

Table 1. Overview of psychiatric TEAEs and TEAEs related to hostility/aggression^a in pediatric patients (aged 4 to <12 years) during the Study 311 Core Study and Extension A (Safety Analysis Set)

	POS (n=149)	SGS (n=54)	PGTCS (n=31)	Total (N=180)
TEAEs, n (%)	136 (91.3)	53 (98.1)	26 (83.9)	162 (90.0)
Psychiatric TEAEs, n (%)	58 (38.9)	18 (33.3)	13 (41.9)	71 (39.4)
Most common psychiatric TEAEs (≥ 2 patients), n (%)				
Irritability	19 (12.8)	8 (14.8)	5 (16.1)	24 (13.3)
Aggression	16 (10.7)	2 (3.7)	2 (6.5)	18 (10.0)
Agitation	7 (4.7)	3 (5.6)	2 (6.5)	9 (5.0)
Insomnia	5 (3.4)	3 (5.6)	1 (3.2)	6 (3.3)
Anxiety	3 (2.0)	2 (3.7)	2 (6.5)	5 (2.8)
Bradyphrenia	5 (3.4)	0 (0.0)	0 (0.0)	5 (2.8)
Attention deficit/hyperactivity disorder	4 (2.7)	0 (0.0)	0 (0.0)	4 (2.2)
Anger	3 (2.0)	1 (1.9)	0 (0.0)	3 (1.7)
Dysphemia	1 (0.7)	0 (0.0)	1 (3.2)	2 (1.1)
Enuresis	3 (2.0)	2 (3.7)	0 (0.0)	3 (1.7)
Restlessness	2 (1.3)	2 (3.7)	0 (0.0)	2 (1.1)
TEAEs related to hostility/aggression,^a n (%)	48 (32.2)	12 (22.2)	13 (41.9)	61 (33.9)
Most common TEAEs related to hostility/aggression^a (≥ 2 patients), n (%)				
Irritability	19 (12.8)	8 (14.8)	5 (16.1)	24 (13.3)
Aggression	16 (10.7)	2 (3.7)	2 (6.5)	18 (10.0)
Agitation	7 (4.7)	3 (5.6)	2 (6.5)	9 (5.0)
Psychomotor hyperactivity	5 (3.4)	0 (0.0)	2 (6.5)	7 (3.9)
Laceration	3 (2.0)	0 (0.0)	3 (9.7)	6 (3.3)
Anger	3 (2.0)	1 (1.9)	0 (0.0)	3 (1.7)

Patients with ≥ 2 TEAEs in the same system organ class (or with the same preferred term) are counted only once for that system organ class (or preferred term)

^aBased on Narrow and Broad MedDRA SMQ Terms

MedDRA, Medical Dictionary for Regulatory Activities; PGTCS, primary generalized tonic-clonic seizures; POS, partial-onset seizures; SGS, secondarily generalized seizures; SMQ, Standardized MedDRA Queries; TEAE, treatment-emergent adverse event