

**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Foreign Body Sensation	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	63.9 (34.22)	54.1 (35.46)	66.9 (32.39)	61.6 (34.11)
		Median	75.0	64.5	78.0	71.0
		Q1, Q3	47.0, 95.0	21.0, 84.0	43.0, 96.0	38.0, 94.0
		Min, Max	0, 100	0, 100	0, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	47.7 (33.03)	49.4 (37.84)	53.6 (29.24)	50.3 (33.16)
		Median	51.5	58.0	48.5	50.5
		Q1, Q3	15.5, 79.5	7.5, 84.5	35.0, 82.0	19.0, 82.0
		Min, Max	0, 98	0, 100	0, 97	0, 100
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-15.0 (23.21)	-8.2 (23.65)	-13.3 (26.39)	-12.2 (24.38)
		Median	-14.5	-2.5	-9.0	-7.5
		Q1, Q3	-26.5, -3.5	-13.0, 2.0	-24.0, 0.0	-24.0, 0.0
		Min, Max	-63, 42	-77, 46	-86, 31	-86, 46

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Foreign Body Sensation	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	45.9 (33.55)	42.2 (35.17)	45.7 (30.85)	44.6 (32.84)
		Median	48.5	41.5	56.0	50.0
		Q1, Q3	9.5, 75.0	9.5, 75.0	13.0, 72.0	10.0, 75.0
		Min, Max	0, 95	0, 100	0, 100	0, 100
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-20.0 (22.29)	-15.6 (26.32)	-21.2 (26.53)	-19.0 (24.98)
		Median	-16.0	-9.0	-22.5	-15.0
		Q1, Q3	-33.5, -7.5	-23.5, 0.0	-33.0, -4.0	-32.0, -3.0
		Min, Max	-88, 20	-91, 33	-85, 46	-91, 46
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	40.9 (29.41)	48.4 (34.10)	44.7 (26.03)	44.9 (29.84)
		Median	43.0	45.5	48.5	44.5
		Q1, Q3	8.5, 63.5	19.5, 87.5	22.5, 66.0	21.5, 67.0
		Min, Max	0, 86	0, 100	0, 83	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Foreign Body Sensation	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-23.3 (22.20)	-8.9 (24.87)	-22.1 (30.38)	-17.8 (26.72)
		Median	-17.5	-7.5	-27.0	-14.0
		Q1, Q3	-43.5, -10.0	-19.0, 3.5	-43.0, 1.5	-37.5, -0.5
		Min, Max	-71, 31	-76, 38	-78, 36	-78, 38
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	37.9 (29.76)	34.2 (32.57)	36.9 (24.30)	36.3 (28.79)
		Median	36.0	22.0	38.0	31.0
		Q1, Q3	11.0, 56.0	7.5, 60.5	10.0, 55.0	10.0, 55.0
		Min, Max	0, 100	0, 96	0, 80	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-30.2 (24.62)	-20.2 (29.58)	-32.4 (34.05)	-27.5 (29.91)
		Median	-31.0	-19.5	-34.0	-29.0
		Q1, Q3	-48.0, -10.0	-37.0, -1.0	-61.0, -8.0	-52.5, -3.5
		Min, Max	-74, 13	-73, 56	-86, 45	-86, 56

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Foreign Body Sensation	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	34.0 (25.94)	39.6 (31.54)	32.6 (25.58)	35.5 (27.75)
		Median	30.5	46.0	29.0	34.0
		Q1, Q3	12.5, 56.0	2.0, 62.0	10.0, 50.0	9.0, 54.5
		Min, Max	0, 91	0, 100	0, 85	0, 100
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-33.1 (25.23)	-16.0 (32.97)	-35.2 (31.89)	-27.7 (31.22)
		Median	-34.5	-14.0	-35.0	-26.5
		Q1, Q3	-53.0, -12.0	-44.0, 0.0	-63.0, -10.0	-52.5, -3.0
		Min, Max	-78, 14	-100, 40	-89, 24	-100, 40
Burning/Stinging	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	59.5 (36.71)	58.9 (30.47)	69.6 (28.70)	62.7 (32.10)
		Median	73.0	67.5	78.5	73.0
		Q1, Q3	22.0, 95.0	28.0, 83.0	48.0, 95.0	32.0, 94.0
		Min, Max	0, 100	1, 100	0, 100	0, 100

**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Burning/Stinging	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	41.3 (34.39)	50.0 (35.18)	45.4 (30.30)	45.5 (33.08)
		Median	38.5	55.0	43.0	43.5
		Q1, Q3	6.0, 73.5	14.5, 85.0	26.0, 76.0	15.0, 80.0
		Min, Max	0, 100	0, 100	0, 97	0, 100
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-17.0 (23.51)	-11.9 (20.24)	-24.2 (28.42)	-17.8 (24.65)
		Median	-20.0	-3.5	-21.5	-14.5
		Q1, Q3	-32.0, -0.5	-24.0, 2.0	-41.0, -8.0	-32.0, 0.0
		Min, Max	-62, 35	-70, 12	-98, 51	-98, 51
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	43.1 (33.74)	47.3 (33.64)	40.8 (29.33)	43.7 (31.97)
		Median	45.5	42.5	46.0	45.0
		Q1, Q3	6.0, 71.5	16.5, 79.5	15.0, 65.0	14.0, 72.0
		Min, Max	0, 92	0, 98	0, 89	0, 98

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Burning/Stinging	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-16.4 (26.02)	-14.0 (22.75)	-28.7 (24.24)	-19.9 (24.95)
		Median	-13.5	-11.0	-28.0	-19.0
		Q1, Q3	-36.0, -1.5	-28.0, -2.0	-44.0, -15.0	-35.0, -6.0
		Min, Max	-64, 52	-62, 54	-90, 45	-90, 54
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	33.8 (30.81)	49.6 (32.46)	38.9 (27.31)	41.1 (30.58)
		Median	24.0	46.5	39.0	39.0
		Q1, Q3	6.5, 58.0	21.0, 84.0	17.0, 58.5	13.0, 64.0
		Min, Max	0, 88	0, 99	0, 88	0, 99
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-23.6 (27.85)	-11.8 (24.83)	-29.9 (27.97)	-21.7 (27.63)
		Median	-18.0	-11.5	-31.5	-21.0
		Q1, Q3	-44.0, -5.0	-26.0, 4.0	-48.0, -8.5	-42.5, -1.0
		Min, Max	-87, 27	-76, 46	-78, 49	-87, 49

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Burning/Stinging	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	36.5 (31.73)	38.6 (33.10)	31.9 (25.85)	35.7 (30.14)
		Median	34.0	23.5	27.0	27.5
		Q1, Q3	8.0, 61.0	13.0, 69.0	8.0, 56.0	10.5, 59.0
		Min, Max	0, 100	0, 100	0, 81	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-23.4 (30.73)	-20.0 (29.71)	-37.7 (34.73)	-27.0 (32.34)
		Median	-18.0	-19.5	-47.0	-24.0
		Q1, Q3	-51.0, 0.0	-43.0, 1.5	-67.0, -16.0	-52.5, -3.0
		Min, Max	-94, 40	-66, 58	-88, 58	-94, 58
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	29.8 (27.89)	36.8 (32.48)	29.7 (24.93)	32.3 (28.54)
		Median	20.5	36.0	26.0	27.5
		Q1, Q3	3.5, 53.0	3.0, 64.0	9.0, 51.0	7.5, 54.0
		Min, Max	0, 87	0, 100	0, 86	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Burning/Stinging	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-28.6 (28.88)	-23.0 (28.51)	-38.6 (29.21)	-29.9 (29.21)
		Median	-23.5	-12.0	-41.0	-26.5
		Q1, Q3	-52.0, -4.5	-45.0, -3.0	-63.0, -24.0	-52.5, -8.5
		Min, Max	-94, 20	-82, 23	-81, 60	-94, 60
Itching	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	57.1 (36.49)	53.2 (34.86)	61.4 (37.58)	57.2 (36.07)
		Median	56.0	60.0	72.5	61.0
		Q1, Q3	34.0, 97.0	12.0, 84.0	22.0, 96.0	22.0, 95.0
		Min, Max	0, 100	0, 100	0, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	37.7 (33.12)	51.4 (35.56)	40.4 (34.90)	43.1 (34.65)
		Median	29.0	57.5	32.0	36.5
		Q1, Q3	6.5, 72.5	10.0, 84.5	8.0, 79.0	9.0, 81.0
		Min, Max	0, 96	0, 100	0, 97	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Itching	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-18.0 (21.02)	-5.1 (28.12)	-21.1 (27.47)	-14.9 (26.40)
		Median	-15.0	-0.5	-11.0	-10.0
		Q1, Q3	-29.5, -1.5	-14.5, 3.5	-44.0, -1.0	-28.0, 0.0
		Min, Max	-79, 22	-65, 70	-91, 15	-91, 70
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	34.2 (33.21)	43.6 (35.90)	37.0 (31.44)	38.2 (33.35)
		Median	20.0	42.0	40.0	35.5
		Q1, Q3	0.5, 68.0	9.0, 78.0	7.0, 67.0	5.0, 67.0
		Min, Max	0, 87	0, 98	0, 88	0, 98
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-24.8 (20.84)	-10.8 (23.86)	-24.5 (27.38)	-20.1 (24.84)
		Median	-24.5	-9.5	-19.0	-16.5
		Q1, Q3	-37.0, -12.0	-24.5, 0.0	-44.0, -6.0	-35.0, -5.0
		Min, Max	-67, 25	-64, 52	-89, 35	-89, 52

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Itching	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	33.1 (30.19)	42.4 (33.46)	31.5 (28.49)	35.8 (30.81)
		Median	28.5	35.0	25.0	31.0
		Q1, Q3	4.0, 53.0	12.0, 73.0	5.5, 54.0	7.5, 58.5
		Min, Max	0, 89	0, 98	0, 92	0, 98
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-25.3 (23.70)	-14.1 (25.03)	-28.3 (30.41)	-22.4 (27.07)
		Median	-28.0	-11.0	-26.0	-20.0
		Q1, Q3	-41.5, -10.5	-29.0, 0.0	-51.5, -2.0	-42.0, -1.0
		Min, Max	-71, 19	-65, 39	-77, 39	-77, 39
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	35.2 (31.23)	35.4 (32.12)	30.3 (27.73)	33.6 (30.13)
		Median	30.0	20.5	20.0	20.5
		Q1, Q3	6.0, 60.0	12.0, 58.0	8.0, 51.0	10.5, 55.0
		Min, Max	0, 100	0, 100	0, 88	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Itching	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-26.5 (24.57)	-18.0 (27.48)	-30.7 (40.75)	-25.0 (31.89)
		Median	-34.0	-11.0	-46.0	-23.5
		Q1, Q3	-44.0, -11.0	-41.0, 3.0	-63.0, 0.0	-51.5, 0.0
		Min, Max	-60, 19	-66, 25	-88, 50	-88, 50
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	30.6 (28.05)	37.7 (32.97)	25.8 (26.15)	31.5 (29.35)
		Median	20.5	47.0	14.0	21.0
		Q1, Q3	4.0, 55.5	6.0, 62.0	7.0, 33.0	6.0, 55.5
		Min, Max	0, 89	0, 100	0, 88	0, 100
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-29.5 (24.22)	-17.7 (29.77)	-36.2 (29.16)	-27.5 (28.64)
		Median	-34.0	-10.0	-40.0	-28.0
		Q1, Q3	-51.5, -6.5	-38.0, 2.0	-65.0, -7.0	-50.5, -2.0
		Min, Max	-77, 13	-84, 47	-79, 8	-84, 47

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Ocular Pain	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	46.2 (43.56)	33.8 (35.11)	58.3 (38.77)	46.1 (40.10)
		Median	42.0	21.5	71.5	42.0
		Q1, Q3	1.0, 98.0	0.0, 69.0	20.0, 95.0	2.0, 94.0
		Min, Max	0, 100	0, 100	0, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	31.5 (36.88)	25.3 (34.80)	38.3 (35.87)	31.8 (35.84)
		Median	8.5	6.5	25.5	13.5
		Q1, Q3	0.0, 74.0	0.0, 47.0	3.0, 79.0	0.0, 71.0
		Min, Max	0, 94	0, 100	0, 98	0, 100
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-12.8 (20.78)	-10.6 (27.21)	-20.1 (25.03)	-14.6 (24.55)
		Median	-6.0	-0.5	-11.0	-7.0
		Q1, Q3	-19.0, 0.0	-24.5, 0.5	-38.0, 0.0	-25.0, 0.0
		Min, Max	-86, 11	-86, 29	-89, 10	-89, 29

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Ocular Pain	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	31.0 (34.45)	29.7 (32.21)	32.6 (31.70)	31.1 (32.42)
		Median	9.5	16.0	25.5	18.5
		Q1, Q3	0.0, 62.0	0.5, 53.0	1.0, 55.0	1.0, 57.0
		Min, Max	0, 94	0, 94	0, 90	0, 94
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-16.9 (19.90)	-6.5 (25.33)	-25.7 (28.01)	-16.6 (25.70)
		Median	-15.0	-2.0	-18.5	-9.5
		Q1, Q3	-25.0, 0.0	-11.5, 1.0	-44.0, -8.0	-29.0, 0.0
		Min, Max	-88, 2	-86, 35	-95, 22	-95, 35
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	29.1 (33.45)	31.5 (36.60)	33.7 (30.86)	31.6 (33.35)
		Median	8.5	11.5	24.5	15.5
		Q1, Q3	0.0, 56.0	1.5, 66.0	3.5, 56.5	0.0, 56.5
		Min, Max	0, 87	0, 97	0, 87	0, 97

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Ocular Pain	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-16.0 (27.54)	-4.7 (29.67)	-25.0 (33.43)	-15.2 (31.25)
		Median	-11.5	-1.5	-23.0	-10.5
		Q1, Q3	-35.0, 0.0	-11.5, 3.5	-41.5, -9.0	-34.5, 0.0
		Min, Max	-68, 62	-76, 66	-91, 75	-91, 75
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	26.4 (32.36)	24.9 (32.11)	32.8 (29.16)	28.1 (31.02)
		Median	9.0	9.0	29.0	14.0
		Q1, Q3	0.0, 51.0	0.0, 42.0	4.0, 57.0	0.0, 51.0
		Min, Max	0, 100	0, 93	0, 95	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-23.1 (22.70)	-8.6 (34.90)	-27.7 (37.61)	-19.6 (33.28)
		Median	-13.0	-4.5	-25.0	-12.5
		Q1, Q3	-43.0, 0.0	-22.0, 0.0	-60.0, 0.0	-45.5, 0.0
		Min, Max	-68, 0	-86, 70	-92, 59	-92, 70

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Ocular Pain	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	25.6 (32.92)	28.8 (31.38)	28.5 (29.11)	27.7 (30.77)
		Median	3.0	16.0	20.0	12.0
		Q1, Q3	0.0, 51.5	0.0, 53.0	3.0, 44.0	0.0, 50.0
		Min, Max	0, 95	0, 100	0, 90	0, 100
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-22.0 (23.99)	-5.9 (29.42)	-32.9 (34.33)	-19.9 (31.33)
		Median	-19.5	-2.0	-33.0	-12.0
		Q1, Q3	-39.0, 0.0	-14.0, 1.0	-64.0, -10.0	-40.0, 0.0
		Min, Max	-68, 18	-86, 54	-86, 47	-86, 54
Sticky Feeling	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	51.1 (40.40)	41.2 (36.30)	67.8 (30.61)	53.4 (37.22)
		Median	59.0	49.5	74.5	59.0
		Q1, Q3	8.0, 88.0	1.0, 79.0	46.0, 97.0	12.0, 88.0
		Min, Max	0, 100	0, 100	6, 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.

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sticky Feeling	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	37.8 (37.13)	36.8 (33.79)	49.1 (32.28)	41.4 (34.48)
		Median	29.5	31.0	54.5	36.5
		Q1, Q3	1.0, 80.0	2.5, 66.0	19.0, 78.0	4.0, 78.0
		Min, Max	0, 95	0, 99	0, 97	0, 99
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-11.6 (26.30)	-4.5 (21.46)	-18.7 (21.15)	-11.8 (23.51)
		Median	-10.0	-3.0	-17.0	-10.5
		Q1, Q3	-17.0, 0.0	-14.5, 0.0	-32.0, -6.0	-25.0, 0.0
		Min, Max	-80, 59	-45, 70	-80, 28	-80, 70
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	41.2 (34.26)	33.5 (33.50)	41.1 (31.00)	38.7 (32.72)
		Median	47.0	27.0	46.5	39.5
		Q1, Q3	2.0, 70.5	4.5, 53.0	8.0, 74.0	5.0, 68.0
		Min, Max	0, 95	0, 97	0, 90	0, 97

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sticky Feeling	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-11.4 (27.67)	-10.6 (25.96)	-26.7 (26.60)	-16.5 (27.49)
		Median	-10.5	-5.5	-24.5	-15.0
		Q1, Q3	-25.0, 0.0	-33.0, 2.5	-40.0, -13.0	-33.0, 0.0
		Min, Max	-78, 51	-60, 45	-89, 27	-89, 51
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	39.7 (31.09)	39.4 (36.91)	40.6 (29.27)	39.9 (32.25)
		Median	44.0	27.0	39.5	38.0
		Q1, Q3	4.0, 63.0	2.0, 76.5	12.5, 66.5	6.5, 67.0
		Min, Max	0, 93	0, 98	0, 87	0, 98
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-13.3 (24.64)	-4.4 (29.55)	-27.0 (23.02)	-15.0 (27.35)
		Median	-9.5	-1.0	-29.0	-11.0
		Q1, Q3	-26.5, 0.0	-23.5, 3.5	-46.0, -11.0	-35.5, 0.0
		Min, Max	-78, 34	-60, 71	-70, 22	-78, 71

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sticky Feeling	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	38.9 (31.20)	33.9 (33.97)	29.9 (25.13)	34.1 (30.19)
		Median	41.0	26.5	23.0	30.0
		Q1, Q3	8.0, 57.0	6.0, 64.0	8.0, 52.0	6.0, 56.0
		Min, Max	0, 100	0, 96	0, 80	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-16.7 (28.30)	-6.7 (25.54)	-39.8 (23.78)	-21.0 (29.18)
		Median	-22.0	-2.0	-37.0	-21.0
		Q1, Q3	-35.0, 0.0	-23.5, 4.5	-62.0, -21.0	-43.5, 0.0
		Min, Max	-78, 46	-54, 43	-87, -1	-87, 46
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	33.5 (25.70)	31.8 (35.04)	31.9 (28.37)	32.4 (29.77)
		Median	33.0	14.0	24.0	26.5
		Q1, Q3	11.5, 51.5	0.0, 70.0	6.0, 59.0	5.0, 59.0
		Min, Max	0, 94	0, 100	0, 89	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sticky Feeling	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-20.3 (27.24)	-10.2 (29.02)	-36.5 (28.58)	-22.1 (30.04)
		Median	-21.0	-8.0	-41.0	-19.0
		Q1, Q3	-38.5, 0.0	-22.0, 0.0	-60.0, -14.0	-45.5, -0.5
		Min, Max	-78, 31	-72, 50	-80, 29	-80, 50
Blurred Vision	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	56.8 (37.46)	40.3 (32.26)	64.3 (36.44)	53.8 (36.47)
		Median	54.0	37.5	80.0	54.0
		Q1, Q3	26.0, 97.0	8.0, 68.0	36.0, 97.0	24.0, 93.0
		Min, Max	0, 100	0, 98	0, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	40.1 (35.81)	37.9 (34.51)	45.3 (35.19)	41.2 (34.90)
		Median	35.0	32.0	48.0	40.0
		Q1, Q3	3.5, 80.0	3.5, 67.5	10.0, 73.0	6.0, 77.0
		Min, Max	0, 100	0, 97	0, 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.

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Blurred Vision	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-15.2 (17.91)	-2.5 (24.49)	-19.0 (26.46)	-12.4 (24.12)
		Median	-13.0	-2.5	-11.5	-10.0
		Q1, Q3	-22.5, -3.0	-12.0, 7.5	-39.0, -1.0	-25.0, 0.0
		Min, Max	-55, 28	-57, 69	-72, 52	-72, 69
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	43.1 (32.82)	39.8 (33.42)	38.1 (30.79)	40.3 (32.01)
		Median	48.0	32.0	39.5	39.0
		Q1, Q3	6.5, 73.0	13.0, 72.5	6.0, 66.0	10.0, 70.0
		Min, Max	0, 94	0, 99	0, 91	0, 99
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-15.7 (18.89)	-2.4 (24.90)	-26.2 (30.85)	-15.0 (27.05)
		Median	-14.0	-0.5	-23.0	-14.0
		Q1, Q3	-26.0, -6.0	-17.5, 16.5	-44.0, -9.0	-33.0, 0.0
		Min, Max	-60, 17	-65, 44	-85, 53	-85, 53

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Blurred Vision	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	36.8 (30.61)	43.1 (32.91)	38.4 (30.79)	39.6 (31.21)
		Median	41.0	45.0	42.0	42.5
		Q1, Q3	0.5, 59.5	15.5, 53.5	5.0, 65.0	9.5, 62.5
		Min, Max	0, 89	0, 100	0, 87	0, 100
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-20.5 (24.38)	0.4 (25.16)	-25.8 (30.26)	-15.1 (28.93)
		Median	-23.0	-0.5	-27.0	-11.5
		Q1, Q3	-35.5, -3.0	-8.5, 14.0	-49.0, -0.5	-35.5, 0.0
		Min, Max	-66, 21	-52, 57	-79, 47	-79, 57
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	33.8 (29.34)	36.8 (34.60)	29.1 (23.06)	33.2 (29.26)
		Median	29.0	25.0	28.0	28.5
		Q1, Q3	6.0, 53.0	6.5, 66.5	7.0, 49.0	6.5, 51.0
		Min, Max	0, 100	0, 100	0, 76	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Blurred Vision	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-26.4 (21.61)	-3.7 (26.14)	-36.1 (34.65)	-21.8 (31.04)
		Median	-20.0	-3.5	-42.0	-19.0
		Q1, Q3	-45.0, -8.0	-16.0, 8.0	-66.0, -18.0	-47.0, 0.0
		Min, Max	-70, 1	-62, 59	-84, 49	-84, 59
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	30.9 (27.32)	37.0 (32.78)	34.8 (29.30)	34.4 (29.71)
		Median	25.0	37.0	30.0	30.0
		Q1, Q3	6.5, 53.0	0.0, 63.0	8.0, 64.0	4.5, 61.5
		Min, Max	0, 85	0, 100	0, 83	0, 100
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-27.7 (21.82)	-5.0 (21.64)	-28.8 (38.37)	-20.0 (30.09)
		Median	-28.5	-9.0	-29.0	-16.5
		Q1, Q3	-43.0, -12.0	-17.0, 0.0	-58.0, -5.0	-40.0, -2.0
		Min, Max	-65, 21	-57, 46	-81, 60	-81, 60

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Photophobia	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	65.2 (34.82)	58.2 (35.62)	71.4 (36.32)	64.9 (35.62)
		Median	72.0	65.0	91.5	78.0
		Q1, Q3	32.0, 98.0	25.0, 88.0	49.0, 98.0	32.0, 98.0
		Min, Max	0, 100	0, 100	0, 100	0, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	46.4 (33.43)	50.6 (33.93)	52.6 (37.03)	50.0 (34.58)
		Median	50.0	52.0	67.0	53.0
		Q1, Q3	13.0, 76.5	19.5, 80.5	10.0, 84.0	16.0, 82.0
		Min, Max	0, 100	0, 100	0, 100	0, 100
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-17.5 (15.00)	-8.9 (23.97)	-18.8 (33.07)	-15.2 (25.43)
		Median	-15.0	-1.5	-9.0	-11.5
		Q1, Q3	-26.5, -6.0	-23.5, 1.5	-37.0, 0.0	-26.0, 0.0
		Min, Max	-55, 5	-66, 48	-87, 35	-87, 48

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Photophobia	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	51.6 (34.82)	52.3 (35.44)	46.8 (35.62)	50.2 (34.98)
		Median	57.5	58.5	52.0	53.5
		Q1, Q3	14.0, 83.0	20.0, 86.0	6.0, 80.0	12.0, 82.0
		Min, Max	0, 100	0, 99	0, 100	0, 100
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-13.9 (25.08)	-9.5 (24.12)	-24.6 (30.89)	-16.2 (27.42)
		Median	-15.0	-5.5	-22.5	-13.5
		Q1, Q3	-27.0, -3.5	-21.0, 1.5	-44.0, -7.0	-28.0, -1.0
		Min, Max	-57, 61	-54, 60	-92, 41	-92, 61
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	43.7 (32.04)	53.8 (35.87)	42.1 (33.11)	46.6 (33.78)
		Median	45.0	48.5	37.5	47.0
		Q1, Q3	12.0, 68.0	17.0, 92.5	9.0, 72.0	13.5, 78.5
		Min, Max	0, 100	0, 100	0, 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.

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Photophobia	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-18.0 (21.68)	-6.3 (31.21)	-27.7 (33.88)	-17.3 (30.72)
		Median	-12.0	-0.5	-22.5	-13.0
		Q1, Q3	-37.5, -4.0	-31.0, 8.5	-57.5, -7.0	-37.5, 0.0
		Min, Max	-70, 22	-66, 62	-93, 44	-93, 62
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	40.1 (31.86)	52.4 (35.99)	35.0 (30.27)	42.7 (33.29)
		Median	39.0	62.0	27.0	39.0
		Q1, Q3	9.0, 73.0	18.0, 85.5	3.0, 68.0	11.0, 73.5
		Min, Max	0, 100	0, 100	0, 82	0, 100
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-24.2 (22.28)	-6.4 (28.92)	-34.4 (36.76)	-21.4 (31.97)
		Median	-23.0	-0.5	-26.0	-16.5
		Q1, Q3	-39.0, -7.0	-22.5, 1.5	-70.0, -7.0	-39.5, 0.0
		Min, Max	-80, 21	-77, 65	-97, 29	-97, 65

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Photophobia	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	36.3 (28.39)	47.5 (34.06)	34.5 (33.26)	39.7 (32.21)
		Median	37.5	50.0	23.0	33.5
		Q1, Q3	8.5, 57.0	15.0, 78.0	10.0, 65.0	10.0, 68.5
		Min, Max	0, 85	0, 100	0, 99	0, 100
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-26.7 (20.20)	-13.5 (28.32)	-36.6 (39.79)	-25.3 (31.67)
		Median	-24.0	-7.0	-33.0	-19.5
		Q1, Q3	-41.5, -10.5	-30.0, 0.0	-73.0, -7.0	-49.5, -4.0
		Min, Max	-67, 0	-70, 75	-100, 49	-100, 75
Sum of All VAS	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	399.9 (235.12)	339.7 (188.96)	459.8 (201.48)	399.8 (212.59)
		Median	350.0	347.5	446.0	368.0
		Q1, Q3	194.0, 671.0	176.0, 463.0	292.0, 672.0	213.0, 646.0
		Min, Max	50, 700	6, 680	129, 690	6, 700

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sum of All VAS	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	282.5 (222.91)	301.2 (214.92)	324.7 (196.73)	303.3 (209.68)
		Median	206.0	328.0	240.0	239.0
		Q1, Q3	106.0, 538.0	81.0, 466.0	182.0, 510.0	128.0, 486.0
		Min, Max	2, 649	6, 681	91, 684	2, 684
	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-107.1 (106.67)	-51.6 (108.40)	-135.1 (154.03)	-98.8 (129.08)
		Median	-102.5	-39.0	-112.0	-79.5
		Q1, Q3	-146.5, -36.5	-91.5, 1.0	-223.0, -28.0	-160.0, -16.0
		Min, Max	-464, 75	-297, 201	-516, 118	-516, 201
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	290.1 (210.55)	288.4 (203.81)	282.2 (181.95)	286.8 (196.43)
		Median	247.5	266.5	242.5	250.0
		Q1, Q3	123.5, 466.0	109.0, 384.0	134.0, 409.0	121.0, 448.0
		Min, Max	2, 646	0, 664	10, 606	0, 664

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sum of All VAS	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-119.1 (125.15)	-69.4 (109.15)	-177.6 (155.43)	-123.3 (137.86)
		Median	-111.0	-64.0	-167.0	-112.5
		Q1, Q3	-166.5, -34.0	-146.5, -23.5	-254.0, -88.0	-177.0, -41.0
		Min, Max	-473, 110	-339, 216	-611, 126	-611, 216
	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	257.1 (200.24)	308.2 (208.88)	269.9 (172.28)	279.5 (192.89)
		Median	265.0	250.5	253.5	253.5
		Q1, Q3	77.0, 383.0	135.5, 465.5	129.0, 399.0	115.0, 409.5
		Min, Max	7, 617	14, 690	4, 603	4, 690
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-140.1 (132.71)	-49.8 (134.27)	-185.9 (167.99)	-124.5 (155.94)
		Median	-103.0	-30.5	-178.0	-88.0
		Q1, Q3	-235.5, -48.5	-94.5, 22.5	-291.0, -45.0	-235.5, -13.0
		Min, Max	-434, 93	-384, 215	-508, 100	-508, 215

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sum of All VAS	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	248.8 (203.55)	256.1 (201.27)	225.9 (153.77)	243.6 (185.43)
		Median	220.0	194.5	212.0	207.0
		Q1, Q3	71.0, 368.0	84.0, 388.0	80.0, 308.0	82.0, 366.5
		Min, Max	0, 700	6, 667	3, 561	0, 700
	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-170.6 (141.04)	-83.6 (150.66)	-238.9 (208.70)	-163.2 (179.88)
		Median	-144.0	-91.0	-271.0	-123.0
		Q1, Q3	-275.0, -99.0	-125.0, 1.5	-424.0, -86.0	-296.0, -38.5
		Min, Max	-441, 67	-403, 243	-603, 116	-603, 243
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	220.8 (175.51)	259.1 (195.34)	217.9 (163.14)	233.4 (177.65)
		Median	169.5	265.0	201.0	208.5
		Q1, Q3	75.0, 346.5	66.0, 381.0	86.0, 277.0	75.0, 320.0
		Min, Max	0, 626	10, 700	0, 609	0, 700

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
Sum of All VAS	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-188.0 (131.53)	-91.3 (151.68)	-244.8 (193.89)	-172.3 (171.76)
		Median	-178.5	-76.0	-286.0	-153.5
		Q1, Q3	-249.0, -87.5	-162.0, 8.0	-391.0, -116.0	-294.0, -40.5
		Min, Max	-463, -1	-406, 237	-551, 120	-551, 237
VAS Mean	Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
		Mean (SD)	57.2 (33.54)	48.5 (27.03)	65.7 (28.89)	57.1 (30.40)
		Median	50.0	50.0	63.5	53.0
		Q1, Q3	28.0, 96.0	25.0, 66.0	42.0, 96.0	30.0, 92.0
		Min, Max	7, 100	1, 97	18, 99	1, 100
	Week 2	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	40.3 (31.89)	43.0 (30.71)	46.5 (28.12)	43.3 (29.98)
		Median	29.5	47.0	34.0	34.0
		Q1, Q3	15.0, 76.5	11.5, 66.5	26.0, 73.0	18.0, 69.0
		Min, Max	0, 93	1, 97	13, 98	0, 98

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
VAS Mean	Week 2 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-15.4 (15.26)	-7.3 (15.39)	-19.2 (22.02)	-14.1 (18.43)
		Median	-15.0	-5.5	-15.5	-11.5
		Q1, Q3	-21.5, -5.0	-12.5, 0.5	-32.0, -4.0	-23.0, -2.0
		Min, Max	-66, 11	-43, 28	-74, 17	-74, 28
	Week 4	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	41.4 (29.97)	41.1 (29.16)	40.3 (26.00)	40.9 (28.04)
		Median	35.5	38.0	35.0	36.0
		Q1, Q3	17.5, 66.5	15.5, 55.0	19.0, 58.0	17.0, 64.0
		Min, Max	0, 92	0, 95	1, 87	0, 95
	Week 4 change from Baseline	n (missing)	28 (1)	28 (2)	30 (0)	86 (3)
		Mean (SD)	-17.1 (17.82)	-10.0 (15.65)	-25.4 (22.39)	-17.7 (19.76)
		Median	-16.0	-9.5	-24.5	-16.0
		Q1, Q3	-24.0, -5.0	-20.5, -3.5	-37.0, -13.0	-26.0, -6.0
		Min, Max	-67, 16	-48, 31	-88, 18	-88, 31

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
VAS Mean	Week 8	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	36.7 (28.58)	44.0 (29.79)	38.5 (24.58)	39.9 (27.52)
		Median	38.0	36.0	36.0	36.0
		Q1, Q3	11.0, 54.5	19.5, 66.5	18.0, 57.0	16.0, 58.5
		Min, Max	1, 88	2, 99	1, 86	1, 99
	Week 8 change from Baseline	n (missing)	24 (5)	28 (2)	28 (2)	80 (9)
		Mean (SD)	-20.0 (19.02)	-7.1 (19.07)	-26.6 (24.24)	-17.8 (22.37)
		Median	-14.5	-4.5	-25.5	-12.5
		Q1, Q3	-33.5, -6.5	-13.5, 3.5	-41.5, -6.5	-33.5, -2.0
		Min, Max	-62, 13	-54, 30	-73, 15	-73, 30
	Week 12	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	35.6 (29.04)	36.6 (28.68)	32.3 (22.02)	34.8 (26.47)
		Median	31.0	28.0	30.0	29.5
		Q1, Q3	10.0, 53.0	12.0, 55.5	11.0, 44.0	11.5, 52.5
		Min, Max	0, 100	1, 95	0, 80	0, 100

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

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**Table 14.2-2.67: Summary of Visual Analogue Scale 7 Symptoms (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 (%)
VAS Mean	Week 12 change from Baseline	n (missing)	25 (4)	28 (2)	27 (3)	80 (9)
		Mean (SD)	-24.4 (20.17)	-11.9 (21.36)	-34.1 (29.86)	-23.3 (25.67)
		Median	-20.0	-13.0	-39.0	-17.0
		Q1, Q3	-39.0, -14.0	-18.0, 0.5	-61.0, -12.0	-42.5, -5.5
		Min, Max	-63, 9	-57, 34	-86, 17	-86, 34
	Week 16 (Follow Up)	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	31.4 (25.09)	37.0 (27.89)	31.2 (23.33)	33.3 (25.39)
		Median	24.0	38.0	29.0	29.5
		Q1, Q3	10.5, 49.5	9.0, 54.0	12.0, 40.0	10.5, 45.5
		Min, Max	0, 89	1, 100	0, 87	0, 100
	Week 16 (Follow Up) change from Baseline	n (missing)	24 (5)	27 (3)	25 (5)	76 (13)
		Mean (SD)	-27.0 (18.80)	-13.0 (21.75)	-35.0 (27.94)	-24.6 (24.66)
		Median	-25.5	-11.0	-41.0	-22.0
		Q1, Q3	-36.0, -13.0	-23.0, 1.0	-56.0, -17.0	-42.0, -6.0
		Min, Max	-67, 0	-58, 34	-79, 18	-79, 34

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

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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Mean VAS symptom score	Week 2	1% Pro-ocular	28	-6.29 (-13.63, 1.05)	-
		0.5% Pro-ocular	28	-13.51 (-20.94, -6.09)	-
		Placebo	30	-15.64 (-23.20, -8.08)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		9.35 (0.11, 18.59)	0.047
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		2.13 (-6.96, 11.22)	0.643
	Week 4	1% Pro-ocular	28	-9.64 (-17.07, -2.21)	-
		0.5% Pro-ocular	28	-14.92 (-22.32, -7.52)	-
		Placebo	30	-21.50 (-29.12, -13.89)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.87 (2.52, 21.21)	0.013
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		6.58 (-2.61, 15.78)	0.158
	Week 8	1% Pro-ocular	28	-7.78 (-16.00, 0.45)	-
		0.5% Pro-ocular	24	-18.74 (-27.49, -9.98)	-
		Placebo	28	-23.12 (-31.89, -14.35)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		15.35 (4.89, 25.80)	0.005
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		4.38 (-6.39, 15.16)	0.420

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Mean VAS symptom score	Week 12	1% Pro-ocular	28	-15.05 (-24.36, -5.74)	-
		0.5% Pro-ocular	25	-22.34 (-32.08, -12.61)	-
		Placebo	27	-30.14 (-39.99, -20.29)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		15.09 (3.36, 26.81)	0.012
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		7.79 (-3.94, 19.53)	0.190
	Week 16 (Follow Up)	1% Pro-ocular	27	-16.52 (-25.73, -7.31)	-
		0.5% Pro-ocular	24	-26.14 (-36.01, -16.27)	-
		Placebo	25	-31.81 (-41.83, -21.80)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		15.29 (3.99, 26.59)	0.009
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		5.67 (-5.77, 17.12)	0.326
Foreign body sensation	Week 2	1% Pro-ocular	28	-7.13 (-16.76, 2.51)	-
		0.5% Pro-ocular	28	-12.63 (-22.41, -2.85)	-
		Placebo	30	-9.80 (-19.63, 0.03)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		2.67 (-9.29, 14.63)	0.658
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-2.83 (-14.69, 9.03)	0.636

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Foreign body sensation	Week 4	1% Pro-ocular	28	-15.83 (-25.91, -5.76)	-
		0.5% Pro-ocular	28	-17.84 (-27.91, -7.77)	-
		Placebo	30	-18.75 (-29.00, -8.51)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		2.92 (-9.59, 15.43)	0.643
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.91 (-11.52, 13.34)	0.884
	Week 8	1% Pro-ocular	28	-9.52 (-19.37, 0.33)	-
		0.5% Pro-ocular	24	-20.93 (-31.44, -10.42)	-
		Placebo	28	-18.87 (-29.29, -8.45)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		9.36 (-3.00, 21.72)	0.136
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-2.06 (-14.89, 10.77)	0.750
	Week 12	1% Pro-ocular	28	-22.30 (-33.33, -11.27)	-
		0.5% Pro-ocular	25	-24.81 (-36.39, -13.23)	-
		Placebo	27	-26.70 (-38.27, -15.14)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		4.40 (-9.29, 18.09)	0.524
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		1.89 (-11.97, 15.75)	0.787

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Foreign body sensation	Week 16 (Follow Up)	1% Pro-ocular	27	-18.25 (-29.69, -6.81)	-
		0.5% Pro-ocular	24	-28.16 (-40.42, -15.89)	-
		Placebo	25	-30.19 (-42.43, -17.95)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.94 (-1.85, 25.73)	0.089
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		2.03 (-12.05, 16.12)	0.774
Burning/stinging	Week 2	1% Pro-ocular	28	-11.35 (-21.34, -1.35)	-
		0.5% Pro-ocular	28	-17.45 (-27.60, -7.30)	-
		Placebo	30	-21.82 (-32.13, -11.52)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		10.48 (-1.92, 22.88)	0.097
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		4.37 (-8.06, 16.81)	0.486
	Week 4	1% Pro-ocular	28	-14.29 (-24.02, -4.57)	-
		0.5% Pro-ocular	28	-17.18 (-26.89, -7.46)	-
		Placebo	30	-26.85 (-36.86, -16.83)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.55 (0.46, 24.64)	0.042
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.67 (-2.45, 21.79)	0.116

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Burning/stinging	Week 8	1% Pro-ocular	28	-12.91 (-23.14, -2.69)	-
		0.5% Pro-ocular	24	-26.43 (-37.34, -15.52)	-
		Placebo	28	-27.99 (-38.92, -17.06)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		15.08 (2.27, 27.89)	0.022
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		1.56 (-11.89, 15.02)	0.818
	Week 12	1% Pro-ocular	28	-21.50 (-33.32, -9.68)	-
		0.5% Pro-ocular	25	-23.92 (-36.38, -11.45)	-
		Placebo	27	-33.42 (-46.03, -20.81)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.92 (-2.74, 26.59)	0.110
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.51 (-5.57, 24.58)	0.213
	Week 16 (Follow Up)	1% Pro-ocular	27	-24.87 (-36.09, -13.65)	-
		0.5% Pro-ocular	24	-31.38 (-43.44, -19.33)	-
		Placebo	25	-36.30 (-48.48, -24.11)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.42 (-2.09, 24.93)	0.096
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		4.91 (-9.07, 18.89)	0.486

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Itching	Week 2	1% Pro-ocular	28	-2.01 (-11.96, 7.94)	-
		0.5% Pro-ocular	28	-15.10 (-25.21, -4.98)	-
		Placebo	30	-16.51 (-26.63, -6.40)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		14.50 (2.21, 26.80)	0.021
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		1.42 (-10.84, 13.68)	0.819
	Week 4	1% Pro-ocular	28	-7.97 (-17.10, 1.16)	-
		0.5% Pro-ocular	28	-20.73 (-29.83, -11.63)	-
		Placebo	30	-19.74 (-28.99, -10.49)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.77 (0.49, 23.06)	0.041
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.99 (-12.24, 10.26)	0.862
	Week 8	1% Pro-ocular	28	-10.17 (-19.74, -0.61)	-
		0.5% Pro-ocular	24	-20.33 (-30.53, -10.12)	-
		Placebo	28	-22.62 (-32.69, -12.54)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.44 (0.53, 24.35)	0.041
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		2.29 (-10.15, 14.73)	0.715

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Itching	Week 12	1% Pro-ocular	28	-17.65 (-29.00, -6.31)	-
		0.5% Pro-ocular	25	-21.41 (-33.27, -9.55)	-
		Placebo	27	-26.80 (-38.63, -14.97)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		9.15 (-4.73, 23.02)	0.193
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		5.39 (-8.85, 19.64)	0.453
	Week 16 (Follow Up)	1% Pro-ocular	27	-20.46 (-31.31, -9.62)	-
		0.5% Pro-ocular	24	-29.76 (-41.39, -18.14)	-
		Placebo	25	-36.06 (-47.64, -24.49)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		15.60 (2.64, 28.56)	0.019
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		6.30 (-7.08, 19.67)	0.351
Pain	Week 2	1% Pro-ocular	28	-10.74 (-20.22, -1.27)	-
		0.5% Pro-ocular	28	-10.28 (-19.84, -0.73)	-
		Placebo	30	-13.28 (-22.99, -3.57)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		2.54 (-9.40, 14.47)	0.674
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		2.99 (-8.71, 14.70)	0.612

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Pain	Week 4	1% Pro-ocular	28	-7.79 (-16.66, 1.08)	-
		0.5% Pro-ocular	28	-14.11 (-22.91, -5.31)	-
		Placebo	30	-18.84 (-27.90, -9.79)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.05 (-0.12, 22.23)	0.053
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		4.73 (-6.21, 15.68)	0.392
	Week 8	1% Pro-ocular	28	-7.50 (-18.71, 3.72)	-
		0.5% Pro-ocular	24	-14.82 (-26.71, -2.94)	-
		Placebo	28	-18.03 (-29.98, -6.09)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		10.54 (-3.79, 24.86)	0.147
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		3.21 (-11.47, 17.88)	0.664
	Week 12	1% Pro-ocular	28	-16.02 (-27.57, -4.47)	-
		0.5% Pro-ocular	25	-21.90 (-33.91, -9.89)	-
		Placebo	27	-21.10 (-33.29, -8.92)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		5.08 (-9.52, 19.68)	0.490
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.79 (-15.32, 13.73)	0.914

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Pain	Week 16 (Follow Up)	1% Pro-ocular	27	-10.36 (-21.57, 0.86)	-
		0.5% Pro-ocular	24	-19.53 (-31.50, -7.56)	-
		Placebo	25	-24.65 (-36.86, -12.45)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		14.30 (0.40, 28.20)	0.044
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		5.12 (-8.81, 19.06)	0.466
sticky feeling	Week 2	1% Pro-ocular	28	-5.39 (-14.40, 3.62)	-
		0.5% Pro-ocular	28	-10.69 (-19.80, -1.57)	-
		Placebo	30	-13.23 (-22.76, -3.70)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		7.84 (-3.80, 19.48)	0.184
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		2.54 (-8.77, 13.86)	0.656
	Week 4	1% Pro-ocular	28	-12.42 (-22.55, -2.30)	-
		0.5% Pro-ocular	28	-10.14 (-20.23, -0.05)	-
		Placebo	30	-19.85 (-30.46, -9.24)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		7.43 (-5.56, 20.42)	0.258
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.71 (-2.98, 22.41)	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.

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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
sticky feeling	Week 8	1% Pro-ocular	28	-7.35 (-17.31, 2.61)	-
		0.5% Pro-ocular	24	-12.83 (-23.44, -2.23)	-
		Placebo	28	-21.92 (-32.77, -11.06)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		14.57 (1.63, 27.50)	0.028
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.08 (-4.07, 22.24)	0.173
	Week 12	1% Pro-ocular	28	-11.86 (-21.65, -2.08)	-
		0.5% Pro-ocular	25	-15.62 (-25.89, -5.36)	-
		Placebo	27	-34.00 (-44.66, -23.34)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		22.13 (9.43, 34.83)	<.001
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		18.37 (5.90, 30.85)	0.004
	Week 16 (Follow Up)	1% Pro-ocular	27	-19.14 (-30.08, -8.19)	-
		0.5% Pro-ocular	24	-23.57 (-35.32, -11.82)	-
		Placebo	25	-34.62 (-46.81, -22.44)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		15.48 (1.72, 29.25)	0.028
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		11.05 (-2.69, 24.79)	0.113

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Blurred vision	Week 2	1% Pro-ocular	28	-3.13 (-12.58, 6.32)	-
		0.5% Pro-ocular	28	-12.46 (-22.02, -2.91)	-
		Placebo	30	-14.17 (-23.95, -4.39)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		11.04 (-1.01, 23.10)	0.072
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		1.71 (-9.90, 13.32)	0.770
	Week 4	1% Pro-ocular	28	-3.21 (-12.62, 6.20)	-
		0.5% Pro-ocular	28	-10.57 (-19.96, -1.18)	-
		Placebo	30	-19.25 (-28.92, -9.59)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		16.04 (4.09, 27.99)	0.009
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		8.68 (-2.88, 20.25)	0.139
	Week 8	1% Pro-ocular	28	-3.74 (-13.84, 6.37)	-
		0.5% Pro-ocular	24	-18.68 (-29.45, -7.90)	-
		Placebo	28	-22.00 (-32.84, -11.16)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		18.27 (5.28, 31.25)	0.006
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		3.33 (-9.82, 16.48)	0.616

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Blurred vision	Week 12	1% Pro-ocular	28	-10.33 (-20.42, -0.25)	-
		0.5% Pro-ocular	25	-23.45 (-34.07, -12.83)	-
		Placebo	27	-31.92 (-42.67, -21.18)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		21.59 (8.77, 34.41)	0.001
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		8.47 (-4.19, 21.14)	0.187
	Week 16 (Follow Up)	1% Pro-ocular	27	-10.47 (-21.03, 0.08)	-
		0.5% Pro-ocular	24	-24.02 (-35.39, -12.65)	-
		Placebo	25	-24.75 (-36.24, -13.26)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		14.28 (1.27, 27.29)	0.032
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.74 (-12.30, 13.77)	0.911
Photophobia	Week 2	1% Pro-ocular	28	-7.92 (-17.94, 2.10)	-
		0.5% Pro-ocular	28	-15.54 (-25.69, -5.40)	-
		Placebo	30	-14.91 (-25.11, -4.71)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		6.99 (-5.46, 19.44)	0.267
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.64 (-12.97, 11.70)	0.918

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Photophobia	Week 4	1% Pro-ocular	28	-8.70 (-19.33, 1.94)	-
		0.5% Pro-ocular	28	-12.04 (-22.65, -1.43)	-
		Placebo	30	-21.40 (-32.20, -10.59)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		12.70 (-0.50, 25.90)	0.059
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.36 (-3.79, 22.51)	0.161
	Week 8	1% Pro-ocular	28	-6.26 (-17.46, 4.95)	-
		0.5% Pro-ocular	24	-16.82 (-28.77, -4.87)	-
		Placebo	28	-24.79 (-36.63, -12.95)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		18.53 (4.48, 32.59)	0.010
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		7.97 (-6.68, 22.62)	0.282
	Week 12	1% Pro-ocular	28	-8.63 (-19.93, 2.66)	-
		0.5% Pro-ocular	25	-23.63 (-35.49, -11.77)	-
		Placebo	27	-33.23 (-45.09, -21.37)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		24.60 (10.66, 38.53)	<.001
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		9.60 (-4.69, 23.88)	0.185

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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**Table 14.2-2.68: Analysis of Visual Analogue Scale 7 Symptoms (Full Analysis Set)**

Parameter	Visit		Adjusted Mean		P-value
			n	LS Mean (95% CI)	
Photophobia	Week 16 (Follow Up)	1% Pro-ocular	27	-13.95 (-25.86, -2.04)	-
		0.5% Pro-ocular	24	-24.28 (-37.08, -11.48)	-
		Placebo	25	-32.45 (-45.29, -19.60)	-
		LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		18.50 (4.14, 32.85)	0.012
		LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		8.16 (-6.66, 22.99)	0.276

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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