

Table 5.1
Adverse Events
By Body System, Preferred Term, and Greatest Severity

Body System Preferred Term Severity	Active N= 36	Placebo N= 34	Overall N= 70
Any Event	6 (16.7%)	8 (23.5%)	14 (20.0%)
Mild	4 (11.1%)	1 (2.9%)	5 (7.1%)
Moderate		5 (14.7%)	5 (7.1%)
Severe	2 (5.6%)	2 (5.9%)	4 (5.7%)
Cardiac disorders	2 (5.6%)	2 (5.9%)	4 (5.7%)
Mild	1 (2.8%)		1 (1.4%)
Moderate		2 (5.9%)	2 (2.9%)
Severe	1 (2.8%)		1 (1.4%)
Atrial flutter	1 (2.8%)		1 (1.4%)
Mild	1 (2.8%)		1 (1.4%)
Cardiac failure		1 (2.9%)	1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)
Palpitation		1 (2.9%)	1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)
Palpitations	1 (2.8%)		1 (1.4%)
Severe	1 (2.8%)		1 (1.4%)
Tachycardia		1 (2.9%)	1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)
Gastrointestinal disorders	3 (8.3%)	3 (8.8%)	6 (8.6%)
Mild	3 (8.3%)		3 (4.3%)
Moderate		2 (5.9%)	2 (2.9%)
Severe		1 (2.9%)	1 (1.4%)
Abdominal pain		1 (2.9%)	1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)

(Continued)

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Anal ulcer		1 (2.9%)	1 (1.4%)
Mild		1 (2.9%)	1 (1.4%)
Constipation	2 (5.6%)		2 (2.9%)
Mild	2 (5.6%)		2 (2.9%)
Dyspepsia		1 (2.9%)	1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)
Flatulence		1 (2.9%)	1 (1.4%)
Severe		1 (2.9%)	1 (1.4%)
Hiatus hernia	1 (2.8%)		1 (1.4%)
Mild	1 (2.8%)		1 (1.4%)
Nervous system disorders	1 (2.8%)	2 (5.9%)	3 (4.3%)
Mild	1 (2.8%)		1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)
Severe		1 (2.9%)	1 (1.4%)
Convulsion		1 (2.9%)	1 (1.4%)
Moderate		1 (2.9%)	1 (1.4%)
Dizziness		1 (2.9%)	1 (1.4%)
Severe		1 (2.9%)	1 (1.4%)
Essential tremor	1 (2.8%)		1 (1.4%)
Mild	1 (2.8%)		1 (1.4%)
Psychiatric disorders	1 (2.8%)	2 (5.9%)	3 (4.3%)
Mild		2 (5.9%)	2 (2.9%)

(Continued)

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Severe	1 (2.8%)		1 (1.4%)
Confusional state	1 (2.8%)		1 (1.4%)
Severe	1 (2.8%)		1 (1.4%)
Delirium		2 (5.9%)	2 (2.9%)
Mild		2 (5.9%)	2 (2.9%)
Sleep disorder		1 (2.9%)	1 (1.4%)
Mild		1 (2.9%)	1 (1.4%)