

**Table 69 Summary of Conjunctival Hyperemia (Safety Set)**

Visit	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
<b>Randomisation, pre-randomisation</b>				
0 = None	—	—	1 (3.4)	1 (1.1)
1 = Mild	13 (41.9)	11 (36.7)	11 (37.9)	35 (38.9)
2 = Moderate	14 (45.2)	15 (50.0)	16 (55.2)	45 (50.0)
3 = Severe	4 (12.9)	3 (10.0)	1 (3.4)	8 (8.9)
Missing	—	—	1	1
<b>Randomisation, post-randomisation</b>				
0 = None	—	—	1 (3.6)	1 (1.1)
1 = Mild	15 (50.0)	13 (43.3)	13 (46.4)	41 (46.6)
2 = Moderate	10 (33.3)	13 (43.3)	13 (46.4)	36 (40.9)
3 = Severe	5 (16.7)	2 (6.7)	1 (3.6)	8 (9.1)
Missing	1	—	2	3
<b>Week 2</b>				
0 = None	—	—	1 (3.3)	1 (1.2)
1 = Mild	15 (55.6)	13 (46.4)	18 (60.0)	46 (54.1)
2 = Moderate	9 (33.3)	12 (42.9)	11 (36.7)	32 (37.6)
3 = Severe	3 (11.1)	3 (10.7)	—	6 (7.1)
Missing	2	—	—	2
<b>Week 4</b>				
0 = None	—	—	—	—
1 = Mild	12 (42.9)	12 (42.9)	16 (55.2)	40 (47.1)
2 = Moderate	14 (50.0)	14 (50.0)	11 (37.9)	39 (45.9)
3 = Severe	1 (3.6)	2 (7.1)	2 (6.9)	5 (5.9)
Missing	1	1	1	3
<b>Week 8</b>				
0 = None	—	—	1 (3.6)	1 (1.3)
1 = Mild	11 (50.0)	10 (37.0)	13 (46.4)	34 (44.2)
2 = Moderate	10 (45.5)	12 (44.4)	13 (46.4)	35 (45.5)
3 = Severe	1 (4.5)	4 (14.8)	1 (3.6)	6 (7.8)
Missing	5	2	—	7
<b>Week 12</b>				
0 = None	—	—	—	—
1 = Mild	14 (58.3)	13 (46.4)	12 (44.4)	39 (49.4)
2 = Moderate	7 (29.2)	10 (35.7)	13 (48.1)	30 (38.0)
3 = Severe	2 (8.3)	4 (14.3)	2 (7.4)	8 (10.1)
Missing	2	—	—	2

Source: Table 14.3.5.1.9, Statistical Output in Appendix 16.2.

**Table 70      Analysis of Conjunctival Hyperemia (Safety Set)**

<b>Visit</b>	<b>P-value</b>
<b>Week 2</b>	
1% Pro-ocular vs Placebo	0.044
0.5% Pro-ocular vs Placebo	0.194
<b>Week 4</b>	
1% Pro-ocular vs Placebo	0.345
0.5% Pro-ocular vs Placebo	0.352
<b>Week 8</b>	
1% Pro-ocular vs Placebo	0.057
0.5% Pro-ocular vs Placebo	0.611
<b>Week 12</b>	
1% Pro-ocular vs Placebo	0.460
0.5% Pro-ocular vs Placebo	0.919

Source: Table 14.3.5.1.10, Statistical Output in Appendix 16.2.

p-value from Cochran-Mantel-Haenszel test.

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