

A statistically significantly difference in Conjunctival Fluorescein Staining (with LOCF) was



**Table 24 Summary of Conjunctival Fluorescein Staining by NEI Scale with LOCF (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 (%)
<b>Nasal Section Total Score LOCF</b>					
Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	3.7 (2.89)	4.2 (2.70)	5.0 (3.27)	4.3 (2.98)
	Median	3.0	4.0	5.0	4.0
	Q1, Q3	1.0, 6.0	2.0, 6.0	2.0, 8.0	2.0, 7.0
	Min, Max	0, 9	0, 9	0, 9	0, 9
Week 12	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	2.0 (2.35)	3.3 (2.74)	3.5 (3.33)	3.0 (2.88)
	Median	1.0	2.5	2.0	2.0
	Q1, Q3	1.0, 2.0	1.0, 5.0	1.0, 6.0	1.0, 5.0
	Min, Max	0, 9	0, 9	0, 9	0, 9
Week 12 change from Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	-1.6 (2.24)	-0.9 (1.55)	-1.5 (2.40)	-1.3 (2.09)
	Median	-1.0	-0.5	0.0	-1.0
	Q1, Q3	-2.0, 0.0	-2.0, 0.0	-2.0, 0.0	-2.0, 0.0
	Min, Max	-7, 1	-4, 3	-8, 2	-8, 3

Visit		Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
<b>Temporal Section Total Score LOCF</b>					
Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	3.3 (3.15)	3.8 (2.62)	4.5 (3.22)	3.9 (3.01)
	Median	2.0	4.0	4.0	4.0
	Q1, Q3	0.0, 7.0	1.0, 6.0	2.0, 8.0	1.0, 6.0
	Min, Max	0, 9	0, 9	0, 9	0, 9
Week 12	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	1.8 (2.38)	2.7 (2.71)	3.6 (3.31)	2.7 (2.88)
	Median	1.0	2.0	2.5	1.0
	Q1, Q3	0.0, 3.0	1.0, 4.0	1.0, 7.0	0.0, 4.0
	Min, Max	0, 9	0, 9	0, 9	0, 9
Week 12 change from Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	-1.5 (2.44)	-1.1 (1.37)	-0.9 (2.60)	-1.2 (2.20)
	Median	0.0	-1.0	0.0	0.0
	Q1, Q3	-2.0, 0.0	-2.0, 0.0	-1.0, 0.0	-2.0, 0.0
	Min, Max	-8, 2	-4, 1	-7, 3	-8, 3

Source: Table 14.2.2.23, 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 25 Analysis of Conjunctival Fluorescein Staining by NEI Scale with LOCF (Full Analysis Set)**

Visit: Week 12	Adjusted Mean		
	n	LS Mean (95% CI)	P-value
<b>Nasal Section LOCF</b>			
1% Pro-ocular	30	-0.90 (-1.71;-0.09)	-
0.5% Pro-ocular	29	-1.77 (-2.59;-0.95)	-
Placebo	30	-1.19 (-2.05;-0.33)	-
LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		0.28 (-0.73;1.29)	0.577
LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.58 (-1.62;0.45)	0.266
<b>Temporal Section LOCF</b>			
1% Pro-ocular	30	-1.03 (-1.87;-0.20)	-
0.5% Pro-ocular	29	-1.61 (-2.45;-0.76)	-
Placebo	30	-0.58 (-1.45;0.30)	-
LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-0.46 (-1.50;0.58)	0.386
LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-1.03 (-2.09;0.03)	0.056

Source: Table 14.2.2.24, Statistical Output in Appendix 16.2.

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