

MEDICATION GUIDE
VALTOCO® (val-toe-koe)
(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 (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency medical help right away if any of the following happens:
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation)Do not drive or operate heavy machinery until you know how taking VALTOCO with opioids affects you.
- **Risk of abuse, misuse, and addiction.** There is a risk for abuse, misuse, and addiction with benzodiazepines, including VALTOCO, which can lead to overdose and serious side effects including coma and death.
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including diazepam (the active ingredient in VALTOCO).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - You can develop an addiction even if you use VALTOCO as prescribed by your healthcare provider.
 - **Use VALTOCO exactly as your healthcare provider prescribed.**
 - Do not share your VALTOCO with other people.
 - Keep VALTOCO in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Benzodiazepines, including VALTOCO, can cause physical dependence and withdrawal reactions, especially if you use VALTOCO daily. VALTOCO is not intended for daily use.
 - **Do not suddenly stop using VALTOCO without talking to your healthcare provider.** Stopping VALTOCO suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.**
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
 - Do not use more VALTOCO than prescribed or use VALTOCO more often than prescribed.
- **VALTOCO can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how VALTOCO affects you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while using VALTOCO without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, VALTOCO may make your sleepiness or dizziness worse.
- **Like other antiepileptic medicines, VALTOCO may cause suicidal thoughts or actions in a small number of people, about 1 in 500. Call your 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.

What is VALTOCO?

- VALTOCO is a prescription medicine used for short-term treatment of seizure clusters (also known as “acute repetitive seizures”) in people 6 years of age and older.
- **VALTOCO is a federally controlled substance (C-IV) because it contains diazepam that 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.

Do not use VALTOCO if you:

- are allergic to diazepam or any of the ingredients in VALTOCO. See the end of this Medication Guide for a complete list of ingredients in VALTOCO.
- have an eye problem called acute narrow angle glaucoma.

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 behaviors.
- have liver or kidney problems.
- are pregnant or plan to become pregnant.
 - Taking VALTOCO late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone) and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems).
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with VALTOCO.
 - If you become pregnant while using VALTOCO, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. You can register by calling 1-888-233-2334. For more information about the registry, go to <http://www.aedpregnancyregistry.org>. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- are breastfeeding or plan to breastfeed. VALTOCO passes into your breast milk and may harm your baby.
 - Breastfeeding during treatment with VALTOCO may cause your baby to have sleepiness, feeding problems, and decreased weight gain.
 - 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. Using VALTOCO with certain other medicines can cause side effects or affect how well VALTOCO or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I use VALTOCO?

- **Read the Instructions for Use that comes with this Medication Guide for detailed information about the right way to use VALTOCO.**
- Use VALTOCO exactly as prescribed by your 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 it 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.
- Make a note of the time VALTOCO was given.
- Call for emergency help if any of the following happen:
 - seizure cluster behavior is different than other seizure clusters 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?

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

What are the possible side effects of VALTOCO?

VALTOCO may cause serious side effects, including:

- See “**What is the most important information I should know about VALTOCO?**”
- **Increase in eye pressure in people with open-angle glaucoma.** See “**Do not use VALTOCO if you:**”

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 doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

How should I store VALTOCO?

- Store VALTOCO at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze VALTOCO.
- Keep VALTOCO in its blister pack until ready to use. Protect it from light.
- **Keep VALTOCO and all medicines out of the reach of children.**

General information about the safe and effective use of VALTOCO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VALTOCO for a condition for which it was not prescribed. Do not give VALTOCO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VALTOCO that is written for health professionals.

What are the ingredients in VALTOCO?

Active ingredient: diazepam

Inactive ingredients: benzyl alcohol, dehydrated alcohol, n-dodecyl beta-D-maltoside, and vitamin E.

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