

Table 34 Summary of Dry Eye-Related Quality-of-Life (Full Analysis Set)

Visit		Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	4.3 (1.11)	3.6 (1.25)	4.3 (1.15)	4.1 (1.20)
	Median	4.0	4.0	4.0	4.0
	Q1, Q3	4.0, 5.0	3.0, 4.0	3.0, 5.0	3.0, 5.0
	Min, Max	2, 6	1, 6	2, 6	1, 6
Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
	Mean (SD)	2.9 (0.95)	3.2 (1.03)	3.2 (0.89)	3.1 (0.96)
	Median	3.0	3.0	3.0	3.0
	Q1, Q3	3.0, 4.0	3.0, 4.0	3.0, 4.0	3.0, 4.0
	Min, Max	1, 4	1, 6	2, 6	1, 6
Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
	Mean (SD)	-1.6 (1.26)	-0.4 (1.32)	-1.2 (1.64)	-1.0 (1.48)
	Median	-1.0	-1.0	-1.0	-1.0
	Q1, Q3	-3.0, -1.0	-1.0, 0.0	-2.0, -1.0	-2.0, 0.0
	Min, Max	-4, 1	-3, 3	-4, 3	-4, 3

Source: Table 14.2.2.60, Statistical Output in Appendix 16.2.

Abbreviations: N, total number of patients per group; n, number of non-missing observations; SD; standard deviation, Q1 / Q3, first and third quartile.

Table 35 Analysis of Dry Eye-Related Quality-of-Life (Full Analysis Set)

Visit: Week 12	Adjusted Mean		
	n	LS Mean (95% CI)	P-value
1% Pro-ocular	28	-12.19 (-20.77;-3.62)	-
0.5% Pro-ocular	25	-26.58 (-35.41;-17.74)	-
Placebo	27	-26.10 (-34.95;-17.24)	-
LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		13.90 (3.25;24.56)	0.011
LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.48 (-11.11;10.15)	0.928

Source: Table 14.2.2.61, Statistical Output in Appendix 16.2.

Abbreviations: N, total number of patients per group; n, number of non-missing observations; CI, confidence interval.

The change from Baseline is analysed by means of an ANCOVA model by Visit with treatment as fixed effect and baseline measure and stratification factor (male, female: menopausal, female: non-menopausal) as covariates.