

Table 14.3.5-1.5: Summary of Best Corrected Visual Acuity (Safety Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Best Corrected Visual Acuity	Baseline	n (missing)	31 (0)	30 (0)	30 (0)	91 (0)
		Mean (SD)	0.07 (0.122)	0.04 (0.112)	0.03 (0.096)	0.05 (0.111)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.10	0.00, 0.02	0.00, 0.00	0.00, 0.10
		Min, Max	-0.1, 0.5	-0.1, 0.5	-0.1, 0.3	-0.1, 0.5
	Week 2	n (missing)	28 (3)	28 (2)	30 (0)	86 (5)
		Mean (SD)	0.08 (0.129)	-0.54 (3.035)	0.03 (0.095)	-0.14 (1.735)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.10	0.00, 0.00	0.00, 0.10	0.00, 0.10
		Min, Max	0.0, 0.5	-16.0, 0.5	-0.1, 0.2	-16.0, 0.5
	Week 2 change from Baseline	n (missing)	28 (3)	28 (2)	30 (0)	86 (5)
		Mean (SD)	0.01 (0.039)	-0.57 (2.998)	-0.00 (0.051)	-0.18 (1.712)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Min, Max	-0.1, 0.1	-15.9, 0.5	-0.2, 0.1	-15.9, 0.5

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Best Corrected Visual Acuity	Week 4	n (missing)	28 (3)	29 (1)	30 (0)	87 (4)
		Mean (SD)	0.07 (0.106)	0.04 (0.126)	0.02 (0.095)	0.04 (0.110)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.10	0.00, 0.00	0.00, 0.08	0.00, 0.10
		Min, Max	0.0, 0.5	-0.1, 0.5	-0.2, 0.2	-0.2, 0.5
	Week 4 change from Baseline	n (missing)	28 (3)	29 (1)	30 (0)	87 (4)
		Mean (SD)	0.00 (0.049)	0.00 (0.092)	-0.01 (0.050)	-0.00 (0.066)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Min, Max	-0.1, 0.1	-0.1, 0.4	-0.2, 0.1	-0.2, 0.4
	Week 8	n (missing)	24 (7)	28 (2)	28 (2)	80 (11)
		Mean (SD)	0.09 (0.161)	0.06 (0.145)	0.02 (0.101)	0.05 (0.138)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.10	0.00, 0.10	0.00, 0.05	0.00, 0.10
		Min, Max	0.0, 0.6	-0.1, 0.5	-0.2, 0.2	-0.2, 0.6

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Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Best Corrected Visual Acuity	Week 8 change from Baseline	n (missing)	24 (7)	28 (2)	28 (2)	80 (11)
		Mean (SD)	0.02 (0.139)	0.02 (0.108)	-0.01 (0.057)	0.01 (0.105)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Min, Max	-0.2, 0.6	-0.1, 0.5	-0.2, 0.1	-0.2, 0.6
	Week 12	n (missing)	24 (7)	28 (2)	27 (3)	79 (12)
		Mean (SD)	0.06 (0.113)	0.06 (0.136)	0.04 (0.151)	0.05 (0.134)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.10	0.00, 0.10	0.00, 0.10	0.00, 0.10
		Min, Max	0.0, 0.5	-0.1, 0.5	-0.2, 0.6	-0.2, 0.6
	Week 12 change from Baseline	n (missing)	24 (7)	28 (2)	27 (3)	79 (12)
		Mean (SD)	-0.00 (0.036)	0.02 (0.088)	0.01 (0.088)	0.01 (0.076)
		Median	0.00	0.00	0.00	0.00
		Q1, Q3	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Min, Max	-0.1, 0.1	-0.2, 0.2	-0.1, 0.3	-0.2, 0.3

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Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Snellen Equivalent	Baseline	20/10	—	—	—	—
		20/13	—	—	—	—
		20/16	1 (3.2)	—	3 (10.0)	4 (4.4)
		20/20	18 (58.1)	23 (76.7)	20 (66.7)	61 (67.0)
		20/25	7 (22.6)	5 (16.7)	3 (10.0)	15 (16.5)
		20/32	2 (6.5)	—	2 (6.7)	4 (4.4)
		20/40	2 (6.5)	1 (3.3)	2 (6.7)	5 (5.5)
		20/50	—	—	—	—
		20/63	—	1 (3.3)	—	1 (1.1)
		20/80	1 (3.2)	—	—	1 (1.1)
		20/100	—	—	—	—
		Missing	—	—	—	—
	Randomization, post-randomization	20/10	—	—	—	—
		20/13	—	—	—	—
		20/16	1 (3.3)	—	3 (10.0)	4 (4.4)
		20/20	17 (56.7)	23 (76.7)	19 (63.3)	59 (65.6)
		20/25	8 (26.7)	5 (16.7)	4 (13.3)	17 (18.9)

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Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Snellen Equivalent	Randomization, post-randomization	20/32	1 (3.3)	—	3 (10.0)	4 (4.4)
		20/40	2 (6.7)	2 (6.7)	1 (3.3)	5 (5.6)
		20/50	—	—	—	—
		20/63	—	—	—	—
		20/80	1 (3.3)	—	—	1 (1.1)
		20/100	—	—	—	—
		Missing	1	—	—	1
	Week 2	20/10	—	1 (3.6)	—	1 (1.2)
		20/13	—	1 (3.6)	—	1 (1.2)
		20/16	—	1 (3.6)	5 (16.7)	6 (7.0)
		20/20	16 (57.1)	19 (67.9)	16 (53.3)	51 (59.3)
		20/25	8 (28.6)	3 (10.7)	4 (13.3)	15 (17.4)
		20/32	1 (3.6)	—	4 (13.3)	5 (5.8)
		20/40	1 (3.6)	1 (3.6)	1 (3.3)	3 (3.5)
		20/50	1 (3.6)	—	—	1 (1.2)
		20/63	—	2 (7.1)	—	2 (2.3)
		20/80	1 (3.6)	—	—	1 (1.2)

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Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Snellen Equivalent	Week 2	20/100	—	—	—	—
		Missing	1	—	—	1
	Week 4	20/10	—	—	—	—
		20/13	—	—	1 (3.3)	1 (1.1)
		20/16	—	3 (10.3)	3 (10.0)	6 (6.9)
		20/20	16 (57.1)	20 (69.0)	19 (63.3)	55 (63.2)
		20/25	9 (32.1)	2 (6.9)	3 (10.0)	14 (16.1)
		20/32	2 (7.1)	1 (3.4)	4 (13.3)	7 (8.0)
		20/40	—	2 (6.9)	—	2 (2.3)
		20/50	—	—	—	—
		20/63	—	1 (3.4)	—	1 (1.1)
		20/80	1 (3.6)	—	—	1 (1.1)
		20/100	—	—	—	—
		Missing	1	—	—	1
	Week 8	20/10	—	—	—	—
		20/13	—	—	2 (7.1)	2 (2.5)

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Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Snellen Equivalent	Week 8	20/16	—	2 (7.1)	2 (7.1)	4 (5.0)
		20/20	14 (58.3)	17 (60.7)	17 (60.7)	48 (60.0)
		20/25	7 (29.2)	6 (21.4)	4 (14.3)	17 (21.3)
		20/32	1 (4.2)	—	2 (7.1)	3 (3.8)
		20/40	—	1 (3.6)	1 (3.6)	2 (2.5)
		20/50	—	—	—	—
		20/63	—	2 (7.1)	—	2 (2.5)
		20/80	1 (4.2)	—	—	1 (1.3)
		20/100	1 (4.2)	—	—	1 (1.3)
		Missing	3	1	—	4
	Week 12	20/10	—	—	—	—
		20/13	—	—	2 (7.4)	2 (2.5)
		20/16	—	2 (7.1)	3 (11.1)	5 (6.3)
		20/20	15 (62.5)	16 (57.1)	12 (44.4)	43 (54.4)
		20/25	6 (25.0)	5 (17.9)	7 (25.9)	18 (22.8)
		20/32	2 (8.3)	2 (7.1)	2 (7.4)	6 (7.6)
		20/40	—	2 (7.1)	1 (3.7)	3 (3.8)

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Snellen Equivalent	Week 12	20/50	—	—	—	—
		20/63	—	1 (3.6)	—	1 (1.3)
		20/80	1 (4.2)	—	—	1 (1.3)
		20/100	—	—	—	—
		Missing	2	—	—	2

Table 14.3.5-1.6: Analysis of Best Corrected Visual Acuity (Safety Set)

Visit		Adjusted Mean		P-value
		n	LS Mean (95% CI)	
Week 2	1% Pro-ocular	28	-0.72 (-1.43, -0.01)	-
	0.5% Pro-ocular	28	-0.24 (-0.96, 0.48)	-
	Placebo	30	-0.23 (-0.96, 0.51)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-0.49 (-1.37, 0.38)	0.265
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.02 (-0.90, 0.87)	0.973
Week 4	1% Pro-ocular	29	0.00 (-0.03, 0.03)	-
	0.5% Pro-ocular	28	0.00 (-0.02, 0.03)	-
	Placebo	30	-0.01 (-0.04, 0.02)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		0.01 (-0.02, 0.05)	0.487
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.01 (-0.02, 0.05)	0.395
Week 8	1% Pro-ocular	28	0.02 (-0.03, 0.06)	-
	0.5% Pro-ocular	24	0.03 (-0.02, 0.07)	-
	Placebo	28	-0.01 (-0.06, 0.03)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		0.03 (-0.02, 0.09)	0.244
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.04 (-0.02, 0.10)	0.182

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Visit		Adjusted Mean		P-value
		n	LS Mean (95% CI)	
Week 12	1% Pro-ocular	28	0.01 (-0.02, 0.05)	-
	0.5% Pro-ocular	24	-0.01 (-0.04, 0.03)	-
	Placebo	27	0.00 (-0.04, 0.04)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		0.01 (-0.03, 0.05)	0.548
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.01 (-0.05, 0.04)	0.735