

Table 7: Summary of Overall Flushing Events in First 4 Weeks, MGFSS

Biogen ASSURE 109MS406 (Interim)

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Summary of overall flushing events in first 4 weeks, MGFSS

	ASA placebo BID (N=81)	ASA 75 mg QAM (N=80)	ASA 150 mg BID (N=80)
Weeks 1 - 4 Combined			
Numbers of subjects evaluable	80 (98.8%)	79 (98.8%)	80 (100)
Numbers of subjects with overall side effects	72 (90.0%)	73 (92.4%)	71 (88.8%)
Difference in percentage		2.4 (4.49)	-1.3 (4.87)
95% CI [1]		-6.4 , 11.2	-10.8 , 8.3
Week 1			
Numbers of subjects evaluable	80 (98.8%)	77 (96.3%)	80 (100)
Numbers of subjects with overall side effects	67 (83.8%)	66 (85.7%)	67 (83.8%)
Difference in percentage		2.0 (5.74)	0.0 (5.83)
95% CI [1]		-9.3 , 13.2	-11.4 , 11.4
Week 2			
Numbers of subjects evaluable	77 (95.1%)	76 (95.0%)	79 (98.8%)
Numbers of subjects with overall side effects	59 (76.6%)	47 (61.8%)	55 (69.6%)
Difference in percentage		-14.8 (7.37)	-7.0 (7.07)
95% CI [1]		-29.2 , -0.3	-20.9 , 6.9
Week 3			
Numbers of subjects evaluable	74 (91.4%)	74 (92.5%)	76 (95.0%)
Numbers of subjects with overall side effects	54 (73.0%)	41 (55.4%)	41 (53.9%)
Difference in percentage		-17.6 (7.75)	-19.0 (7.70)
95% CI [1]		-32.8 , -2.4	-34.1 , -3.9
Week 4			
Numbers of subjects evaluable	72 (88.9%)	71 (88.8%)	71 (88.8%)
Numbers of subjects with overall side effects	43 (59.7%)	39 (54.9%)	39 (54.9%)
Difference in percentage		-4.8 (8.26)	-4.8 (8.26)
95% CI [1]		-21.0 , 11.4	-21.0 , 11.4

[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.

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