

Table 1. Treatment-Emergent Adverse Events (TEAEs) by Frequency of Diazepam Nasal Spray Use

TEAEs	Incidence, n (%)		
	Total (N=158)	Moderate, <2 doses/month (n=69)	Frequent, ≥2 doses/month (n=89)
Any TEAE	119 (75.3)	49 (71.0)	70 (78.7)
TEAEs leading to study discontinuation	0	0	0
Serious TEAEs	45 (28.5)	22 (31.9)	23 (25.8)
Treatment-related TEAEs	26 (16.5)	8 (11.6)	18 (20.2)
Most common TEAEs (≥5% in either usage group)			
Seizure	23 (14.6)	13 (18.8)	10 (11.2)
Nasopharyngitis	12 (7.6)	1 (1.4)	11 (12.4)
Upper respiratory tract infection	12 (7.6)	8 (11.6)	4 (4.5)
Pneumonia	11 (7.0)	6 (8.7)	5 (5.6)
Pyrexia	10 (6.3)	4 (5.8)	6 (6.7)
Nasal discomfort	9 (5.7)	3 (4.3)	6 (6.7)
Influenza	8 (5.1)	1 (1.4)	7 (7.9)
Dizziness	7 (4.4)	5 (7.2)	2 (2.2)
Headache	7 (4.4)	2 (2.9)	5 (5.6)
Somnolence	7 (4.4)	2 (2.9)	5 (5.6)
Sinusitis	6 (3.8)	4 (5.8)	2 (2.2)
Status epilepticus	5 (3.2)	0	5 (5.6)
Most common treatment-related TEAEs (≥2% in either usage group)			
Nasal discomfort	9 (5.7)	3 (4.3)	6 (6.7)
Headache	4 (2.5)	1 (1.4)	3 (3.4)
Epistaxis	3 (1.9)	1 (1.4)	2 (2.2)
Somnolence	3 (1.9)	1 (1.4)	2 (2.2)
Rhinalgia	2 (1.3)	0	2 (2.2)
Rhinorrhea	2 (1.3)	0	2 (2.2)