

Table. Overview of TEAEs and most common TEAEs (occurring in ≥ 2 patients) by age group (Safety Analysis Set)

	Age group		Total (N=12 ^a)
	>6 to \leq 12 months (n=4)	>12 to <24 months (n=8)	
TEAEs, n (%)	4 (100.0)	7 (87.5)	11 (91.7)
Treatment-related TEAEs, n (%)	3 (75.0)	6 (75.0)	9 (75.0)
Severe TEAEs, n (%)	0 (0.0)	2 (25.0)	2 (16.7)
Serious TEAEs^{b,c}, n (%)	2 (50.0)	3 (37.5)	5 (41.7)
Deaths	0 (0.0)	0 (0.0)	0 (0.0)
TEAEs leading to dose adjustment, n (%)	3 (75.0)	5 (62.5)	8 (66.7)
Dose reduction	2 (50.0)	5 (62.5)	7 (58.3)
Dose interruption	1 (25.0)	0 (0.0)	1 (8.3)
Withdrawal	0 (0.0)	0 (0.0)	0 (0.0)
Most common TEAEs occurring in ≥ 2 patients, n (%)			
Upper respiratory tract infection	1 (25.0)	5 (62.5)	6 (50.0)
Pyrexia	1 (25.0)	4 (50.0)	5 (41.7)
Nasopharyngitis	2 (50.0)	2 (25.0)	4 (33.3)
Somnolence	2 (50.0)	2 (25.0)	4 (33.3)
Diarrhea	0 (0.0)	3 (37.5)	3 (25.0)
Ataxia	1 (25.0)	1 (12.5)	2 (16.7)
Irritability	0 (0.0)	2 (25.0)	2 (16.7)
Nasal congestion	1 (25.0)	1 (12.5)	2 (16.7)
Seizure	0 (0.0)	2 (25.0)	2 (16.7)
Vomiting	0 (0.0)	2 (25.0)	2 (16.7)

^aOne patient did not have AE data entered in the database, thus only data from 11 patients are summarized

^bSerious TEAEs are those that required inpatient hospitalization or prolongation of existing hospitalization

^cAll serious TEAEs were deemed not to be related to study drug

AE, adverse event; TEAE, treatment emergent adverse event