VALTOCO®
(diazepam nasal spray) CIV

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 optimized for nasal delivery.[1-3]

Diazepam

- Recognized as safe and effective seizure treatment for more than 50 years[2]
- Prescribed as a seizure rescue treatment 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 volume[8]
- Coats the nasal cavity[9]

Contraindications: VALTOCO is contraindicated in patients with:

- Known hypersensitivity to diazepam
- Acute narrow-angle glaucoma

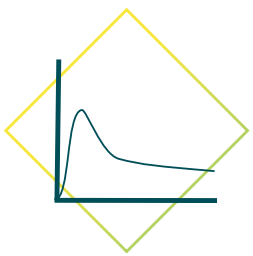
Please see Important Safety Information on page 11 and accompanying full Prescribing Information.

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 variability[1]

SUSTAINED LEVELS

Maintained plasma levels for over 24 hours[1]

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 Important Safety Information on page 11 and accompanying full Prescribing Information.

VALTOCO—SPECIFIC, INDIVIDUALIZED DOSING

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

Each box of VALTOCO contains 2 blister packs[1]

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 Important Safety Information on page 11 and accompanying full Prescribing Information.

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 used[12]

WITH A SINGLE DOSE

- Ongoing open-label, repeat-dose safety study*
  - 177 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 required[1]

*Data from a 12-month, open-label, repeat-dose safety study in epilepsy subjects (CSR Study 05).

Contraindications: VALTOCO is contraindicated in patients with:

- Known hypersensitivity to diazepam
- Acute narrow-angle glaucoma

Please see Important Safety Information on page 11 and accompanying full Prescribing Information.

VALTOCO—PROVEN SAFETY AND TOLERABILITY[1]

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 dosing strategy[1]
  - The most frequent adverse reactions (at least 4%) were somnolence, headache, and diarrhea. Adverse events were usually mild or moderate in intensity[1]

*Data from an open-label, repeat-dose pharmacokinetic study in epilepsy subjects under seizure and normal conditions (CSR Study 04) and a 12-month, open-label, repeat-dose safety study in epilepsy subjects (CSR Study 05).

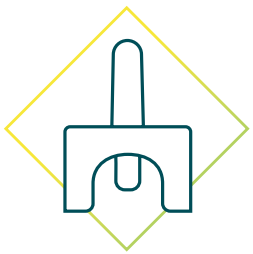
Adverse Reactions
The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort.
Please see Important Safety Information on page 11 and accompanying full Prescribing Information.

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 weight[1]



READY-TO-USE DESIGN

Designed for prompt administration by anyone[1]

SMALL PACKAGING, SMALL DEVICE

Discreet and easy to carry for use whenever needed[1]

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 Important Safety Information on page 11 and accompanying full Prescribing Information.

VALTOCO® (diazepam nasal spray) CV

VALTOCO—AT HOME OR AWAY

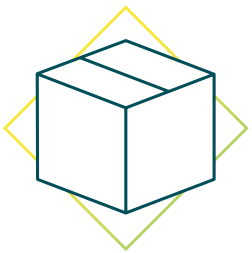
In this time of social distancing and remote medicine, VALTOCO is there for your patients—wherever, whenever.

RESCUE TREATMENT AT HOME

VALTOCO is designed for use by anyone. Treating at home may help to avoid exposure to COVID-19 in a medical setting[1]

ONLINE TOOLS & RESOURCES

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



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 free delivery

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 Important Safety Information on page 11 and accompanying full Prescribing Information.

VALTOCO® (diazepam nasal spray) CV

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. And, with our copay savings program, eligible patients may pay as little as $20.*

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!

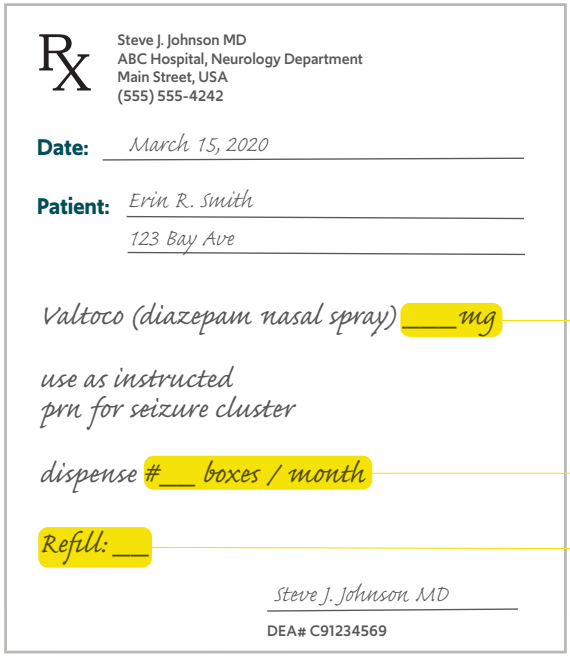
Visit www.MaxorSpecialty.com or call 1-866-629-6779 Monday-Friday, 8 AM to 5 PM CT, for more information

*For commercial patients only.

VALTOCO® (diazepam nasal spray) CV

HOW TO WRITE A VALTOCO PRESCRIPTION

EXAMPLE SCRIPT



Insert dose:
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 Important Safety Information on page 11 and accompanying full Prescribing Information.

VALTOCO® (diazepam nasal spray) CV

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**

Contraindications: VALTOCO is contraindicated in patients with:

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Central Nervous System (CNS) Depression

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Suicidal Behavior and Ideation

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Adverse Reactions

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

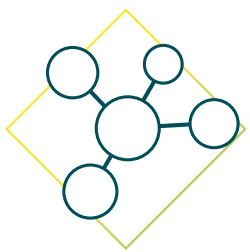
Diazepam, the active ingredient in VALTOCO, is a Schedule IV controlled substance.

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.

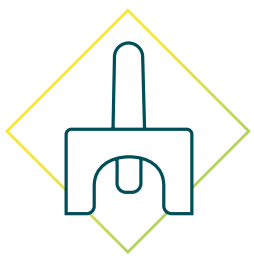
SUMMARY

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

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

REFERENCES

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NEURELIS®
OUR PASSION IS PROGRESS