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The Best VisionNewsletter

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Restasis Approved by FDA for the Treatment of Dry Eye

Restasis (cyclosporine ophthalmic emulsion, 0.05%, Allergan), has recently been approved by the FDA for the treatment of dry eye disease. This topical therapy is indicated for patients with keratoconjunctivitis sicca whose tear production is presumed to be suppressed due to ocular inflammation. Although the exact mechanism of action is not known, it is thought that cyclosporine downregulates the inflammatory response (by preventing cytokine release from T cells) that is a component of dry eye disease.

In Phase III studies, Restasis demonstrated statistically significant and clinically relevant increases in Schirmer wetting versus vehicle at six months in randomized, controlled trials of 1,200 patients diagnosed as suffering from moderate to severe keratoconjunctivitis sicca. It is worth noting that therapy may require *six months* before an improvement is realized. Increased tear production was not demonstrated in patients currently receiving topical anti-inflammatory drugs or using punctal plugs.

Restasis may provide an alternative to the treatment of dry eye disease in difficult to treat populations such as Sjogren's, rheumatoid arthritis or other systemic inflammatory disease. Twice daily dosing is recommended and may be concurrently implemented with artificial tears. The most common side effects in the trials were ocular burning (approximately 17 percent of patients), conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging and blurring (1 to 5 percent).

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