

**Table 14.2-2.39: Summary of Fluorescein Tear Film Break Up Time (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)	2.3 (0.61)	2.6 (1.12)	2.3 (1.02)	2.4 (0.95)
	Median	2.3	2.0	2.0	2.0
	Q1, Q3	2.0, 3.0	2.0, 3.3	1.3, 3.0	2.0, 3.0
	Min, Max	1, 3	1, 5	1, 4	1, 5
Week 12	n (missing)	24 (5)	28 (2)	27 (3)	79 (10)
	Mean (SD)	3.8 (2.55)	3.2 (2.78)	4.2 (2.76)	3.7 (2.71)
	Median	3.0	2.7	3.0	3.0
	Q1, Q3	2.0, 5.0	2.0, 3.0	2.0, 5.7	2.0, 4.0
	Min, Max	1, 11	1, 16	1, 10	1, 16
Week 12 change from Baseline	n (missing)	24 (5)	28 (2)	27 (3)	79 (10)
	Mean (SD)	1.4 (2.35)	0.6 (2.77)	1.9 (2.57)	1.3 (2.61)
	Median	0.3	0.0	1.0	0.3
	Q1, Q3	0.0, 2.5	-1.0, 1.0	0.0, 3.7	0.0, 2.0
	Min, Max	-1, 8	-2, 13	-2, 8	-2, 13

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Visit		Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
	Mean (SD)	3.6 (1.70)	3.0 (1.72)	3.0 (1.31)	3.2 (1.60)
	Median	3.5	2.3	2.7	3.0
	Q1, Q3	2.7, 4.3	2.0, 4.0	2.0, 4.0	2.0, 4.0
	Min, Max	1, 10	1, 8	1, 6	1, 10
Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
	Mean (SD)	1.3 (1.62)	0.3 (1.89)	0.6 (1.32)	0.7 (1.66)
	Median	1.0	0.0	0.0	0.7
	Q1, Q3	0.2, 2.2	-1.0, 1.0	-0.3, 1.7	-0.2, 1.7
	Min, Max	-1, 6	-2, 6	-2, 3	-2, 6

**Table 14.2-2.40: Analysis of Fluorescein Tear Film Break Up Time (Full Analysis Set)**

Visit		Adjusted Mean		P-value
		n	LS Mean (95% CI)	
Week 12	1% Pro-ocular	28	0.87 (-0.30, 2.03)	-
	0.5% Pro-ocular	24	1.70 (0.45, 2.95)	-
	Placebo	27	2.16 (0.95, 3.38)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-1.30 (-2.72, 0.13)	0.074
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.46 (-1.93, 1.00)	0.530
Week 16 (Follow Up)	1% Pro-ocular	27	0.54 (-0.19, 1.27)	-
	0.5% Pro-ocular	24	1.36 (0.58, 2.14)	-
	Placebo	25	0.71 (-0.07, 1.49)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-0.17 (-1.04, 0.70)	0.699
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.65 (-0.25, 1.55)	0.153

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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