

## **NEURELIS, INC. CONFIRMATION OF UNINTERRUPTED VALTOCO® (DIAZEPAM NASAL SPRAY) AVAILABILITY IN RESPONSE TO UCB ANNOUNCEMENT OF NAYZILAM® SUPPLY SHORTAGE**

Neurelis, Inc. is completely committed to the well being of people with epilepsy and those providing care for them. Our team is focused on ensuring uninterrupted access to VALTOCO® (diazepam nasal spray) so that those who experience seizure clusters will be able to more effectively manage their condition.

In early October, UCB announced a shortage of NAYZILAM® (midazolam) nasal spray due to an unforeseen manufacturing delay. In response to this communication, Neurelis has received inquiries about VALTOCO and wants to reassure the epilepsy community that there are no issues with the supply of VALTOCO.

VALTOCO was approved by the U.S. Food and Drug Administration (FDA) earlier this year for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in adult and pediatric patients 6 years of age and older.

Neurelis encourages people impacted by this shortage to consult with their health care provider.

For more information on VALTOCO, please visit [www.valtoco.com](http://www.valtoco.com).

### **What is VALTOCO® (diazepam nasal spray)?**

- VALTOCO is a prescription medicine used for the short-term treatment of seizure clusters (also known as “acute repetitive seizures”) in patients 6 years of age and older.
- VALTOCO is a federal controlled substance (CIV) because it can be abused or lead to dependence. Keep VALTOCO in a safe place to prevent misuse and abuse. Selling or giving away VALTOCO may harm others and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription drugs, or street drugs.
- It is not known if VALTOCO is safe and effective in children under 6 years of age.

### **IMPORTANT SAFETY INFORMATION**

**Important Safety Information you should know about VALTOCO® (diazepam nasal spray), CIV**

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

- VALTOCO is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.

- VALTOCO can make you sleepy or dizzy and can slow your thinking and your motor skills. Do not drive, operate heavy machinery, or do other dangerous activities until you know how VALTOCO affects you.
- Like other antiepileptic drugs, VALTOCO may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:
  - Thoughts about suicide or dying
  - Feeling agitated or restless
  - Acting aggressive, being angry, or violent
  - Attempts to commit suicide
  - Panic attacks
  - Acting on dangerous impulses
  - Trouble sleeping (insomnia)
  - An extreme increase in activity and talking (mania)
  - New or worse anxiety
  - New or worse irritability
  - Other unusual changes in behavior or mood
  - New or worse depression

#### **How can I watch for early symptoms of suicidal thoughts or actions?**

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms. Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

#### **Do not use VALTOCO if you:**

- Are allergic to diazepam.
- Have an eye problem called acute narrow-angle glaucoma.

#### **What should I tell my doctor before taking VALTOCO?**

Before using VALTOCO, tell your healthcare provider about all of your medical conditions, including if you:

- Have asthma, emphysema, bronchitis, chronic obstructive pulmonary disease, or other breathing problems.
- Have a history of alcohol or drug abuse.
- Have a history of depression, mood problems, or suicidal thoughts or behavior.
- Have liver or kidney problems.
- Are pregnant or plan to become pregnant. VALTOCO may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. VALTOCO passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you use VALTOCO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### **How should I use VALTOCO?**

- Read the Instructions for Use for detailed information about the right way to use VALTOCO.
- Use VALTOCO exactly as prescribed by the healthcare provider.
- Your healthcare provider will tell you:
  - What seizure clusters are
  - Exactly how much VALTOCO to give
  - When to give VALTOCO
  - How to give VALTOCO
  - What to do after you give VALTOCO if the seizures do not stop or there is a change in breathing, behavior, or condition that worries you
- You should carry VALTOCO with you in case you need to control your seizure clusters.
- Family members, care providers, and other people who may have to give VALTOCO should know where you keep your VALTOCO and how to give VALTOCO before a seizure cluster happens.
- VALTOCO is given in the nose (nasal) only.
- VALTOCO comes ready to use.
- Each VALTOCO only sprays 1 time and cannot be reused. Do not test or prime the nasal spray before use.
- Each dose of VALTOCO is provided in an individual pack. Use all of the medicine in 1 pack for a complete dose.

### **What should I do after I give VALTOCO?**

- Stay with the person after you give VALTOCO and watch them closely.
- Keep or move the person onto their side.
- Make a note of the time VALTOCO was given.
- Call for emergency help if any of the following happen:
  - Seizure behavior is different than other seizures the person has had.
  - You are alarmed by how often the seizures happen, by how severe the seizure is, by how long the seizure lasts, or by the color or breathing of the person.
- Throw away (discard) the used VALTOCO.

If needed, a second dose may be given at least 4 hours after the first dose, using a new pack of VALTOCO. Do not give more than 2 doses of VALTOCO to treat a seizure cluster.

A second dose should not be given if there is concern about the person's breathing, they need help with their breathing, or have extreme drowsiness.

Do not use VALTOCO for more than 1 seizure cluster episode every 5 days. Do not use VALTOCO for more than 5 seizure cluster episodes in 1 month.

### **What should I avoid while using VALTOCO?**

- Do not drink alcohol or take opioid medicines that make you sleepy or dizzy while taking VALTOCO until you talk to your healthcare provider. When taken with alcohol or medicines that can cause sleepiness or dizziness, VALTOCO may make your sleepiness or dizziness worse.

### **What are the most common side effects of VALTOCO?**

The most common side effects of VALTOCO include:

- Feeling sleepy or drowsy
- Headache
- Nose discomfort

These are not all of the possible side effects of VALTOCO. Call your healthcare provider for medical advice about side effects. You may report side effects to Neurelis, Inc. at 1-866-696-3873 or to FDA at 1-800-FDA-1088.

Please see full [Prescribing Information](#) and [Medication Guide](#) for additional important safety information.

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