

January 2021

IMPORTANT PRESCRIBING INFORMATION

**Subject: VALTOCO® (diazepam nasal spray) Incorrect Dosing Information (Misprint):
Correcting Dosing and Administration Information**

Dear Health Care Provider:

The purpose of this letter is to inform you of incorrect dosing information in Table 1 of the prescribing information (PI) for VALTOCO® (diazepam nasal spray), a benzodiazepine 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 6 years of age and older. The PI located inside the carton contains an error in Section 2.2 “Dosing Information” Table 1, which incorrectly states that the number of sprays required to administer the 5 mg and 10 mg doses is “One spray in **each** nostril” instead of the correct dosing instructions “One spray in **one** nostril” [emphasis added]. This error is located only in Table 1 of the printed PI located in the product cartons. The dosing instructions are correct in all other locations and patient information, such as the Instructions for Use that are included in each blister pack and in all online sources (e.g., DailyMed, VALTOCO websites, etc.). Table 1 below shows the corrected dosing and administration information.

Dosing and Administration

The recommended dose of VALTOCO nasal spray is 0.2 mg/kg or 0.3 mg/kg, depending on the patient’s age and weight. See Table 1 for specific recommendations.

Table 1: Recommended Dosage for Adults and Pediatric Patients 6 Years of Age and Older

Dose Based on Age and Weight			Administration	
6 to 11 Years of Age (0.3 mg/kg)	12 Years of Age and Older (0.2 mg/kg)	Dose (mg)	Number of Nasal Spray Devices	Number of Sprays
Weight (kg)	Weight (kg)			
10 to 18	14 to 27	5	One 5 mg device	One spray in one nostril
19 to 37	28 to 50	10	One 10 mg device	One spray in one nostril
38 to 55	51 to 75	15	Two 7.5 mg devices	One spray in each nostril
56 to 74	76 and up	20	Two 10 mg devices	One spray in each nostril

Neurelis, Inc.

Provider Action

Counsel patients about the correct dosing and administration information to ensure that patients prescribed the 5 mg or 10 mg dose use only one spray in one nostril for a complete dose. Also, direct patients to the patient-friendly Instructions for Use that are in each blister pack for information on how to use the product correctly. Product with the incorrect Dosing Information (Section 2.2, Table 1) is being distributed currently to avoid a drug shortage. Cartons (all dosing strengths) with a correct PI should be available through the distribution system by 22 February 2021.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events and medication errors in patients who have been given VALTOCO to Neurelis at 1-866-696-3873.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

You may also contact our medical information department at 1-866-696-3873 if you have any questions about the information contained in this letter or the safe and effective use of VALTOCO.

This letter is not intended to be a complete description of the benefits and risks related to the use of VALTOCO. Please refer to the enclosed full prescribing information and medication guide.

For additional information, please call 1-866-696-3873 or visit www.valtochcp.com.

Sincerely,

David F. Cook, PhD
Executive Director, Scientific Operations
Neurelis, Inc.

Enclosure: VALTOCO Full Prescribing Information and Medication Guide