

Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

Therapeutic Class:

Ophthalmic Anti-inflammatory Immunomodulator-Type Products

Overview:

Cyclosporine 0.05% ophthalmic emulsion (Restasis[®]) is an anti-inflammatory immunomodulator-type topical product that is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with a condition known as keratoconjunctivitis sicca. The exact mechanism of action is unknown.

Restasis[®] is available as a 0.05 % ophthalmic emulsion packaged in single use vials containing 0.4 ml of emulsion. The approved dosing is one drop in each eye twice daily (approximately 12 hours apart) and it can be used concomitantly with artificial tears, allowing a 15 minute interval between products. Cyclosporine ophthalmic emulsion should not be administered while wearing contact lenses.

Although cyclosporine is an immunosuppressant agent when given systemically, blood concentrations remain undetectable when administered as an ophthalmic emulsion in recommended doses. Common adverse events associated with the use of Restasis[®] include ocular burning, conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Generic Name	Brand Name	Manufacturer
Cyclosporine 0.05% ophthalmic emulsion	Restasis [®]	Allergan, Inc.

Summary:

Cyclosporine 0.05% ophthalmic emulsion (Restasis[®]), an anti-inflammatory immunomodulator-type product, increases tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with a condition known as keratoconjunctivitis sicca. It currently is the only agent in this pharmacologic class and its exact mechanism of action is unknown. While it was relatively well tolerated in clinical trials, the most common adverse events associated with therapy are ocular burning, conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).