References for CEQUA® (cyclosporine ophthalmic solution) 0.09%

[a]**Study design:** Patient survey feedback was collected from dry eye disease patients who were nominally compensated for their time. Patients participating in the survey were supplied with a 5-day CEQUA sample along with their prescription. Participants completed 4 surveys: one at registration (prior to using CEQUA) (n=255), and one at 1 month (n=136), 2 months (n=142), and 3 months (n=123).[1]

[b]The safety of CEQUA was evaluated in clinical trials that included 769 patients who received at least 1 dose of study treatment.[3]

[c]**Study design:** Single-arm, open-label study evaluating 60 (46 assessable) patients at 7, 14, and 28 days. The primary endpoint was corneal higher-order aberrations. Exclusion criteria were similar to past studies with the exception that patients switching from another dry eye medication were not excluded.[1]

[d]Grade 0 is no staining and 1 represents minimal staining.

References:

1. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
2. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.
3. Goldberg DF, Malhotra RP, Schechter BA, Justice A, Weiss SL, Sheppard JD. A phase 3, randomized, double-masked study of OTX-101 ophthalmic solution 0.09% in the treatment of dry eye disease. *Ophthalmology*. 2019;126(9):1230-1237.

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