Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Frequency of Symptoms (mm)	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	72.0 (26.58)	65.7 (28.12)	75.5 (23.69)	71.0 (26.21)
		Median	79.0	68.0	75.5	75.0
		Q1, Q3	54.0, 96.0	49.0, 88.0	62.0, 98.0	54.0, 96.0
		Min, Max	21, 100	0, 100	23, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	61.6 (26.33)	59.8 (32.21)	58.1 (27.84)	59.8 (28.57)
		Median	67.0	66.0	57.0	65.5
		Q1, Q3	48.0, 85.0	30.5, 89.0	35.0, 83.0	35.0, 85.0
		Min, Max	4, 96	2, 100	5, 100	2, 100
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-9.4 (21.33)	-8.4 (14.41)	-17.3 (19.59)	-11.8 (18.92)
		Median	-7.0	-5.5	-12.0	-7.0
		Q1, Q3	-22.0, -0.5	-11.5, -1.0	-28.0, -4.0	-22.0, -1.0
		Min, Max	-50, 68	-51, 19	-67, 12	-67, 68

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Frequency of Symptoms (mm)	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	56.4 (24.85)	53.0 (31.20)	53.1 (27.67)	54.1 (27.73)
		Median	56.5	60.5	52.5	56.5
		Q1, Q3	44.5, 74.5	30.0, 78.5	32.0, 75.0	35.0, 76.0
		Min, Max	2, 95	0, 97	3, 100	0, 100
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-16.3 (18.64)	-14.5 (17.53)	-22.4 (22.91)	-17.8 (19.97)
		Median	-15.0	-9.0	-18.5	-15.0
		Q1, Q3	-25.0, -4.0	-27.5, -1.5	-39.0, -8.0	-29.0, -5.0
		Min, Max	-68, 21	-57, 12	-72, 18	-72, 21
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	50.4 (23.32)	57.6 (28.52)	49.2 (26.31)	52.5 (26.22)
		Median	45.0	64.0	52.0	55.0
		Q1, Q3	31.5, 71.5	32.5, 77.5	28.5, 68.0	31.0, 74.0
		Min, Max	1, 91	2, 99	8, 100	1, 100

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Frequency of Symptoms (mm)	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-22.8 (21.72)	-11.3 (21.37)	-25.2 (25.70)	-19.6 (23.61)
		Median	-19.0	-5.5	-23.5	-16.0
		Q1, Q3	-38.5, -6.0	-22.5, 0.5	-39.5, -4.0	-36.5, -2.0
		Min, Max	-70, 19	-57, 34	-90, 11	-90, 34
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	47.7 (28.56)	43.9 (30.52)	44.6 (26.51)	45.3 (28.29)
		Median	42.0	43.5	50.0	46.5
		Q1, Q3	30.0, 74.0	13.0, 68.5	26.0, 62.0	19.5, 69.0
		Min, Max	0, 100	2, 96	2, 100	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-27.6 (27.43)	-22.3 (24.60)	-31.5 (27.50)	-27.0 (26.44)
		Median	-24.0	-18.5	-35.0	-23.5
		Q1, Q3	-45.0, -7.0	-40.0, -2.0	-49.0, -5.0	-46.0, -3.0
		Min, Max	-94, 28	-77, 21	-91, 3	-94, 28

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Frequency of Symptoms (mm)	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	44.8 (27.35)	44.5 (27.71)	36.2 (23.28)	41.9 (26.17)
		Median	40.5	45.0	38.0	40.0
		Q1, Q3	20.0, 66.0	23.0, 65.0	19.0, 44.0	20.0, 63.0
		Min, Max	0, 93	0, 98	0, 88	0, 98
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-29.7 (25.97)	-23.4 (18.92)	-39.6 (24.81)	-30.7 (23.95)
		Median	-28.5	-22.0	-44.0	-30.0
		Q1, Q3	-48.0, -8.0	-36.0, -7.0	-58.0, -26.0	-48.5, -10.0
		Min, Max	-94, 11	-64, 3	-79, 9	-94, 11
Severity of Symptoms (mm)	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	69.1 (26.54)	63.0 (31.31)	74.5 (23.11)	68.9 (27.30)
		Median	75.0	69.5	73.5	74.0
		Q1, Q3	48.0, 96.0	37.0, 90.0	53.0, 97.0	48.0, 96.0
		Min, Max	19, 100	1, 100	30, 100	1, 100

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Severity of Symptoms (mm)	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	60.0 (26.16)	59.3 (30.78)	60.3 (26.81)	59.9 (27.64)
		Median	59.5	73.5	67.0	67.0
		Q1, Q3	43.5, 81.5	29.0, 87.0	37.0, 78.0	36.0, 85.0
		Min, Max	1, 97	2, 96	3, 100	1, 100
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-8.0 (15.95)	-6.1 (12.18)	-14.2 (20.13)	-9.5 (16.68)
		Median	-4.5	-5.5	-8.5	-5.0
		Q1, Q3	-16.0, 0.0	-10.0, -1.5	-26.0, -2.0	-15.0, -2.0
		Min, Max	-50, 33	-41, 24	-70, 38	-70, 38
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	57.3 (24.75)	51.9 (30.71)	52.6 (26.49)	53.9 (27.19)
		Median	56.5	56.5	55.5	56.0
		Q1, Q3	40.0, 79.5	26.5, 77.5	31.0, 70.0	32.0, 76.0
		Min, Max	2, 99	1, 96	1, 100	1, 100

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Severity of Symptoms (mm)	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-11.9 (18.78)	-13.9 (15.71)	-21.9 (19.27)	-16.0 (18.33)
		Median	-9.0	-11.5	-19.5	-15.0
		Q1, Q3	-22.5, -1.5	-24.0, -5.0	-32.0, -9.0	-25.0, -4.0
		Min, Max	-67, 26	-53, 25	-72, 7	-72, 26
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	48.6 (24.59)	55.1 (30.03)	47.0 (24.96)	50.3 (26.65)
		Median	45.5	55.0	50.0	49.5
		Q1, Q3	29.5, 70.5	28.0, 82.0	27.5, 64.0	29.0, 74.0
		Min, Max	0, 87	3, 97	8, 100	0, 100
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-21.9 (20.90)	-11.7 (21.39)	-27.4 (23.94)	-20.3 (22.90)
		Median	-12.5	-7.5	-23.5	-14.5
		Q1, Q3	-41.0, -5.0	-21.0, 0.5	-39.0, -7.0	-36.0, -3.0
		Min, Max	-70, 2	-61, 33	-88, 3	-88, 33

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Severity of Symptoms (mm)	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	46.0 (28.71)	43.0 (33.54)	43.8 (26.17)	44.2 (29.36)
		Median	43.0	33.5	49.0	46.0
		Q1, Q3	30.0, 67.0	9.0, 76.5	16.0, 64.0	15.5, 66.5
		Min, Max	0, 100	3, 100	2, 100	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-25.7 (28.30)	-20.6 (22.31)	-32.3 (27.77)	-26.2 (26.29)
		Median	-19.0	-21.5	-35.0	-25.0
		Q1, Q3	-43.0, -9.0	-38.0, -2.0	-53.0, -4.0	-46.0, -4.5
		Min, Max	-73, 30	-68, 30	-90, 13	-90, 30
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	43.5 (25.90)	42.4 (31.09)	37.7 (23.08)	41.2 (26.79)
		Median	43.5	45.0	40.0	41.5
		Q1, Q3	22.0, 62.0	16.0, 70.0	18.0, 59.0	19.0, 60.0
		Min, Max	0, 95	0, 99	4, 83	0, 99

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Severity of Symptoms (mm)	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-27.5 (24.01)	-22.8 (24.03)	-37.9 (27.11)	-29.2 (25.56)
		Median	-32.0	-17.0	-42.0	-32.0
		Q1, Q3	-44.5, -9.5	-39.0, -5.0	-59.0, -26.0	-48.5, -7.5
		Min, Max	-73, 27	-92, 6	-82, 30	-92, 30
Global Score (mm)	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	70.2 (26.01)	63.9 (29.25)	74.7 (22.97)	69.6 (26.29)
		Median	77.0	68.2	73.2	73.0
		Q1, Q3	54.4, 93.5	43.9, 87.5	58.7, 97.0	53.5, 94.0
		Min, Max	20, 100	0, 100	28, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	60.5 (25.59)	58.9 (31.14)	58.7 (26.94)	59.4 (27.65)
		Median	59.3	66.9	57.3	62.5
		Q1, Q3	47.5, 82.5	31.8, 87.5	37.8, 80.5	36.4, 84.0
		Min, Max	2, 96	2, 97	4, 100	2, 100

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Global Score (mm)	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-8.7 (17.54)	-7.4 (12.33)	-16.0 (19.01)	-10.8 (16.86)
		Median	-6.0	-5.5	-12.5	-6.5
		Q1, Q3	-16.5, -0.3	-9.3, -1.4	-25.5, -3.5	-17.3, -2.0
		Min, Max	-50, 48	-39, 18	-69, 22	-69, 48
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	56.0 (24.61)	52.3 (30.78)	52.2 (26.78)	53.5 (27.22)
		Median	60.5	57.4	50.9	55.9
		Q1, Q3	41.1, 73.9	29.2, 77.5	30.7, 74.5	32.5, 75.0
		Min, Max	2, 97	0, 97	2, 100	0, 100
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-14.5 (17.85)	-14.0 (15.91)	-22.5 (20.82)	-17.1 (18.58)
		Median	-13.3	-10.2	-20.8	-15.5
		Q1, Q3	-24.2, -3.0	-25.6, -5.5	-32.0, -9.5	-26.1, -5.5
		Min, Max	-68, 24	-55, 19	-71, 13	-71, 24

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Global Score (mm)	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	49.1 (23.55)	56.0 (28.62)	48.0 (25.45)	51.1 (25.99)
		Median	44.0	62.0	51.5	51.5
		Q1, Q3	30.5, 71.7	31.2, 78.5	28.2, 65.9	30.2, 73.9
		Min, Max	0, 89	2, 98	8, 100	0, 100
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-22.4 (20.74)	-11.5 (21.18)	-26.3 (24.17)	-20.0 (22.80)
		Median	-15.9	-6.7	-22.2	-14.2
		Q1, Q3	-40.0, -6.7	-25.2, 0.1	-42.5, -4.3	-35.7, -2.3
		Min, Max	-70, 10	-58, 30	-89, 3	-89, 30
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	46.6 (28.22)	42.8 (31.54)	44.0 (26.14)	44.4 (28.45)
		Median	42.5	35.2	49.0	43.6
		Q1, Q3	30.0, 68.5	10.6, 72.4	18.3, 61.5	18.1, 66.8
		Min, Max	0, 100	2, 95	2, 100	0, 100

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Global Score (mm)	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-26.6 (27.60)	-21.6 (22.35)	-31.9 (27.20)	-26.7 (25.77)
		Median	-22.6	-22.1	-38.1	-23.3
		Q1, Q3	-44.6, -9.0	-37.6, -3.0	-50.5, -4.5	-46.4, -4.5
		Min, Max	-83, 30	-69, 21	-91, 5	-91, 30
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	43.8 (26.30)	43.1 (29.42)	36.7 (22.99)	41.2 (26.30)
		Median	45.0	46.5	37.2	40.5
		Q1, Q3	20.7, 61.9	19.2, 68.0	19.4, 50.1	20.0, 61.4
		Min, Max	0, 94	0, 97	0, 85	0, 97
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-28.5 (24.63)	-23.0 (20.90)	-38.9 (25.43)	-30.0 (24.27)
		Median	-30.9	-16.7	-43.0	-31.6
		Q1, Q3	-45.0, -8.3	-37.0, -5.9	-58.7, -26.0	-45.6, -8.9
		Min, Max	-83, 20	-72, 5	-81, 18	-83, 20

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.25: Summary of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Global Score LOCF (mm)	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	70.2 (26.01)	63.9 (29.25)	74.7 (22.97)	69.6 (26.29)
		Median	77.0	68.2	73.2	73.0
		Q1, Q3	54.4, 93.5	43.9, 87.5	58.7, 97.0	53.5, 94.0
		Min, Max	20, 100	0, 100	28, 100	0, 100
	Week 12	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	48.4 (28.23)	44.1 (32.25)	45.1 (25.62)	45.8 (28.57)
		Median	43.1	35.2	49.3	47.4
		Q1, Q3	30.0, 70.4	11.2, 74.6	25.5, 61.5	20.8, 68.5
		Min, Max	0, 100	2, 98	2, 100	0, 100
	Week 12 change from Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	-21.8 (30.07)	-19.9 (22.66)	-29.7 (26.89)	-23.8 (26.71)
		Median	-17.5	-18.6	-24.8	-19.2
		Q1, Q3	-42.5, -5.0	-37.1, -1.5	-49.6, -4.5	-44.6, -4.3
		Min, Max	-83, 54	-69, 21	-91, 5	-91, 54

N: total number of patients per group, n: number of non-missing observations, SD: standard deviation, Q1, Q3: First and Third Quartile.

Table 14.2-2.26: Analysis of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit		Adjusted Mean n	Adjusted Mean LS Mean (95% CI)	P-value
Frequency of Symptoms	Week 2	1% Pro-ocular	28	-9.16 (-17.02, -1.30)	-
		0.5% Pro-ocular	28	-10.01 (-17.98, -2.04)	-
		Placebo	30	-17.60 (-25.60, -9.60)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		8.44 (-1.30, 18.19)	0.089
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		7.59 (-2.09, 17.27)	0.123
	Week 4	1% Pro-ocular	28	-14.43 (-22.70, -6.16)	-
		0.5% Pro-ocular	28	-15.06 (-23.31, -6.82)	-
		Placebo	30	-20.59 (-28.98, -12.19)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		6.16 (-4.11, 16.42)	0.236
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		5.52 (-4.67, 15.72)	0.284
	Week 8	1% Pro-ocular	28	-10.24 (-19.33, -1.15)	-
		0.5% Pro-ocular	24	-19.69 (-29.37, -10.02)	-
		Placebo	28	-22.31 (-31.88, -12.74)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.07 (0.73, 23.41)	0.037
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		2.62 (-9.20, 14.43)	0.660

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.

Table 14.2-2.26: Analysis of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit		Adjusted Mean n	Adjusted Mean LS Mean (95% CI)	P-value
Frequency of Symptoms	Week 12	1% Pro-ocular	28	-23.17 (-34.24, -12.11)	-
		0.5% Pro-ocular	25	-24.46 (-36.00, -12.93)	-
		Placebo	27	-28.43 (-39.93, -16.92)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		5.25 (-8.35, 18.85)	0.444
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		3.96 (-9.89, 17.81)	0.570
	Week 16 (Follow Up)	1% Pro-ocular	27	-24.16 (-34.23, -14.09)	-
		0.5% Pro-ocular	24	-26.97 (-37.75, -16.20)	-
		Placebo	25	-37.14 (-47.89, -26.39)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.98 (0.89, 25.07)	0.036
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		10.17 (-2.23, 22.56)	0.106
Severity of Symptoms	Week 2	1% Pro-ocular	28	-6.10 (-13.00, 0.79)	-
		0.5% Pro-ocular	28	-7.69 (-14.67, -0.70)	-
		Placebo	30	-12.96 (-19.97, -5.96)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		6.86 (-1.69, 15.41)	0.114
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		5.27 (-3.22, 13.76)	0.220

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.

Table 14.2-2.26: Analysis of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit		Adjusted Mean n	Adjusted Mean LS Mean (95% CI)	P-value
Severity of Symptoms	Week 4	1% Pro-ocular	28	-14.09 (-21.50, -6.69)	-
		0.5% Pro-ocular	28	-11.34 (-18.72, -3.96)	-
		Placebo	30	-20.33 (-27.84, -12.81)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		6.23 (-2.96, 15.43)	0.181
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		8.99 (-0.16, 18.13)	0.054
	Week 8	1% Pro-ocular	28	-10.73 (-19.56, -1.90)	-
		0.5% Pro-ocular	24	-19.34 (-28.72, -9.95)	-
		Placebo	28	-24.03 (-33.32, -14.75)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		13.30 (2.27, 24.33)	0.019
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		4.70 (-6.77, 16.16)	0.417
	Week 12	1% Pro-ocular	28	-20.68 (-31.70, -9.66)	-
		0.5% Pro-ocular	25	-22.49 (-33.95, -11.02)	-
		Placebo	27	-28.09 (-39.56, -16.62)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		7.41 (-6.20, 21.02)	0.282
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		5.60 (-8.20, 19.40)	0.421

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.

Table 14.2-2.26: Analysis of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit		Adjusted Mean n	Adjusted Mean LS Mean (95% CI)	P-value
Severity of Symptoms	Week 16 (Follow Up)	1% Pro-ocular	27	-23.51 (-34.23, -12.79)	-
		0.5% Pro-ocular	24	-25.07 (-36.52, -13.62)	-
		Placebo	25	-33.98 (-45.43, -22.52)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		10.47 (-2.45, 23.39)	0.111
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		8.90 (-4.30, 22.11)	0.183
Global Score	Week 2	1% Pro-ocular	28	-7.85 (-14.85, -0.85)	-
		0.5% Pro-ocular	28	-8.91 (-16.00, -1.82)	-
		Placebo	30	-15.74 (-22.86, -8.63)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		7.89 (-0.79, 16.57)	0.074
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		6.83 (-1.78, 15.45)	0.119
	Week 4	1% Pro-ocular	28	-14.00 (-21.65, -6.35)	-
		0.5% Pro-ocular	28	-13.70 (-21.32, -6.08)	-
		Placebo	30	-20.93 (-28.69, -13.16)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		6.93 (-2.57, 16.43)	0.151
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		7.23 (-2.21, 16.67)	0.132

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.

Table 14.2-2.26: Analysis of Intensity of dryness/irritation patient feeling assessed by SANDE (Full Analysis Set)

Parameter	Visit		Adjusted Mean n	Adjusted Mean LS Mean (95% CI)	P-value
Global Score	Week 8	1% Pro-ocular	28	-10.49 (-19.28, -1.71)	-
		0.5% Pro-ocular	24	-19.63 (-28.98, -10.29)	-
		Placebo	28	-23.08 (-32.32, -13.84)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.59 (1.61, 23.56)	0.025
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		3.45 (-7.96, 14.86)	0.549
	Week 12	1% Pro-ocular	28	-22.06 (-32.92, -11.21)	-
		0.5% Pro-ocular	25	-23.49 (-34.78, -12.19)	-
		Placebo	27	-28.23 (-39.51, -16.94)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		6.16 (-7.22, 19.55)	0.362
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		4.74 (-8.84, 18.31)	0.489
	Week 16 (Follow Up)	1% Pro-ocular	27	-23.76 (-34.03, -13.49)	-
		0.5% Pro-ocular	24	-26.05 (-37.02, -15.07)	-
		Placebo	25	-35.77 (-46.74, -24.80)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.01 (-0.36, 24.37)	0.057
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.72 (-2.92, 22.37)	0.130

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.