**Indication and Usage:** RESTASIS® ophthalmic emulsion is 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.

**Important Safety Information**

**Contraindications:** RESTASIS® is contraindicated in patients with active ocular infections and in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

**Warning:** RESTASIS® has not been studied in patients with a history of herpes keratitis.

**Precautions:** The emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration. Do not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. RESTASIS® should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion.

**Adverse Reactions:** The most common adverse event was ocular burning (upon instillation)—17%. Other events reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Please see accompanying product information for RESTASIS® ophthalmic emulsion.
When tear production is reduced by inflammation due to Chronic Dry Eye
RESTASIS® helps you make more of your own real tears

What is Chronic Dry Eye?
- Chronic Dry Eye is a disease that can be caused by advanced age, contact lens wear, certain medications, eye diseases, other medical conditions, or environmental factors
- One type of Chronic Dry Eye is caused by decreased tear production due to inflammation
- Without enough tears, the film protecting the eye can break down, creating dry spots on the cornea

What is RESTASIS®?
- If your Chronic Dry Eye is caused by decreased tear production due to inflammation and requires continuous therapy, your doctor may prescribe RESTASIS® (cyclosporine ophthalmic emulsion) 0.05%, the only prescription eye drop that helps increase your eyes’ natural ability to produce tears
- RESTASIS® did not increase tear production in patients using anti-inflammatory eye drops or tear duct plugs

How is RESTASIS® different from artificial tears?
- Artificial tears are lubricants that can provide temporary relief of Dry Eye symptoms, but only RESTASIS® can help increase your natural ability to produce tears

How is RESTASIS® supplied and used?
- A 30-day supply is 2 trays (60 vials)

Use one drop in each eye in the morning from one vial; discard vial. Repeat in the evening.

What should I expect from RESTASIS®?

1 month
Your eyes may begin producing more of their own real tears

3 months
You may begin to notice an increase in tear production

6 months
You may experience a significant increase in tear production and may rely less on artificial tears

The benefits of RESTASIS® only continue with continued use

Individual results may vary.

- Just as it took time for your type of Chronic Dry Eye to develop, it will take time to improve your tear production—it could take 3 to 6 months after beginning therapy for you to notice an increase in tear production
- You may experience a temporary stinging or burning sensation when you first start using RESTASIS®. This is a response to treatment, but if you have any concerns, or this persists, contact your eye doctor immediately concerning the continued use of RESTASIS®
- RESTASIS® can be used with artificial tears, such as REFRESH® Brand Lubricant Eye Drops. Allow for 15 minutes between products. You may use fewer artificial tears as your eyes begin producing more of their own real tears with RESTASIS®

Please see product information for RESTASIS® ophthalmic emulsion on next page.
Cyclosporine is a fine white powder. RESTASIS® appears as a white opaque to slightly translucent homogenous emulsion. It has an osmolality of 230 to 320 mOsmol/kg and a pH of 6.5-8.0.

Each mL of RESTASIS® ophthalmic emulsion contains: Active: cyclosporine 0.05%. Inactives: glycerin; castor oil; polysorbate 80; carbomer copolymer type A; purified water; and sodium hydroxide to adjust pH.

CLINICAL PHARMACOLOGY
Mechanism 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.

Pharmacokinetics
Blood cyclosporin A concentrations were measured using a specific high pressure liquid chromatography-mass spectrometry assay. Blood concentrations of cyclosporine, in all the samples collected, after topical administration of RESTASIS® 0.05%, BID, in humans for up to 12 months, were below the quantitation limit of 0.1 ng/mL. There was no detectable drug accumulation in blood during 12 months of treatment with RESTASIS® ophthalmic emulsion.

Clinical Evaluations
Four multicenter, randomized, adequate and well-controlled clinical studies were performed in approximately 1200 patients with moderate to severe keratoconjunctivitis sicca.

INDICATIONS AND USAGE
RESTASIS® ophthalmic emulsion is 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 is not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

CONTRAINDICATIONS
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WARNING
RESTASIS® ophthalmic emulsion has not been studied in patients with a history of herpes keratitis.

PRECAUTIONS
General: For ophthalmic use only.

Information for Patients
The emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes; the remaining contents should be discarded immediately after administration.

ADVERSE REACTIONS
The most common adverse event following the use of RESTASIS® was ocular burning (17%). Other events reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

DOSE AND ADMINISTRATION
Invert the unit dose vial a few times to obtain a uniform, white, opaque emulsion before using. Instil one drop of RESTASIS® ophthalmic emulsion twice a day in each eye approximately 12 hours apart.

HOW SUPPLIED
RESTASIS® ophthalmic emulsion is packaged in single use vials. Each vial contains 0.4 mL fill in a 0.9 mL LDPE vial; 30 vials are packaged in a polypropylene tray with an aluminum peelable lid. The entire contents of each tray (30 vials) must be dispensed intact. RESTASIS® is also provided in a 60 count (2 x 30) package (one month supply) that must be dispensed intact.


KEEP OUT OF THE REACH OF CHILDREN.

Rx Only

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