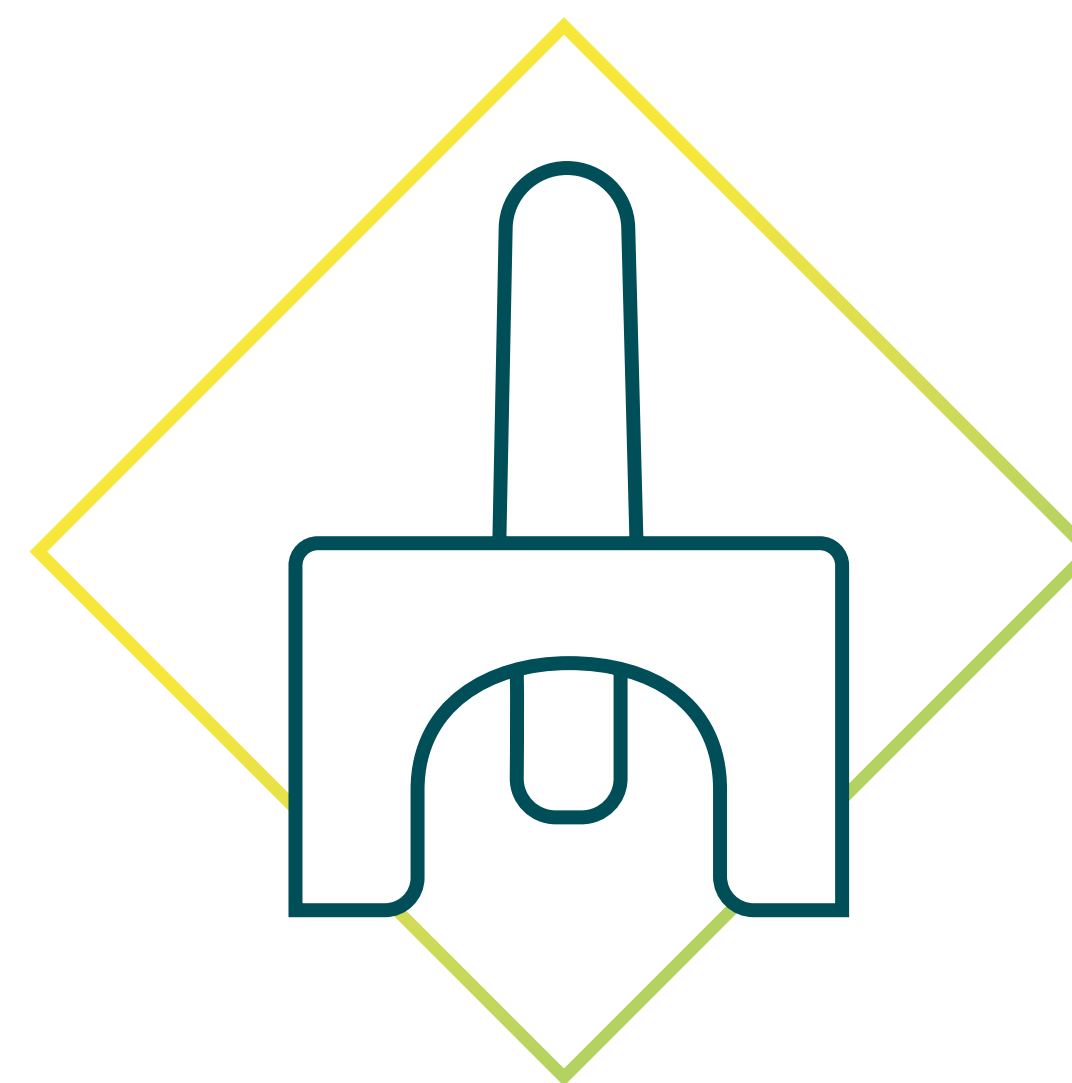
VALTOCO—RELIABLE RESCUE, READY WHEN THEY NEED IT

Reliable rescue for unpredictable seizures



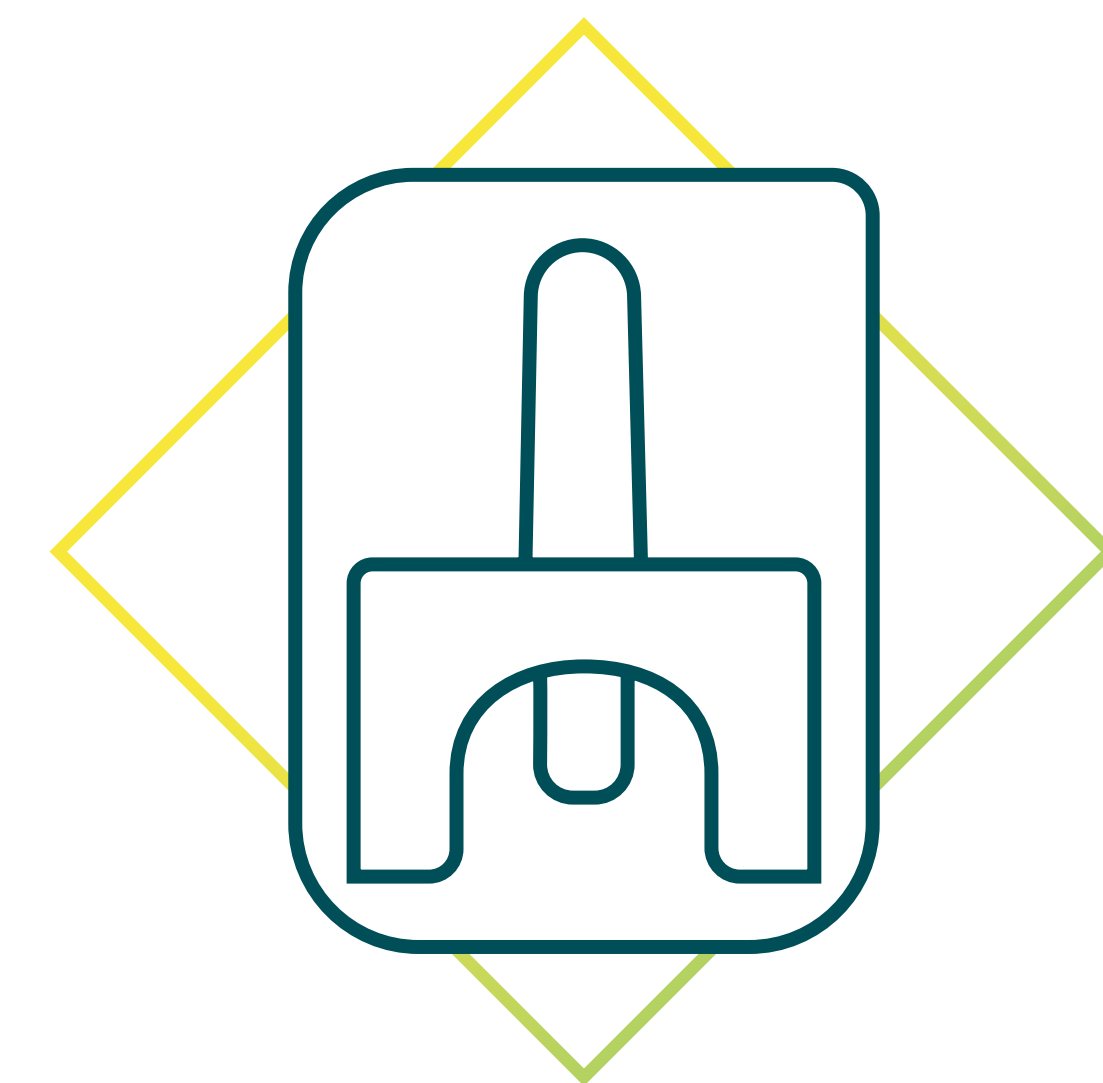
SPECIFIC, INDIVIDUALIZED DOSING

Four available doses—
5 mg, 10 mg, 15 mg, 20 mg—
based on age and weight¹



READY-TO-USE DESIGN

Designed for prompt
administration by anyone¹



SMALL PACKAGING, SMALL DEVICE

Discreet and easy to carry for
use whenever needed¹

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. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to a healthcare provider. **Please see full Important Safety Information on page 11.**

VALTOCO—AT HOME OR AWAY

In this time of social distancing and remote medicine, VALTOCO is there for your patients—wherever, whenever.



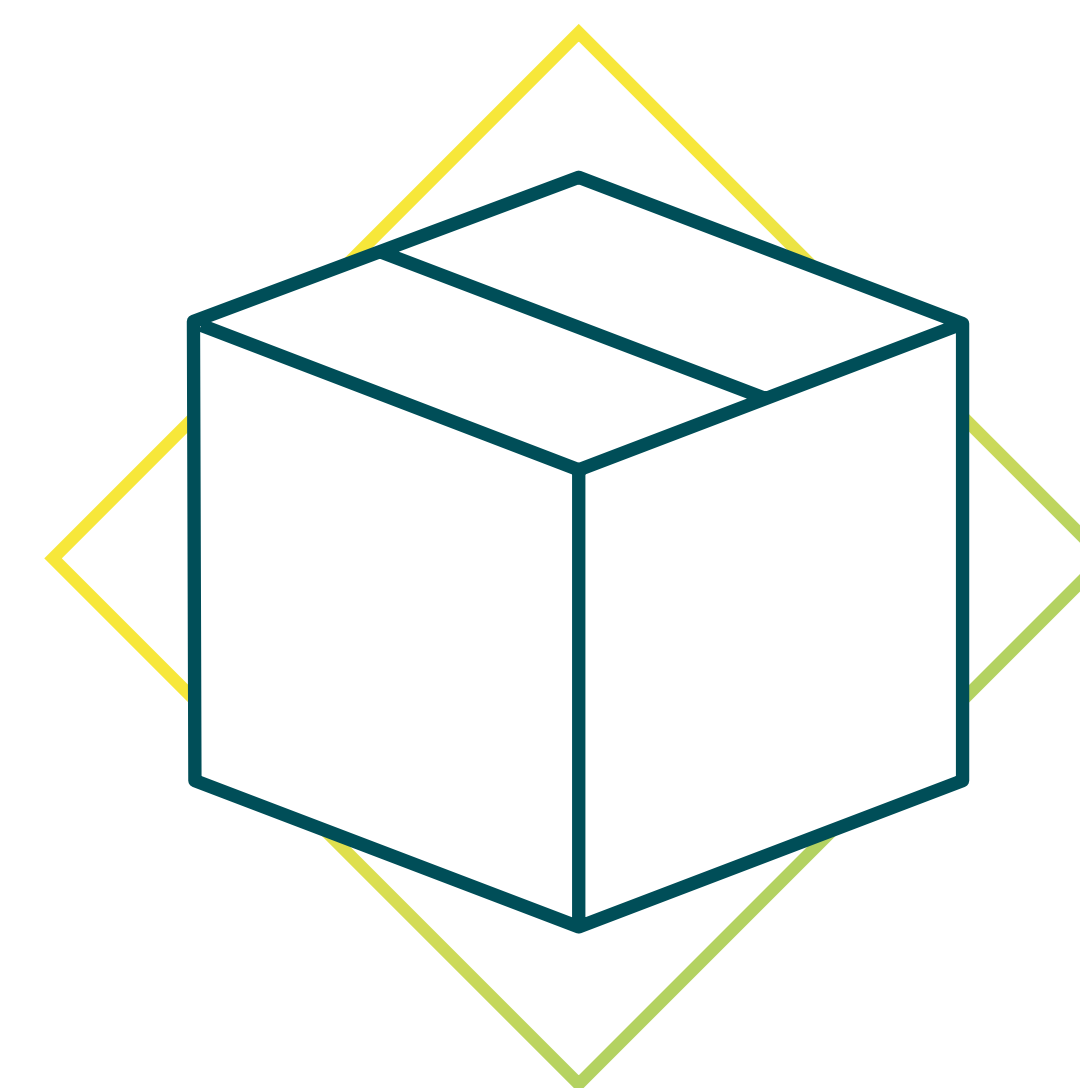
RESCUE TREATMENT AT HOME

VALTOCO is designed for use by anyone outside the medical setting, helping minimize exposure to COVID-19 and other contagious illnesses¹



RESOURCES FOR YOU TO USE DURING REMOTE CONSULTATIONS

At Neurelis, we have simple, electronic resources to help you introduce and prescribe VALTOCO



DOORSTEP DELIVERY

Maxor Specialty Pharmacy, our partner providing white glove service, is here to help. Prescribe VALTOCO and Maxor will deliver it to your patient's doorstep with no additional charge



VIRTUAL EDUCATION & SUPPORT

Through myNEURELIS[™], patients and their care partners can connect with a registered nurse via online chat or phone. Nurses are available to answer questions and provide one-on-one educational instruction

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.

Please see full Important Safety Information on page 11.

SIMPLY PRESCRIBE VALTOCO— MAXOR WILL TAKE IT FROM THERE

We've partnered with Maxor Specialty Pharmacy to further support your patients. Just follow these 5 simple steps, and VALTOCO will be delivered right to their door.

- 1.** First, submit the VALTOCO prescription to Maxor Specialty Pharmacy via fax (1-866-217-8034) or e-prescription to:

Maxor Specialty Pharmacy
216 S Polk, Amarillo, TX 79101
Ph: 1-866-629-6779
NCPDPID: 5905661
- 2.** Next, ensure dosage, **number of boxes**, and refill amount are included along with patient first name and last name, DOB, gender, and pharmacy benefit information: BIN, PCN, Group ID#.
- 3.** A Maxor representative will contact you within 24 hours if prior authorization or clarification is needed.
- 4.** After that, Maxor will initiate the process and work with the insurer, you/your staff, and the patient so it's ready to go.
- 5.** Last, Maxor will ship it to your patient's door via FedEx or UPS. It requires no additional shipping cost, and adds the benefit of patients not having to leave their home. All they have to do is sign for it!

Visit www.MaxorSpecialty.com or call 1-866-629-6779 Monday-Friday, 8 AM to 5 PM CT, for more information

HOW TO WRITE A VALTOCO PRESCRIPTION

EXAMPLE SCRIPT

R_x

Steve J. Johnson MD
 ABC Hospital, Neurology Department
 Main Street, USA
 (555) 555-4242

Date: March 15, 2020

Patient: Erin R. Smith
123 Bay Ave

Valtoco (diazepam nasal spray) mg

use as instructed
 prn for seizure cluster

dispense # boxes / month

Refill:

Steve J. Johnson MD
 DEA# C91234569

Insert dose strength:
5 mg, 10 mg, 15 mg, or 20 mg

Insert number of boxes;
each box contains two rescue doses

Insert number of refills

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.

Please see full Important Safety Information on page 11.

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

RISK FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- **Reserve concomitant prescribing of these drugs for use in 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**

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Central Nervous System (CNS) Depression

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Suicidal Behavior and Ideation

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depression, suicidal thoughts or behavior, and/or unusual changes in mood or behavior. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to a healthcare provider.

Glaucoma

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Adverse Reactions

The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort.

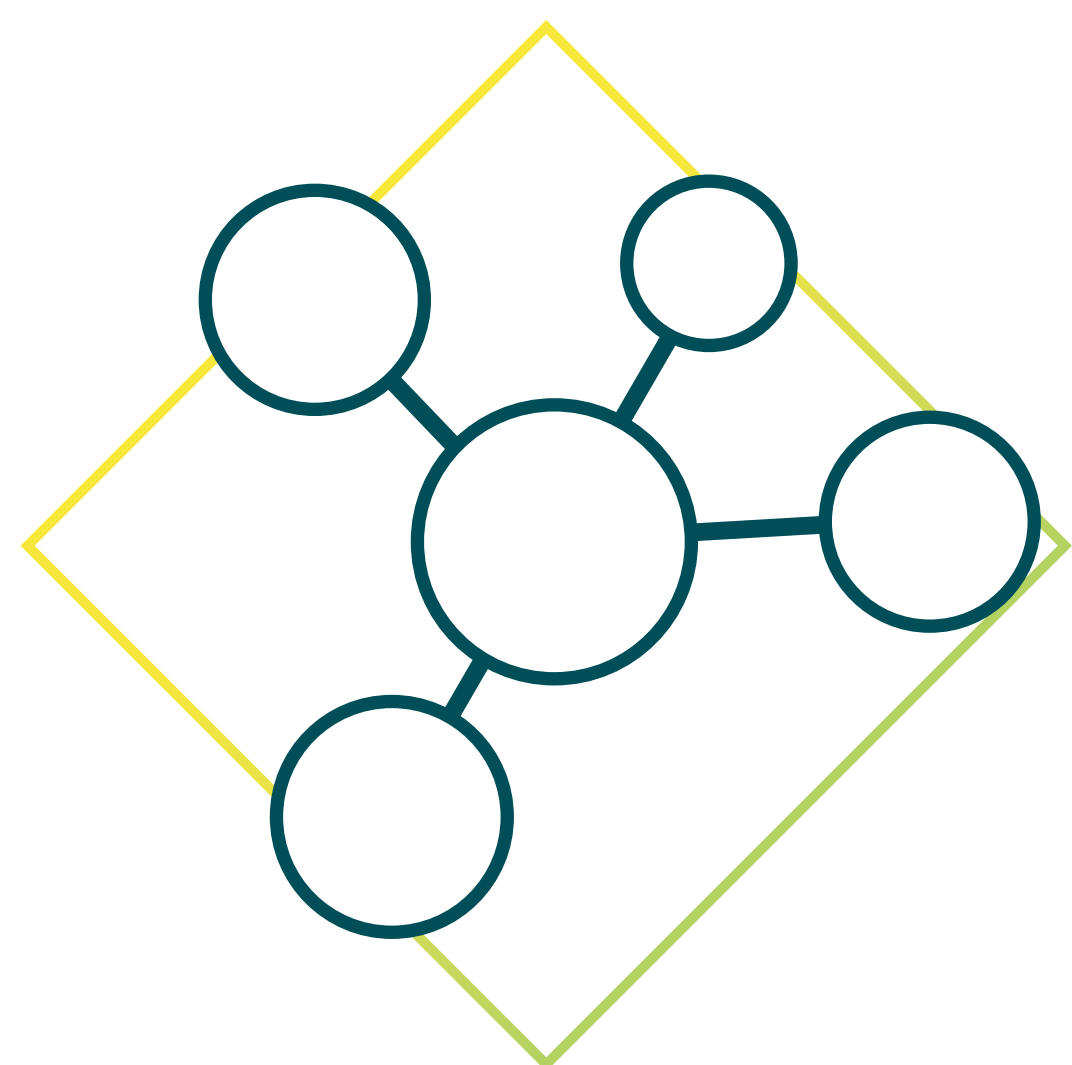
Diazepam, the active ingredient in VALTOCO, is a Schedule IV controlled substance.

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.

SUMMARY

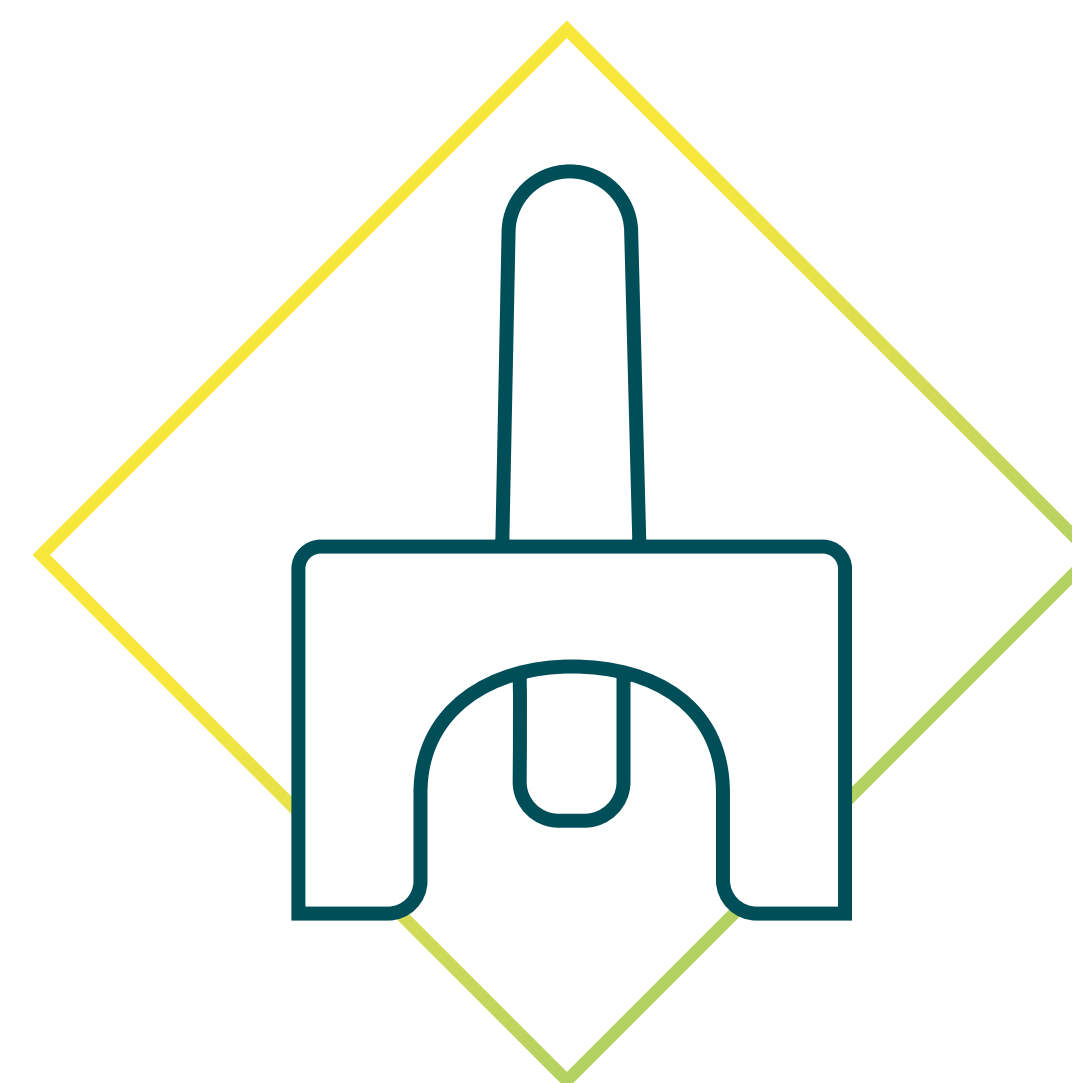
VALTOCO is here for you and your patients, providing reliable rescue treatment whenever they need it, wherever they may be.



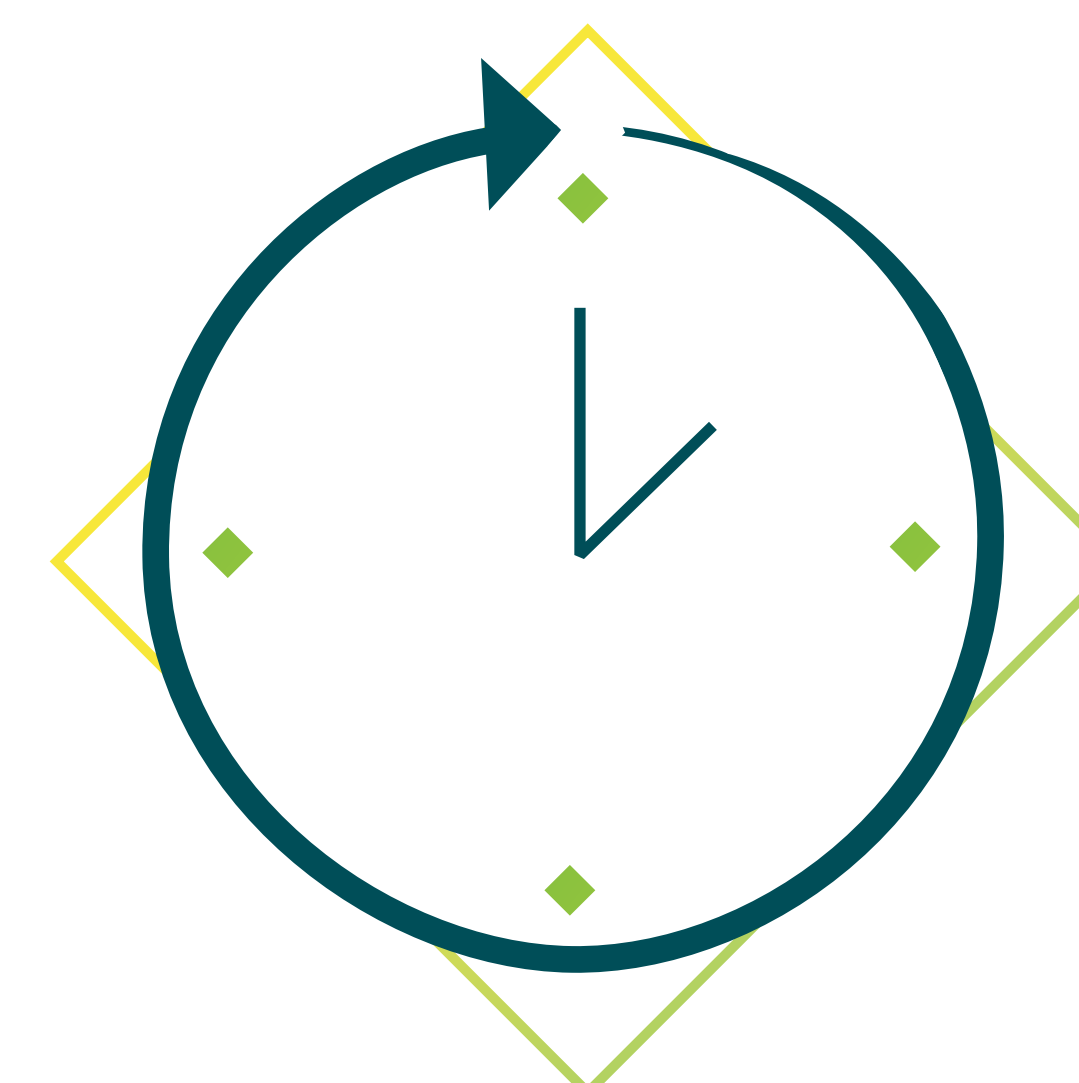
**HERITAGE MEETS
INNOVATION**



RELIABLE RESCUE



**INDIVIDUALIZED
DOSING**



**THROUGHOUT
THE DAY**

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To learn more, go to **VALTOCOHCP.com**

REFERENCES

1. VALTOCO® (diazepam nasal spray) Prescribing Information. Neurelis, Inc.
2. Parsonage MJ, Norris JW. Use of diazepam in treatment of severe status epilepticus. *Br Med J*. 1967;3:85-88.
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