

Table 32 Summary of Schirmer's Test Results (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)	3.2 (2.44)	3.6 (2.59)	2.9 (1.78)	3.3 (2.29)
	Median	2.0	3.0	3.0	3.0
	Q1, Q3	2.0, 4.0	2.0, 5.0	1.0, 4.0	2.0, 4.0
	Min, Max	1, 9	1, 9	1, 8	1, 9
Week 4	n (missing)	28 (1)	29 (1)	30 (0)	87 (2)
	Mean (SD)	4.3 (3.20)	2.9 (2.11)	5.6 (5.20)	4.3 (3.88)
	Median	4.0	2.0	4.0	3.0
	Q1, Q3	2.0, 5.5	1.0, 4.0	3.0, 6.0	2.0, 6.0
	Min, Max	0, 13	0, 8	1, 25	0, 25
Week 4 change from Baseline	n (missing)	28 (1)	29 (1)	30 (0)	87 (2)
	Mean (SD)	0.9 (2.49)	-0.8 (2.63)	2.6 (4.90)	0.9 (3.79)
	Median	1.0	0.0	1.0	0.0
	Q1, Q3	-1.0, 2.0	-2.0, 1.0	0.0, 3.0	-1.0, 2.0
	Min, Max	-3, 7	-8, 4	-2, 20	-8, 20

Visit		Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
	Mean (SD)	6.8 (7.05)	4.6 (3.65)	5.9 (6.45)	5.7 (5.84)
	Median	5.0	3.0	4.0	4.0
	Q1, Q3	3.0, 7.0	2.0, 8.0	3.0, 6.0	2.0, 7.0
	Min, Max	1, 35	0, 11	1, 35	0, 35
Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
	Mean (SD)	3.4 (6.83)	0.9 (3.19)	2.9 (5.88)	2.4 (5.51)
	Median	2.0	1.0	2.0	1.0
	Q1, Q3	0.0, 4.0	-1.0, 2.0	0.0, 3.0	0.0, 3.5
	Min, Max	-2, 33	-8, 7	-2, 30	-8, 33

Source: Table 14.2.2.53, Statistical Output in Appendix 16.2.

Results of the Schirmer's Test are provided in millimetres.

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

Schirmer's Test, when compared to active treatment (

A statistically significantly different in the tear product, as measured by Schirmer's Test, was

Table 33 Analysis of Schirmer's Test Results (Full Analysis Set)

Visit	Adjusted Mean		
	n	LS Mean (95% CI)	P-value
Week 4			
1% Pro-ocular	29	-0.70 (-2.17;0.78)	-
0.5% Pro-ocular	28	0.92 (-0.58;2.42)	-
Placebo	30	2.54 (0.99;4.09)	-
LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-3.24 (-5.09;-1.39)	<.001
LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-1.62 (-3.47;0.23)	0.085
Week 12			
1% Pro-ocular	28	0.09 (-2.33;2.50)	-
0.5% Pro-ocular	25	2.60 (0.04;5.16)	-
Placebo	27	1.85 (-0.75;4.45)	-
LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-1.76 (-4.76;1.24)	0.246
LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.75 (-2.32;3.81)	0.628

Source: Table 14.2.2.54, Statistical Output in Appendix 16.2.

Results of the Schirmer's Test are provided in millimetres.

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.

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