

Table 14.3.5-1.3: Summary of Undilated Funoscopy (Safety Set)

Eye Structure	Visit	Status	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Vitreous	Week 12	Normal	24 (100.0)	28 (100.0)	26 (96.3)	78 (98.7)
		Abnormal Not Clinically Significant	—	—	1 (3.7)	1 (1.3)
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	—	2
	Week 16 (Follow Up)	Normal	24 (100.0)	26 (96.3)	24 (96.0)	74 (97.4)
		Abnormal Not Clinically Significant	—	1 (3.7)	1 (4.0)	2 (2.6)
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	1	3
	Early Termination	Normal	1 (100.0)	1 (100.0)	1 (100.0)	3 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	9	4	5	18
Retina/Macula	Week 12	Normal	24 (100.0)	28 (100.0)	26 (96.3)	78 (98.7)
		Abnormal Not Clinically Significant	—	—	1 (3.7)	1 (1.3)
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	—	2

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Retina/Macula	Week 16 (Follow Up)	Normal	24 (100.0)	27 (100.0)	25 (100.0)	76 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	1	3
	Early Termination	Normal	1 (100.0)	1 (100.0)	1 (100.0)	3 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	9	4	5	18
Choroid	Week 12	Normal	24 (100.0)	28 (100.0)	26 (96.3)	78 (98.7)
		Abnormal Not Clinically Significant	—	—	1 (3.7)	1 (1.3)
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	—	2
	Week 16 (Follow Up)	Normal	24 (100.0)	27 (100.0)	25 (100.0)	76 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	1	3

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Choroid	Early Termination	Normal	1 (100.0)	1 (100.0)	1 (100.0)	3 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	9	4	5	18
Optic Nerve	Week 12	Normal	24 (100.0)	28 (100.0)	26 (96.3)	78 (98.7)
		Abnormal Not Clinically Significant	—	—	1 (3.7)	1 (1.3)
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	—	2
	Week 16 (Follow Up)	Normal	24 (100.0)	27 (100.0)	25 (100.0)	76 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	2	—	1	3
	Early Termination	Normal	1 (100.0)	1 (100.0)	1 (100.0)	3 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	9	4	5	18

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Eye Structure	Visit	Status	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Cup/Disc Ratio	Week 12	Normal	24 (100.0)	27 (96.4)	26 (96.3)	77 (97.5)
		Abnormal Not Clinically Significant	—	—	1 (3.7)	1 (1.3)
		Abnormal Clinically Significant	—	1 (3.6)	—	1 (1.3)
		Missing	2	—	—	2
	Week 16 (Follow Up)	Normal	24 (100.0)	26 (96.3)	25 (100.0)	75 (98.7)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	1 (3.7)	—	1 (1.3)
		Missing	2	—	1	3
	Early Termination	Normal	1 (100.0)	1 (100.0)	1 (100.0)	3 (100.0)
		Abnormal Not Clinically Significant	—	—	—	—
		Abnormal Clinically Significant	—	—	—	—
		Missing	9	4	5	18

Table 14.3.5-1.4: Analysis of Undilated Funoscopy (Safety Set)

Eye structure	Visit	Comparison	p-value
Vitreous	Week 12	1% Pro-ocular vs Placebo	0.329
		0.5% Pro-ocular vs Placebo	0.353
	Week 16 (Follow Up)	1% Pro-ocular vs Placebo	0.886
		0.5% Pro-ocular vs Placebo	0.157
Retina/Macula	Week 12	1% Pro-ocular vs Placebo	0.329
		0.5% Pro-ocular vs Placebo	0.353
Choroid	Week 12	1% Pro-ocular vs Placebo	0.329
		0.5% Pro-ocular vs Placebo	0.353
Optic Nerve	Week 12	1% Pro-ocular vs Placebo	0.329
		0.5% Pro-ocular vs Placebo	0.353
Cup/Disc Ratio	Week 12	1% Pro-ocular vs Placebo	0.629
		0.5% Pro-ocular vs Placebo	0.353
	Week 16 (Follow Up)	1% Pro-ocular vs Placebo	0.317