



RESTASIS[®] Fact Sheet

About RESTASIS[®] (cyclosporine ophthalmic emulsion) 0.05%

RESTASIS[®], approved by the U.S. Food and Drug Administration in 2002, is currently the only prescription eye drop available believed to treat an underlying cause of chronic dry eye. RESTASIS[®] helps increase tear production in cases where it may be reduced by inflammation due to chronic dry eye. RESTASIS[®] ophthalmic emulsion did not increase tear production in patients using topical steroids or tear duct plugs.

How RESTASIS[®] Works

Eyes need a healthy tear film to maintain and protect the ocular surface. Chronic dry eye is a medical condition that can result from the eyes' reduced ability to produce tears due to inflammation. If left untreated over time, inflammation and reduced tear production can damage the surface of the eye and exacerbate chronic dry eye.¹

It has been shown that patients with chronic dry eye experience increased activation of T-cells, which may cause inflammation and disrupt the normal production of tears, leading to a decrease in the patient's natural ability to produce their own tears. RESTASIS[®] ophthalmic emulsion contains a very small concentration of cyclosporine, believed to help inhibit the activation of T-cells.² The exact mechanism of action for RESTASIS[®] ophthalmic emulsion is unknown.



RESTASIS[®] Key Benefits

- In a real-world study of 3,145 patients, 83 percent surveyed stated that they had an intention to continue using RESTASIS[®] ophthalmic emulsion.³
- RESTASIS[®] ophthalmic emulsion is reimbursed by the majority of prescription plans offered by major health insurers in the United States (99 percent on formulary; or 83 percent coverage and 16 percent coverage with prior authorization).⁴ Reimbursement amounts vary by plan.
- Only five out of 293 patients in clinical trials discontinued RESTASIS[®] ophthalmic emulsion due to burning and stinging.⁵

RESTASIS[®] Efficacy

Four multicenter, randomized, adequate and well-controlled clinical studies were performed in approximately 1,200 patients with moderate to severe keratoconjunctivitis sicca (chronic dry eye). RESTASIS[®] ophthalmic emulsion demonstrated statistically significant increases in Schirmer wetting (a test to measure tear production) of 10 mm versus vehicle at six months in patients whose tear production was presumed to be suppressed due to ocular inflammation.²

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About Dry Eye

Dry eye affects an estimated 21 million people in the United States⁶ and is one of the most common reasons that people visit their eye doctor.⁷ A national survey of 2,003 individuals found that nearly 40 percent of Americans experience dry eye symptoms,⁸ which may include dryness, itching, irritation, blurred vision, sensitivity to light, foreign body sensation and excessive tearing. Dry eye can be aggravated by a number of external factors such as hot, dry or windy environments, high altitudes, heating, air-conditioning, prolonged computer use and smoke.^{9,10,11} Dry eye can also be caused by medical factors, including hormonal changes due to aging and menopause, thyroid problems, vitamin deficiencies, rheumatoid arthritis, diabetes, lupus and Sjögren's syndrome.^{7,8,10,11,12}

Important RESTASIS® Safety Information

RESTASIS® ophthalmic emulsion should not be used by patients with active eye infections and has not been studied in patients with a history of herpes viral infections of the eye. The most common side effect is a temporary burning sensation. For more information about RESTASIS® ophthalmic emulsion, please refer to the full [prescribing information](#) and the product Web site at www.restasis.com.

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Additional Information

For more information about RESTASIS® ophthalmic emulsion, please refer to the full [prescribing information](#) and the product Web site at www.restasis.com.

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¹ Pflugfelder S. Antiinflammatory Therapy for Dry Eye. *Am J Ophthalmol*. 2004; 127:337-342.

² RESTASIS® Prescribing Information.

³ Trattler, W, Katsev, D, Kerney, D. Self-Reported Compliance with Topical Cyclosporine Emulsion 0.05% and Onset of the Effects of Increased Tear Production as Assessed Through Patient Surveys. *Clinical Therapeutics*. 2006.

⁴ Wolters Kluwer Dynamic Claims Analyzer 2nd Quarter Average 2007.

⁵ Sall K, Stevenson, OD, Mundorf, Reis BL, and the CsA Phase 3 Study Group. Two multicenter, randomized studies of the efficacy and safety of cyclosporine ophthalmic emulsion in moderate to severe dry eye disease. *Ophthalmology*. 2000; 107(4):631-639.

⁶ Market Scope. Report on the Global Dry Eye Market. St. Louis, Mo: Market Scope, July 2004.

⁷ Schaumberg D, Sullivan D, Buring J, Dana R. Prevalence of dry eye syndrome among U.S. women. *Am J Ophthalmol*. 2003;136:318-326.

⁸ Multi-sponsor surveys, Inc. Gallup study of dry eye sufferers. Princeton, NJ, 2006.

⁹ Aging Eye Times. Artificial Tears. Available at: <http://www.agingeyenet/dryeyesinformation.php>. Accessed March 7, 2006.

¹⁰ Mader T, Tabin G. Going to High Altitude with Preexisting Ocular Conditions. *High Altitude Medicine & Biology*. 2003; 4:419-430.

¹¹ Blehm C, Vishnu S, Khattak A. Computer vision syndrome: a review. *Surv Ophthalmol*. 2005 May-Jun;50(3):253-62.

¹² Pflugfelder SC, Beuerman RW, Stern ME, eds. Dry Eye and Ocular Surface Disorders. New York, NY: Marcel Dekker, Inc.; 2004.