

Table 42: Summary of Overall Flushing Events, MGFSS

Biogen ASSURE 109MS406 (Interim)

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Summary of overall flushing events, MGFSS

	ASA placebo BID (N=81)	ASA 75 mg QAM (N=80)	ASA 150 mg BID (N=80)
Weeks 5 - 8 Combined			
Numbers of subjects evaluable	71 (87.7%)	71 (88.8%)	70 (87.5%)
Numbers of subjects with overall side effects	53 (74.6%)	52 (73.2%)	56 (80.0%)
Difference in percentage		-1.4 (7.37)	5.4 (7.04)
95% CI [1]		-15.8 , 13.0	-8.4 , 19.1
Weeks 9 - 12 Combined			
Numbers of subjects evaluable	67 (82.7%)	62 (77.5%)	65 (81.3%)
Numbers of subjects with overall side effects	41 (61.2%)	42 (67.7%)	50 (76.9%)
Difference in percentage		6.5 (8.41)	15.7 (7.92)
95% CI [1]		-9.9 , 23.0	0.2 , 31.3

[1] Two sided 95% CI of difference in proportions was constructed based on the normal approximation to the binomial distribution.

Day 1 data is not included in the analysis because MGFSS question refers to last 24 hours flushing score. The patient has not taken the medication in previous day, so the flushing score is not relevant to treatment.