



YOU'VE GOT THIS

Discussing your rescue treatment plan with VALTOCO[®] (diazepam nasal spray)

TALK OPENLY WITH YOUR HEALTHCARE PROVIDER

It's important that you feel comfortable with your rescue treatment plan. Together, you and your care team can discuss if VALTOCO may be right for you. Below are some suggestions on how to get the conversation going.

It may be a good idea to print this out and bring it with you the next time you chat with your healthcare provider.



Be confident and proactive

- Approach the appointment with assurance. You have the right to be a partner in your own healthcare, or in the care of your loved one
- Ask about VALTOCO and if it may be appropriate
- Bring a pen and paper so you can take notes
- Do not rush; if you need more time, you can always make a follow-up appointment



Make sure you are clear on the next steps

- Ask questions about how VALTOCO should be taken
- Inquire about lifestyle changes to consider
- Don't hesitate to ask for clarification if any words or concepts are unfamiliar or confusing
- Be sure to ask about Maxor—a specialty pharmacy that can deliver VALTOCO right to your door



Update your seizure action plan

- Seizures can occur even when your daily anti-seizure medication is taken as directed
- Work with your healthcare provider to create a seizure treatment plan.
 You can download a template from the Epilepsy Foundation <u>here</u>
- Make sure you and your loved ones know what to do in case of seizure

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.

PREPARE FOR YOUR APPOINTMENT

1. If you keep a seizure diary, bring it with you

• Find tools for seizure tracking here: https://diary.epilepsy.com or www.seizuretracker.com

2. If you record seizure information on your own, be sure to include:

• Seizure experience

	Type of seizures							
	How often they occur							
	How long they last							
Medications								
	Anti-seizure drugs							
Other prescription medications								
	Over-the-counter medicines, herbs, and vitamins							
	Medication challenges you've observed							
 Triggers you associate with seizures 								
	Medications, skipped doses, drug interactions							
	Illness, fatigue, emotional stress							
	Recreational drugs, alcohol							
	Flickering or flashing lights, TV or video games							
	Hormonal changes (puberty, menses, menopause)							

• The impact of epilepsy on life, work, and family. Even if it's difficult to talk about, your healthcare providers need to know how epilepsy affects you. Don't assume they understand; only you can explain your experience

3. Make a list of questions in advance. This will aid your memory, and help focus the conversation

1	 	 	 	
2				
3	 	 	 	

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
- New or worse anxiety New or worse irritability

Trouble sleeping (insomnia)

An extreme increase in activity

 Other unusual changes in behavior or mood

and talking (mania)

New or worse depression

Acting on dangerous impulses 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



