

**Table 14.5.1.1: Summary of Adverse Events  
Safety Population**

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
Number of Subjects with Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Number of Subjects with Treatment Emergent Adverse Event	20 (90.9)	18 (94.7)	24 (92.3)	42 (93.3)	62 (92.5)
Number of Subjects with Serious Adverse Events	4 (18.2)	3 (15.8)	6 (23.1)	9 (20.0)	13 (19.4)
Number of Subjects with Severe Adverse Event	4 (18.2)	3 (15.8)	1 (3.8)	4 (8.9)	8 (11.9)

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

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

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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

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

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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

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