

**Table 14.5.1.3: Adverse Events by preferred term, System organ class & Severity
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Any Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Gastrointestinal disorders	18 (81.8)	10 (52.6)	9 (34.6)	19 (42.2)	37 (55.2)
Diarrhea	15 (68.2)	7 (36.8)	5 (19.2)	12 (26.7)	27 (40.3)
Mild	12 (54.5)	6 (31.6)	3 (11.5)	9 (20.0)	21 (31.3)
Moderate	3 (13.6)	1 (5.3)	2 (7.7)	3 (6.7)	6 (9.0)
Severe	0	0	0	0	0
Vomitting	6 (27.3)	3 (15.8)	4 (15.4)	7 (15.6)	13 (19.4)
Mild	4 (18.2)	1 (5.3)	1 (3.8)	2 (4.4)	6 (9.0)
Moderate	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Severe	1 (4.5)	1 (5.3)	0	1 (2.2)	2 (3.0)
Nervous system disorder	15 (68.2)	8 (42.1)	17 (65.4)	25 (55.6)	40 (59.7)
Headache	14 (63.6)	7 (36.8)	14 (53.8)	21 (46.7)	35 (52.2)
Mild	10 (45.5)	5 (26.3)	8 (30.8)	13 (28.9)	23 (34.3)
Moderate	4 (18.2)	1 (5.3)	6 (23.1)	7 (15.6)	11 (16.4)
Severe	2 (9.1)	2 (10.5)	1 (3.8)	3 (6.7)	5 (7.5)
Tremor	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Mild	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Moderate	1 (4.5)	0	1 (3.8)	1 (2.2)	2 (3.0)
Severe	0	0	0	0	0
Vascular disorders	5 (22.7)	6 (31.6)	8 (30.8)	14 (31.1)	19 (28.4)
Hypotension	4 (18.2)	2 (10.5)	5 (19.2)	7 (15.6)	11 (16.4)
Mild	1 (4.5)	2 (10.5)	3 (11.5)	5 (11.1)	6 (9.0)
Moderate	2 (9.1)	0	2 (7.7)	2 (4.4)	4 (6.0)

n = Number of subjects in specified category, N = Number of Subjects

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	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Severe	1 (4.5)	0	0	0	1 (1.5)
Flushing	1 (4.5)	1 (5.3)	2 (7.7)	3 (6.7)	4 (6.0)
Mild	1 (4.5)	1 (5.3)	1 (3.8)	2 (4.4)	3 (4.5)
Moderate	0	0	1 (3.8)	1 (2.2)	1 (1.5)
Severe	0	0	0	0	0
Poor venous access	0	3 (15.8)	2 (7.7)	5 (11.1)	5 (7.5)
Mild	0	3 (15.8)	0	3 (6.7)	3 (4.5)
Moderate	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Severe	0	0	0	0	0
Cardiac disorders	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Tachycardia	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Mild	1 (4.5)	1 (5.3)	0	1 (2.2)	2 (3.0)
Moderate	1 (4.5)	0	0	0	1 (1.5)
Severe	0	0	0	0	0
Eye disorders	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Conjunctivitis allergic	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Mild	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Moderate	0	3 (15.8)	0	3 (6.7)	3 (4.5)
Severe	0	0	0	0	0

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