VALTOCO® (diazepam nasal spray) CIV

PRESCRIPTION FORM FOR PATIENTS ON VALTOCO

Contact Maxor Specialty Pharmacy - Amarillo, Texas
Fax: 1-866-217-8034 · Phone: 1-866-629-6779

PLEASE FILL OUT THE PATIENT INFORMATION AND PATIENT INSURANCE INFORMATION SECTIONS

Patient Information

Patient Name: _____ DOB: ___/___/___ Sex: ☐ M ☐ F ☐ Unspecified

Street Address: _____ City: _____ State: _____ ZIP: _____

Mobile phone: ( ) _____ Home phone: ( ) _____ Email: _____

Your **VALTOCO** prescription will be filled by Maxor Specialty Pharmacy. You will receive a call from Maxor Specialty Pharmacy to confirm delivery of your prescription.

Patient Insurance Information

Prescription Plan Name: _____ Group # _____

Policy # _____ Rx BIN # _____ Rx PCN # _____

Insurance phone: ( ) _____ Policy # _____ Policyholder Name: _____ DOB: __/__/__

THE FOLLOWING SECTION IS TO BE FILLED OUT BY YOUR DOCTOR'S OFFICE

Prescriber Information

Prescriber Name: _____ Specialty: _____ NPI # _____ DEA # _____

Facility Name/Address: _____ City: _____ State: _____ ZIP: _____

Office Contact Name: _____ Email: _____ Phone: ( ) _____ Fax: ( ) _____

Clinical Information for Insurance Prior Authorizations— Please include a copy of patient's clinical notes, if available.

Diagnosis

Diagnosis code(s): _____

_____

Most Recent Antiepileptic Drug Treatment

Approximate Start and End Dates of Most Recent Treatment: _____

Surgical History: _____

Drug Allergies: _____

Prescription (Circle one option for each section)

VALTOCO Dosage Strength: 5 mg 10 mg 15 mg 20 mg

Instructions: _____

BOXES: 1 2 3 4 5 Other# _____ Boxes

REFILLS: 1 2 3 4 5 Other# _____ Refills

Prescriber Authorization (Required)

I authorize the designated pharmacy to act as an agent to initiate and execute the insurance prior authorization process, if necessary, for this prescription and any future fills of the same prescription for the patient listed above. I understand that I can revoke this designation at any time by providing written notice.

Prescriber's Signature: _____ Date __/__/__

Please complete and sign this form. Fax completed form to 1-866-217-8034.

This fax is intended to be delivered to the named addressee. It contains material that is confidential, proprietary, or exempt from disclosure under applicable law. If you are not the named addressee, you should not disseminate, distribute, or copy this fax. Notify sender immediately if you have received this document in error and then destroy this document immediately.

Please see accompanying full Prescribing Information, including Boxed Warning, and full Important Safety Information on the back.

VALTOCO® (diazepam nasal spray) CIV

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

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

- **Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for 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.**
- **The use of benzodiazepines, including VALTOCO, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing VALTOCO and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.**
- **The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although VALTOCO is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of VALTOCO may precipitate acute withdrawal reactions, which can be life-threatening. For patients using VALTOCO more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue VALTOCO.**

Contraindications: VALTOCO is contraindicated in patients with:

- Hypersensitivity to diazepam
- Acute narrow-angle glaucoma

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.

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.

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.

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.

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.

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.

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