References for CEQUA® (cyclosporine ophthalmic solution) 0.09%

[a]**Study design:** In the Phase 2/3 and Phase 3 studies, patients were randomized to receive twice-daily treatment with CEQUA® (n=152) or vehicle (n=152; Phase 2/3), or CEQUA (n=371) or vehicle (n=373; Phase 3) for up to 3 months. The primary efficacy endpoint was the percentage of eyes with improvement from baseline in the Schirmer test score (≥10 mm increase) at month 3 and a key secondary efficacy endpoint was complete clearing of central corneal staining (Phase 3 study). Snellen visual acuity was a safety endpoint in both trials and used in the pooled efficacy analysis in an exploratory manner. Comfort was also evaluated in both trials, as part of the safety/tolerability profile.[1,5]

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

[c]Instillation site pain included burning and stinging.

[d]To participate in the CEQUA (cyclosporine ophthalmic solution) 0.09% Co-Pay Program ("Program"), you must present this card, along with a valid prescription for CEQUA, to your pharmacist. Patients with commercial health insurance who qualify to participate may pay as little as $0 for 60 vials (1 box) of CEQUA. Enrollment is subject to the Eligibility Rules and Terms and Conditions. If you have any questions regarding Eligibility, the Terms and Conditions, or to discontinue participation, please call 855-268-1426 (8:00 AM-8:00 PM EST, Monday-Friday). Please see full terms and conditions at cequapro.com/ways-to-save-on-cequa

[e]PhilRx is a third-party vendor. By participating in the program, patients acknowledge that they currently meet the eligibility criteria. This program is only available for eligible commercially or Medicare Part D insured patients who are prescribed CEQUA through PhilRx.

[f]**Study design:** The Phase 4 trial was a single-arm, 12-week, multicenter study of 124 adults with dry eye disease inadequately controlled (ie, still symptomatic and/or exhibiting disease signs) on current Restasis® therapy (≥3 months). The coprimary endpoints were corneal fluorescein staining (CFS) and modified Symptom Assessment in Dry Eye (mSANDE) at Week 12. Secondary endpoints included central CFS score, frequency of artificial tear use, and patient treatment preference at Week 12. Patients received 1 drop, 2X daily of CEQUA in each eye.[4]

References:

1. CEQUA prescribing information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.
2. 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.
3. Tauber J, Schechter BA, Bacharach J, et al. A phase II/III, randomized, double-masked, vehicle-controlled, dose-ranging study of the safety and efficacy of OTX-101 in the treatment of dry eye disease. *Clin Ophthalmol*. 2018;12:1921-1929.

4. Johnston J, Adler R, Hessen M, et al. Effect of cyclosporine ophthalmic solution 0.09% on signs and symptoms of dry eye disease in patients inadequately controlled on cyclosporine ophthalmic emulsion 0.05%: results from a single-arm, open-label, phase 4 study. *Clin Ophthalmol*. 2026;20:583701.
5. Malhotra R, Devries DK, Luchs J, et al. Effect of OTX-101, a novel nanomicellar formulation of cyclosporine A, on corneal staining in patients with keratoconjunctivitis sicca: a pooled analysis of phase 2b/3 and phase 3 studies. *Cornea*. 2019;38:1259-1265.

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