

Supplementary material

Title

Multi-Symptom Relief with Propylene Glycol-Hydroxypropyl-Guar Nanoemulsion Lubricant Eye Drops in Subjects with Dry Eye Disease: A Post-Marketing Prospective Study

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Prior Presentation

Some data of this study have been previously presented at: 2022 American Academy of Optometry (AAO), San Diego, CA, US (25-31 Oct, 2022); 2023 Association for Research in Vision and Ophthalmology (ARVO), New Orleans, LA, US (23-27 Apr, 2023); 2023 American Optometric Association (AOA) Congress & Annual American Optometric Student Association (AOSA) Conference: Optometry's Meeting, Washington, DC, USA (21-24 Jun, 2023); 2023 European Dry Eye Society (EuDES) meeting, Hilton Munich Park, Munich, Germany (2-3 Jun, 2023); and 2023 American Academy of Optometry (AAO), New Orleans, US (11-14 Oct, 2023).

Supplementary material

Table S1 Frequency and bothersomeness of dry eye symptoms on IDEEL-SB questionnaire

Symptoms on IDEEL-SB questionnaire	Baseline/Day 0 (n = 94)	Day 14 (n = 84)	Day 28 (n = 87)
Dry eye symptoms, n (%)			
None of the time	0 (0.0)	5 (6.0)	8 (9.2)
A little of the time	3 (3.2)	26 (31.0)	39 (44.8)
Some of the time	44 (46.8)	40 (47.6)	29 (33.3)
Most of the time	42 (44.7)	13 (15.5)	10 (11.5)
All of the time	5 (5.3)	0 (0.0)	1 (1.1)
Eyes feel gritty, n (%)			
I did not have this symptom/Not applicable	1 (1.1)	11 (13.1)	20 (23.0)
Not at all	4 (4.3)	20 (23.8)	28 (32.2)
Slightly	37 (39.4)	42 (50.0)	29 (33.3)
Moderately	48 (51.1)	11 (13.1)	9 (10.3)
Very much	4 (4.3)	0 (0.0)	1 (1.1)
Need to close my eyes/not tired, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	4 (4.8)	11 (12.6)
Not at all	1 (1.1)	25 (29.8)	33 (37.9)
Slightly	33 (35.1)	45 (53.6)	35 (40.2)
Moderately	55 (58.5)	9 (10.7)	6 (6.9)
Very much	5 (5.3)	1 (1.2)	2 (2.3)
Burning or stinging eyes, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	6 (7.1)	6 (6.9)
Not at all	1 (1.1)	18 (21.4)	33 (37.9)
Slightly	36 (38.3)	45 (53.6)	36 (41.4)
Moderately	51 (54.3)	11 (13.1)	10 (11.5)
Very much	6 (6.4)	4 (4.8)	2 (2.3)
Tired eyes, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	3 (3.6)	6 (6.9)
Not at all	0 (0.0)	15 (17.9)	30 (34.5)
Slightly	30 (31.9)	49 (58.3)	36 (41.4)
Moderately	53 (56.4)	13 (15.5)	12 (13.8)
Very much	11 (11.7)	4 (4.8)	3 (3.4)
Blurry vision, n (%)			
I did not have this symptom/Not applicable	1 (1.1)	7 (8.3)	9 (10.3)
Not at all	9 (9.6)	27 (32.1)	32 (36.8)
Slightly	48 (51.1)	29 (34.5)	35 (40.2)
Moderately	31 (33.0)	21 (25.0)	8 (9.2)
Very much	5 (5.3)	0 (0.0)	3 (3.4)
Itchy eyes, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	5 (6.0)	9 (10.3)
Not at all	3 (3.2)	21 (25.0)	30 (34.5)
Slightly	40 (42.6)	43 (51.2)	39 (44.8)
Moderately	42 (44.7)	13 (15.5)	6 (6.9)
Very much	9 (9.6)	2 (2.4)	3 (3.4)
Irritated eyes, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	4 (4.8)	5 (5.7)
Not at all	1 (1.1)	20 (23.8)	30 (34.5)
Slightly	28 (29.8)	40 (47.6)	38 (43.7)
Moderately	54 (57.4)	19 (22.6)	11 (12.6)

Supplementary material

Symptoms on IDEEL-SB questionnaire	Baseline/Day 0 (n = 94)	Day 14 (n = 84)	Day 28 (n = 87)
Very much	11 (11.7)	1 (1.2)	3 (3.4)
Eyes feel scratched, n (%)			
I did not have this symptom/Not applicable	4 (4.3)	17 (20.2)	20 (23.0)
Not at all	17 (18.1)	40 (47.6)	48 (55.2)
Slightly	51 (54.3)	21 (25.0)	14 (16.1)
Moderately	19 (20.2)	5 (6.0)	5 (5.7)
Very much	3 (3.2)	1 (1.2)	0 (0.0)
Eye dryness, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	3 (3.6)	3 (3.4)
Not at all	0 (0.0)	8 (9.5)	20 (23.0)
Slightly	12 (12.8)	46 (54.8)	50 (57.5)
Moderately	58 (61.7)	23 (27.4)	9 (10.3)
Very much	24 (25.5)	4 (4.8)	5 (5.7)
Mucus in eyes, n (%)			
I did not have this symptom/Not applicable	6 (6.4)	13 (15.5)	22 (25.3)
Not at all	26 (27.7)	41 (48.8)	38 (43.7)
Slightly	44 (46.8)	24 (28.6)	20 (23.0)
Moderately	14 (14.9)	5 (6.0)	4 (4.6)
Very much	4 (4.3)	1 (1.2)	3 (3.4)
Puffy or swollen eyes, n (%)			
I did not have this symptom/Not applicable	1 (1.1)	6 (7.1)	18 (20.7)
Not at all	20 (21.3)	45 (53.6)	44 (50.6)
Slightly	49 (52.1)	24 (28.6)	19 (21.8)
Moderately	24 (25.5)	7 (8.3)	5 (5.7)
Very much	0 (0.0)	2 (2.4)	1 (1.1)
Eye Redness, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	9 (10.7)	15 (17.2)
Not at all	17 (18.1)	36 (42.9)	36 (41.4)
Slightly	46 (48.9)	28 (33.3)	26 (29.9)
Moderately	23 (24.5)	8 (9.5)	5 (5.7)
Very much	8 (8.5)	3 (3.6)	5 (5.7)
Aching or sore eyes, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	9 (10.7)	13 (14.9)
Not at all	4 (4.3)	29 (34.5)	37 (42.5)
Slightly	58 (61.7)	37 (44.0)	30 (34.5)
Moderately	27 (28.7)	8 (9.5)	4 (4.6)
Very much	5 (5.3)	1 (1.2)	3 (3.4)
Felt something in eyes, n (%)			
I did not have this symptom/Not applicable	1 (1.1)	13 (15.5)	16 (18.4)
Not at all	11 (11.7)	36 (42.9)	38 (43.7)
Slightly	49 (52.1)	27 (32.1)	26 (29.9)
Moderately	28 (29.8)	7 (8.3)	4 (4.6)
Very much	5 (5.3)	1 (1.2)	3 (3.4)
Frequent/rapid blinking, n (%)			
I did not have this symptom/Not applicable	1 (1.1)	10 (11.9)	13 (14.9)
Not at all	19 (20.2)	37 (44.0)	41 (47.1)
Slightly	37 (39.4)	29 (34.5)	26 (29.9)
Moderately	31 (33.0)	6 (7.1)	5 (5.7)

Supplementary material

Symptoms on IDEEL-SB questionnaire	Baseline/Day 0 (n = 94)	Day 14 (n = 84)	Day 28 (n = 87)
Very much	6 (6.4)	2 (2.4)	2 (2.3)
Difficulty blinking, n (%)			
I did not have this symptom/Not applicable	1 (1.1)	11 (13.1)	17 (19.5)
Not at all	28 (29.8)	49 (58.3)	50 (57.5)
Slightly	48 (51.1)	18 (21.4)	16 (18.4)
Moderately	14 (14.9)	5 (6.0)	2 (2.3)
Very much	3 (3.2)	1 (1.2)	2 (2.3)
Sensitivity to light/glare/wind, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	5 (6.0)	6 (6.9)
Not at all	5 (5.3)	17 (20.2)	18 (20.7)
Slightly	30 (31.9)	38 (45.2)	41 (47.1)
Moderately	42 (44.7)	17 (20.2)	13 (14.9)
Very much	17 (18.1)	7 (8.3)	9 (10.3)
Sensitivity to recirculated air, n (%)			
I did not have this symptom/Not applicable	0 (0.0)	5 (6.0)	6 (6.9)
Not at all	3 (3.2)	31 (36.9)	28 (32.2)
Slightly	39 (41.5)	31 (36.9)	33 (37.9)
Moderately	34 (36.2)	15 (17.9)	15 (17.2)
Very much	18 (19.1)	2 (2.4)	5 (5.7)
Headaches associated with dry eye symptoms, n (%)			
I did not have this symptom/Not applicable	5 (5.3)	15 (17.9)	23 (26.4)
Not at all	34 (36.2)	50 (59.5)	51 (58.6)
Slightly	41 (43.6)	16 (19.0)	7 (8.0)
Moderately	11 (11.7)	3 (3.6)	4 (4.6)
Very much	3 (3.2)	0 (0.0)	2 (2.3)

Note: Subjects were asked about how often they experienced dry eye symptoms over the last two weeks. Further, subjects were asked about how bothersome dry eye symptoms were to them over the last two weeks. If subjects had the symptom, they were asked to choose how much the symptom bothered them (not at all, slightly, moderately, or very much). If subjects did not have symptom over the last week, they were asked to choose “I did not have this symptom/Not applicable”. The IDEEL-SB questionnaire was not completed at baseline/day 0 for 1 subject.

Abbreviations: IDEEL-SB, Impact of dry eye on everyday living - symptom bother.

Supplementary material

Table S2 Frequency and intensity of symptoms on DEQ-5 scale

Symptoms on DEQ-5	Baseline/Day 0 (n = 94)	Day 14 (n = 81)	Day 28 (n = 89)
Feel eye discomfort, n (%)			
0 Never	0 (0.0)	0 (0.0)	4 (4.5)
1 Rarely	0 (0.0)	11 (13.6)	35 (39.3)
2 Sometimes	34 (36.2)	45 (55.6)	38 (42.7)
3 Frequently	57 (60.6)	23 (28.4)	10 (11.2)
4 Constantly	3 (3.2)	2 (2.5)	2 (2.2)
Intensity of eye discomfort, n (%)			
0 Never have it	0 (0.0)	1 (1.2)	8 (9.0)
1 Not at all intense	2 (2.1)	15 (18.5)	38 (42.7)
2	21 (22.3)	31 (38.3)	25 (28.1)
3	48 (51.1)	21 (25.9)	11 (12.4)
4	20 (21.3)	12 (14.8)	5 (5.6)
5 Very intense	3 (3.2)	1 (1.2)	2 (2.2)
Feel eye dryness, n (%)			
0 Never	0 (0.0)	0 (0.0)	9 (10.1)
1 Rarely	0 (0.0)	7 (8.6)	27 (30.3)
2 Sometimes	37 (39.4)	47 (58.0)	38 (42.7)
3 Frequently	47 (50.0)	23 (28.4)	12 (13.5)
4 Constantly	10 (10.6)	4 (4.9)	3 (3.4)
Intensity of eye dryness, n (%)			
0 Never have it	0 (0.0)	0 (0.0)	7 (7.9)
1 Not at all intense	1 (1.1)	14 (17.3)	41 (46.1)
2	11 (11.7)	33 (40.7)	20 (22.5)
3	51 (54.3)	19 (23.5)	13 (14.6)
4	25 (26.6)	14 (17.3)	5 (5.6)
5 Very intense	6 (6.4)	1 (1.2)	3 (3.4)
Feel watery eyes, n (%)			
0 Never	0 (0.0)	7 (8.6)	20 (22.5)
1 Rarely	22 (23.4)	35 (43.2)	38 (42.7)
2 Sometimes	43 (45.7)	28 (34.6)	20 (22.5)
3 Frequently	25 (26.6)	9 (11.1)	9 (10.1)
4 Constantly	4 (4.3)	2 (2.5)	2 (2.2)

Note: The DEQ-5 was not completed at baseline for 1 subject.

Abbreviations: DEQ-5, 5-item dry eye questionnaire.

Supplementary material

Table S3 Corneal fluorescein staining of subjects on NEI grading scale at day 0 (n = 95) and day 28 (n = 95)

Corneal regions	Corneal staining on NEI grading scale, n (%)			
	0-Normal	1-Mild	2-Moderate	3-Severe
Central OD				
Baseline/Day 0	84 (88.4)	8 (8.4)	3 (3.2)	0 (0.0)
Day 28	79 (84.0)	12 (12.8)	1 (1.1)	2 (2.1)
Central OS				
Baseline/Day 0	84 (88.4)	9 (9.5)	2 (2.1)	0 (0.0)
Day 28	77 (81.9)	14 (14.9)	3 (3.2)	0 (0.0)
Superior OD				
Baseline/Day 0	87 (91.6)	7 (7.4)	1 (1.1)	0 (0.0)
Day 28	83 (88.3)	11 (11.7)	0 (0.0)	0 (0.0)
Superior OS				
Baseline/Day 0	83 (87.4)	11 (11.6)	1 (1.1)	0 (0.0)
Day 28	81 (86.2)	11 (11.7)	2 (2.1)	0 (0.0)
Nasal OD				
Baseline/Day 0	70 (73.7)	21 (22.1)	3 (3.2)	1 (1.1)
Day 28	66 (70.2)	23 (24.5)	5 (5.3)	0 (0.0)
Nasal OS				
Baseline/Day 0	64 (67.4)	22 (23.2)	4 (4.2)	5 (5.3)
Day 28	59 (62.8)	28 (29.8)	2 (2.1)	5 (5.3)
Inferior OD				
Baseline/Day 0	61 (64.2)	24 (25.3)	9 (9.5)	1 (1.1)
Day 28	55 (58.5)	32 (34.0)	3 (3.2)	4 (4.3)
Inferior OS				
Baseline/Day 0	58 (61.1)	26 (27.4)	7 (7.4)	4 (4.2)
Day 28	50 (53.2)	34 (36.2)	5 (5.3)	5 (5.3)
Temporal OD				
Baseline/Day 0	76 (80.0)	13 (13.7)	4 (4.2)	2 (2.1)
Day 28	72 (76.6)	15 (16.0)	4 (4.3)	3 (3.2)
Temporal OS				
Baseline/Day 0	72 (75.8)	16 (16.8)	5 (5.3)	2 (2.1)
Day 28	71 (75.5)	17 (18.1)	4 (4.3)	2 (2.1)

Note: Corneal fluorescence staining was evaluated on the NEI scale. Each corneal region was graded on 0-3 scale: 0 = normal, negative slit lamp findings; 1 = mild, superficial stippling; 2 = moderate, punctate staining including superficial abrasion of the cornea; 3 = Severe, abrasion or corneal erosion, deep corneal abrasion or recurrent erosion.

Abbreviations: NEI, National Eye Institute; OD, oculus dextrus; OS, oculus sinister.

Supplementary material

Table S4 Osmolarity, visual acuity, and tear breakup time of subjects at day 0 and day 28

Parameters	Baseline/Day 0	Day 28
Osmolarity, mean $\pm$ SD	(n = 94)	(n = 93 [OD]; n = 92[OS])
OD	310.6 $\pm$ 20.73	309.3 $\pm$ 21.68
OS	305.5 $\pm$ 18.07	306.5 $\pm$ 17.52
Visual acuity, mean $\pm$ SD logMAR	(n = 95)	(n = 95)
OD	0.030 $\pm$ 0.12	0.013 $\pm$ 0.12
OS	0.025 $\pm$ 0.12	0.007 $\pm$ 0.13
TBUT, mean $\pm$ SD seconds	(n = 95)	(n = 94)
OD	5.6 $\pm$ 2.21	7.3 $\pm$ 3.09
OS	5.1 $\pm$ 1.96	6.5 $\pm$ 2.56

Abbreviations: OD, oculus dextrus; OD, oculus sinister; SD, Standard deviation; TBUT, Tear breakup time.

Supplementary material

Table S5 Safety outcomes reported throughout the study

Safety outcomes	Safety analysis set, n = 96	
	Events, n	Subjects, n (%)
AEs	3	3 (3.1)
TEAEs*	3	3 (3.1)
Causality of TEAE		
Related	0	0 (0.0)
Not related	3	3 (3.1)
COVID-19	1	1 (1.0)
Herpes Zoster	1	1 (1.0)
Kidney infection	1	1 (1.0)
SAE	1	1 (1.0)
Causality of SAE		
Related	0	0 (0.0)
Not related	1	1 (1.0)
Kidney infection	1	1 (1.0)

Note: *There was no difference between AE and TEAE.

Abbreviations: AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event.