

## References for CEQUA® (cyclosporine ophthalmic solution) 0.09%

**Study Design:** CEQUA was studied in two 12-week, randomized, multicenter, double-masked, vehicle-controlled studies. Patients were randomly assigned to treatment and dosed twice a day. Study 1 included 455 patients (152 received CEQUA) and Study 2 included 744 patients (371 received CEQUA). The co-primary endpoints for Study 1 were conjunctival staining and global symptom scores (change from baseline to Day 84). The primary endpoint for Study 2 was percentage of eyes demonstrating an improvement of  $\geq 10$  mm in Schirmer score after 84 days of treatment. Both studies assessed corneal staining as a secondary endpoint.<sup>2,3,6</sup>

Staining in each region of the conjunctiva was evaluated using a score ranging from 0 (no staining) to 3 (severe staining). Staining in each region of the cornea was evaluated using a score ranging from 0 (no staining) to 4 (severe staining).<sup>2,3</sup>

Patients were excluded from the studies if they experienced prior treatment failure with cyclosporine 0.05% or used the therapy within 3 months prior to screening. Use of artificial tears was not allowed during the studies. The mean age was 59 years (range, 18-90 years). Eighty-three percent of patients were female.<sup>2,3</sup>

### References:

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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.
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5. Karpecki P, Barghout V, Schenkel B, et al. Real-world treatment patterns of OTX-101 ophthalmic solution, cyclosporine ophthalmic emulsion, and lifitegrast ophthalmic solution in patients with dry eye disease: a retrospective analysis. *BMC Ophthalmol*. 2023;23(1):443.
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