FIRST TIME GENERIC APPROVAL

Brand Name	Restasis®
Generic Name	cyclosporine
Drug Manufacturer	Mylan Pharmaceuticals Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

February 2, 2022

LAUNCH DATE

February 14, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 205894

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Cyclosporine ophthalmic emulsion is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

MECHANISMS OF ACTION

Cyclosporine is an immunosuppressive agent when administered systemically.
In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine emulsion is thought to act as a partial immunomodulator. The exact mechanism of action is not known.

DOSE FORM AND STRENGTH

Cyclosporine ophthalmic emulsion 0.5 mg/mL.

DOSE & ADMINISTRATION

Instill one drop of cyclosporine ophthalmic emulsion twice a day in each eye approximately 12 hours apart.