Could you have a type of Chronic Dry Eye disease?

Be your own advocate. Ask to get screened.

If you have Chronic Dry Eye (CDE) disease caused by reduced tear production due to inflammation, prescription RESTASIS® may be right for you.

– Alison Tendler MD,
RESTASIS® User, Eye Doctor

STEP 1

UNDERSTAND CHRONIC DRY EYE DISEASE

HEALTHY EYES NEED TEARS

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. If you use artificial tears often, you may have a type of Chronic Dry Eye disease.

STEP 2

SEE HOW RESTASIS® IS DIFFERENT FROM ARTIFICIAL TEARS

Approved Use
RESTASIS® Ophthalmic Emulsion helps increase your eyes’ natural ability to produce tears, which may be reduced by inflammation due to Chronic Dry Eye. RESTASIS® did not increase tear production in patients using anti-inflammatory eye drops or tear duct plugs.

Important Safety Information
Do not use RESTASIS® Ophthalmic Emulsion if you are allergic to any of the ingredients. To help avoid eye injury and contamination, do not touch the vial tip to your eye or other surfaces. RESTASIS® should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to use of RESTASIS® and may be reinserted after 15 minutes. The most common side effect is a temporary burning sensation. Other side effects include eye redness, discharge, watery eyes, eye pain, foreign body sensation, itching, stinging, and blurred vision.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please click here for full Product Information at the end.
STEP 3

TAKE THE DRY EYE QUIZ
AND ASK TO GET SCREENED FOR CHRONIC DRY EYE DISEASE

Take this quiz to help determine if you may have a type of Chronic Dry Eye disease. After taking the quiz, share your results with an eye doctor and ask to get screened.

Remember:
Only your eye doctor can determine what treatment is appropriate for your dry eyes.

1. I use artificial tears (also known as over-the-counter lubricant eye drops) often.
   - TRUE
   - FALSE
   If true, approximately how often?
   - Less than daily
   - 1 to 2 times per day
   - 3 or more times per day

2. I usually carry artificial tears with me wherever I go.
   - TRUE
   - FALSE

3. I have been using artificial tears for a long time.
   - TRUE
   - FALSE
   If true, approximately how long?
   - Less than 1 year
   - 1 to 2 years
   - More than 2 years

4. I have tried multiple types of over-the-counter artificial tears.
   - TRUE
   - FALSE
   If true, what types? (Check all that apply.)
   - Lubricant eye drops (over-the-counter artificial tear)
   - Lubricant eye gel (artificial tear in the form of a gel)
   - Lubricant eye ointment (artificial tear in the form of an ointment)
   - Contact lens rewetting eye drop
   - All of the above

5. My dry eyes are getting worse.
   - TRUE
   - FALSE

6. Dry eyes affect my daily activities.
   - TRUE
   - FALSE
   If true, approximately how often?
   - Less than daily
   - Parts of the day
   - All day

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STEP 4
SHARE YOUR RESULTS WITH YOUR EYE DOCTOR
MAKE SURE YOU GET SCREENED ON YOUR VISIT

• Tell the front desk you want a medical appointment to get screened for Chronic Dry Eye disease

• Also remind the office technician that you want to get screened

• Share your dry eye quiz results with your eye doctor and let the office staff know you are there to get screened

• Ask your eye doctor for your screening results

STEP 5
ASK ABOUT RESTASIS®
BE YOUR OWN ADVOCATE

• You may be diagnosed with Chronic Dry Eye disease caused by reduced tear production due to inflammation

• RESTASIS® is the only prescription that increases tear production with continued use

• Ask your eye doctor if RESTASIS® may be right for you

STEP 6
MAKE MORE OF YOUR OWN REAL TEARS
TIPS TO KEEP IN MIND FOR MAKING MORE TEARS WITH RESTASIS®

• Give it 3 to 6 months to notice more real tears

• Use one drop of RESTASIS® twice a day in each eye, 12 hours apart—every day

• Talk to your doctor if you have any concerns, like burning and stinging when you use RESTASIS®—he or she may be able to help

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GET SAVINGS AND SUPPORT

Join the My Tears, My Rewards® Program for continuous savings and support
- Continuous savings on prescriptions for RESTASIS®
- Potential savings of hundreds of dollars per year

You get the most value and savings from the 90-day prescription program
- Ask your eye doctor to write you a 90-day prescription for RESTASIS®
- You pay no out-of-pocket expenses up to $90 on every prescription refill during a year‡

You can also save with the 30-day prescription program
- You get up to $20 off your first, second, and third prescription copays§

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Get Support at Every Step
- Helpful information on your treatment journey
- Access to the RESTASIS® Patient Support Center, where trained representatives and nurses can answer your questions
- Free samples of REFRESH® Lubricant Eye Drops, that may be used while you wait to notice more of your own real tears with RESTASIS®
- Download of the MyTears® iPhone app to help with dosing reminders, and to log tear production and artificial tear use

Ask your eye doctor or visit restasis.com/savings for more information.

*The actual reimbursement for a member’s out-of-pocket costs for RESTASIS® will vary according to refill quantity, personal healthcare insurance coverage, and adherence to FDA dosing guidelines. Please review the RESTASIS® My Tears, My Rewards® Program guidelines to learn about the savings you may be eligible for.
†Members whose prescriptions will be paid for in part or in whole by Medicare, Medicaid, or any similar federal or state healthcare program, are not eligible for these rebates according to federal and state law.
‡On average, copays on 90-day prescriptions are $86, so most patients have little to zero out-of-pocket costs for the full year.
§On average, copays on 30-day prescriptions are $54, so most patients will still have an out-of-pocket cost in most months of a year.
A My Tears, My Rewards® member has exactly 1 year from the date of his or her first RESTASIS® prescription fill to redeem refills toward rebate rewards. Members may request a new Program Savings Card to begin a new reward sequence at the end of the 1-year period.
Please click here for full Product Information at the end.
1. Understand Chronic Dry Eye Disease

2. See How RESTASIS® Is Different From Artificial Tears

3. Take the Dry Eye Quiz and Ask to Get Screened for Chronic Dry Eye Disease

4. Share Your Results With Your Eye Doctor

5. Ask Your Eye Doctor About RESTASIS®

6. Make More of Your Own Real Tears

7. Get Savings and Support

“If you use artificial tears often, ask to get screened for a type of Chronic Dry Eye disease today.”

– Alison Tendler MD, RESTASIS® User, Eye Doctor

ASK YOUR DOCTOR IF RESTASIS® MAY BE RIGHT FOR YOU.

For more Savings Program information, visit restasis.com/savings

To learn more about RESTASIS®, call the RESTASIS® Patient Support Center at 1-866-572-5931 or visit restasis.com

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Please click here for full Product Information at the end.
RESTASIS® (cyclosporine ophthalmic emulsion) 0.05%

Initial U.S. Approval: 1983

INDICATIONS AND USAGE

RESTASIS® is a topical immunomodulator 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. (1)

DOSE AND ADMINISTRATION

Instill one drop of RESTASIS® ophthalmic emulsion twice a day in each eye approximately 12 hours apart. (2)

Ophthalmic emulsion containing cyclosporine 0.5 mg/mL (3)

ADVERSE REACTIONS

The following adverse reactions have been identified during post approval use of RESTASIS®:

1. Irritation of the eye, including mild, moderate, and severe irritation may occur.
2. Conjunctival injection (redness of the eye) and ocular burning may occur.
3. Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, ocular burning (17%), (6.1)

CONTRAINDICATIONS

- Hypersensitivity (4)

WARNINGS AND PRECAUTIONS

- To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces. (5.1)

ADVERSE REACTIONS

The most common adverse reaction following the use of RESTASIS® was ocular burning (17%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan, Inc. at 1-800-433-8871 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 06/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

6 ADVERSE REACTIONS

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 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 was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

2 DOSAGE AND ADMINISTRATION

Invert the unit dose vial a few times to obtain a uniform, white, opaque emulsion before using. Instill one drop of RESTASIS® ophthalmic emulsion twice a day in each eye approximately 12 hours apart. RESTASIS® can be used concomitantly with artificial tears, allowing a 15 minute interval between products. Discard vial immediately after use.

3 DOSAGE FORMS AND STRENGTHS

Ophthalmic emulsion containing cyclosporine 0.5 mg/mL.

4 CONTRAINDICATIONS

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

5 WARNINGS AND PRECAUTIONS

5.1 Potential for Eye Injury and Contamination

To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.

5.2 Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (17%).

Other reactions 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).

6.2 Post-marketing Experience

The following adverse reactions have been identified during post approval use of RESTASIS®:

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Reported reactions have included: hypersensitivity (including eye swelling, urticaria, rare cases of severe angioedema, face swelling, tongue swelling, pharyngeal edema, and dyspnea); and superficial injury of the eye (from the vial tip touching the eye during administration).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C

Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 μL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryofetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 3,000 and 10,000 times greater (normalized to body surface area), respectively, than the daily human dose.

Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 postpartum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human topical dose (0.001 mg/kg/day) normalized to body surface area assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (2,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of RESTASIS® in pregnant women. RESTASIS® should be administered to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

Cyclosporine is known to be excreted in human milk following systemic administration, but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of RESTASIS® ophthalmic emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

8.4 Pediatric Use

The safety and efficacy of RESTASIS® ophthalmic emulsion have not been established in pediatric patients below the age of 16.

8.5 Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use RESTASIS® 0.05% safely and effectively. See full prescribing information for RESTASIS®.
Cyclosporine is a fine white powder. RESTASIS® appears as a white opaque to slightly translucent homogeneous 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.

12 CLINICAL PHARMACOLOGY
12.1 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.

12.3 Pharmacokinetics
Blood cyclosporine 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%, twice daily, 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.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 80 times greater (normalized to body surface area) than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Mutagenesis: Cyclosporine has not been found to be mutagenic/genotoxic in the Ames Test, the V79-HGPT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes in vitro gave indication of a positive effect (i.e., induction of SCE).

Impairment of Fertility: No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 2,000 times the human daily dose of 0.001 mg/kg/day normalized to body surface area) for 9 weeks (male) and 2 weeks (female) prior to mating.

14 CLINICAL STUDIES
Four multicenter, randomized, adequate and well-controlled clinical studies were performed in approximately 1,200 patients with moderate to severe keratoconjunctivitis sicca. RESTASIS® demonstrated statistically significant increases in Schirmer wetting of 10 mm versus vehicle at six months in patients whose tear production was presumed to be suppressed due to ocular inflammation. This effect was seen in approximately 15% of RESTASIS® ophthalmic emulsion-treated patients versus approximately 5% of vehicle-treated patients. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

No increase in bacterial or fungal ocular infections was reported following administration of RESTASIS® ophthalmic emulsion.