

Vevye (cyclosporine) - New drug approval

- On May 30, 2023, the <u>FDA approved</u> Novaliq's <u>Vevye (cyclosporine ophthalmic solution)</u>, for the treatment of the signs and symptoms of dry eye disease (DED).
- Other ophthalmic formulations of cyclosporine are available under the brand names <u>Restasis®</u>,
 Cegua®, and Verkazia®. In addition, generics are available for Restasis.
 - Restasis (and its generics) and Cequa are approved for keratoconjunctivitis sicca (dry eye).
 - Verkazia is approved for vernal keratoconjunctivitis.
- The efficacy of Vevye was established in two randomized, vehicle-controlled studies in 1,369 patients with DED. At day 29 across the two studies, there was a statistically significant higher percentage of eyes with increases of ≥ 10 mm from baseline in Schirmer's wetting. This effect was seen in approximately 10% of Vevye-treated patients vs. approximately 6% of vehicle-treated patients.
- Warnings and precautions for Vevye include potential for eye injury and contamination and use with contact lenses.
- The most common adverse reaction with Vevye use was instillation site reactions.
- The recommended dose of Vevye is one drop instilled twice a day in each eye approximately 12 hours apart.
- Novaliq's launch plans for Vevye are pending. Vevye will be available as an ophthalmic solution containing cyclosporine 0.1%.



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