

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

<sup>a</sup>The safety of CEQUA was evaluated in clinical trials that included 769 patients who received at least 1 dose of study treatment.<sup>6</sup>

<sup>b</sup>Instillation site pain included burning and stinging.<sup>2,7</sup>

<sup>c</sup>The first time they tried CEQUA, 9 out of 10 patients reported no or mild discomfort after 3 minutes.<sup>8</sup>

<sup>d</sup>Most patients found CEQUA to be comfortable right from the start.<sup>2,8</sup>

<sup>e</sup>Results are from Study 2. Study 1 found similar results at days 28 and 84.<sup>8</sup>

**Study design:** 2-week efficacy data come from a Phase 2b/3, randomized, multicenter, double-masked, vehicle-controlled, dose-ranging study in 455 patients. The co-primary efficacy endpoints were mean reduction in total conjunctival staining score and mean reduction in global symptom score at Day 84. Conjunctival and corneal staining were assessed at baseline and Days 14, 28, 42, 56, and 84/early discontinuation. Conjunctival staining was assessed in 6 conjunctival zones 1–4 minutes after instilling 1 drop of 1% lissamine green. Corneal staining was evaluated in 5 corneal regions 2–2.5 minutes after instilling 1 drop of 0.5% fluorescein.<sup>9</sup>

**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>6-8</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>7,8</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>7,8</sup>

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