

## References for CEQUA<sup>®</sup> (cyclosporine ophthalmic solution) 0.09%

1. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
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. 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.
4. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.
5. 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.
6. 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.
7. Mandal A, Bisht R, Rupenthal ID, Mitra A. Polymeric micelles for ocular drug delivery: from structural frameworks to recent preclinical studies. *J Control Release*. 2017;248:96-116.
8. US Patent 9,937,225 B2.
9. Cholkar K, Gilger BC, Mitra AK. Topical, aqueous, clear cyclosporine formulation design for anterior and posterior ocular delivery. *Transl Vis Sci Technol*. 2015;4(3):1-16.
10. Xiidra<sup>®</sup> [package insert]. Bridgewater, NJ: Bausch & Lomb, Inc.; 2023.
11. Restasis<sup>®</sup> [package insert]. Irvine, CA: Allergan; 2017.
12. Miebo<sup>®</sup> [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; 2023.
13. Vevye<sup>®</sup> [package insert]. Nashville, TN: Harrow Eye, LLC; 2023.
14. Schechter BA, Urbieta M, Bacharach J, et al. Effect of OTX-101 on patients with dry eye disease at day 14 of treatment: ocular surface endpoint results from the phase 2b/3 clinical trial. *Clin Ophthalmol*. 2022;16:4145-4151.

