Our Commitment to Patients: Why 5 Dose Packaging Matters

Neurelis is continually working to improve care for people living with epilepsy. We strive to provide treatments that empower their lives. We recently shifted our dose packaging to a five-dose box in response to the concerns of physicians and patients who were not being provided adequate treatment to address their needs. The reception from both physicians and patients has been overwhelmingly positive.

Better understanding provider care plans, treatment goals, and empowering patients is at the heart of this decision.

- **Ensuring Access.** Experts consistently recommend patients at risk for episodes of frequent seizures have immediate-use "rescue" medication. Having five doses in a box helps ensure that patients have enough VALTOCO (diazepam nasal spray) doses on hand to treat all episodes of frequent seizures as their health care provider has directed.
- **NCPDP, Physician, and Patient Consultation.** Neurelis thoughtfully researched multiple solutions to this problem, including consultations with the National Council for Prescription Drug Programs (NCPDP). After exhaustive research with doctors, physicians, and patients, we concluded that a five-dose package would optimize patient care and fit within the FDA approved indication for use of VALTOCO.
- **FDA Approval.** Neurelis also submitted the five-dose packaging to the FDA for regulatory review, and the FDA following their processes approved the revised five-dose packaging.
- **Doses to Match Prescriber Intent.** An independent pharmacy audit revealed patients were not receiving the number of VALTOCO doses the prescriber intended. The discrepancy could result in a significant issue in patient care and increased risk for seizures not treated as directed. Our ongoing conversations with patients revealed they are often waiting or reserving doses for what they consider more severe episodes of frequent seizures rather than treating them as directed by their health care provider.
- **Doses to Match Patient Need.** Patients no longer have to ration out doses to select locations and instead medication can be readily available in all settings where they may experience a seizure, including home, school, work, and relatives' homes, with appropriate training and action plans in place for caregivers to help stop a seizure.
- **Pricing Unchanged.** The price of a dose of VALTOCO remains unchanged. Insurance coverage continues to be exceptional for the five-dose carton.
- **Fewer Trips to the Pharmacy with a Longer Shelf Life.** VALTOCO has an extended shelf life and remains stable when stored at room temperature for 32 to 36 months. This is especially convenient for some patients who use only 2 or 3 doses per year.

If needed, a second dose may be used at least 4 hours after the first. Do not use more than 2 doses per episode. Do not use VALTOCO to treat more than 1 episode every 5 days or more than 5 episodes per month.

For more information on VALTOCO talk to your doctor or visit https://valtoco.com/

VALTOCO® (diazepam nasal spray) is indicated 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 patients with epilepsy 2 years of age and older.

Important Safety Information about VALTOCO:

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.**

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 see full Prescribing Information at https://valtoco.com

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