Chronic Dry Eye Patients

RESTASIS® and the My Tears, My Rewards® Program

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:
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.

Please see additional Important Safety Information inside and full Product Information on last page.
Chronic Dry Eye is a disease that may need continuous therapy. It can be caused or exacerbated by advanced age, contact lens wear, certain medications, eye diseases, or other medical conditions.

One type of Chronic Dry Eye is characterized by decreased tear production due to inflammation. For this type of Chronic Dry Eye, RESTASIS® Ophthalmic Emulsion helps increase your eyes’ natural ability to produce tears.

To find out if you have Chronic Dry Eye, fill out the actionnaire. Then, make sure you bring this to your eye doctor at your next visit.

**Remember:** only your eye doctor can determine what treatment is the best choice for managing your eye condition. So the more information you give, the easier it will be for your eye doctor to select treatment that works best for you.

**Important Safety Information:**
RESTASIS® Ophthalmic Emulsion should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to use.

Please see additional Important Safety Information inside and full Product Information on last page.
1. Have you been using artificial tears for a long time?
   Tell your eye doctor exactly how long:

2. Have you tried many types of artificial tears?
   Tell your eye doctor exactly how many:

Tell your eye doctor their names: (Check all that apply)

- Clear Eyes®
- GenTeal®
- TheraTears®
- Visine Tears®
- Other:________________________________________
- Systane®
- Tears Naturale®
- REFRESH® Brand Lubricant Eye Drops
- Soothe® XP

3. Are you using artificial tears often?
   Tell your eye doctor exactly how often:

4. Do you feel like your use of artificial tears has increased over time?
   Tell your eye doctor exactly how much:

Continue on next page
5. Are dry eyes affecting your daily activities?
   - Yes
   - No
   If you answered “Yes,” please let your doctor know what activities are affected:

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6. Are your dry eyes getting worse?
   Let your eye doctor know they have worsened:

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7. Are you satisfied with your current dry eye treatment?
   - Yes
   - No
   If you answered “No,” make sure you tell your eye doctor.

8. Are you ready to discuss prescription treatment options with your doctor?
   - Yes
   - No
   If you answered “Yes,” don’t wait for your annual appointment. Contact your eye doctor TODAY, and make an appointment to discuss treatment options for your eyes.

If you don't currently have an eye doctor, go to Restasis.com and use our physician locator to find an eye doctor in your area.

Clear Eyes is a registered trademark of Prestige Brands, Inc. GenTeal is a registered trademark of Novartis Ophthalmics. Soothe XP is a registered trademark of Bausch & Lomb Incorporated. Systane is a registered trademark of Alcon, Inc. Tears Naturale is a registered trademark of Alcon, Inc. TheraTears is a registered trademark of Advanced Vision Research, Inc. Visine Tears is a registered trademark of McNEIL-PPC, Inc.
RESTASIS®: Make More of Your Own Tears

- RESTASIS® Ophthalmic Emulsion is the only prescription eye drop that helps you make more of your own tears when your ability to make them 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.

- Within 1 month of use, your eyes should start producing more of their own tears, but it could take 3 to 6 months after beginning therapy to see an increase in tear production.

- You may use RESTASIS® in conjunction with artificial tears, such as REFRESH® Brand Lubricant Eye Drops. Your use of artificial tears may decrease as you begin to make more of your own tears.

- Individual results may vary.

RESTASIS® Medication Tips

- Twice a day, morning and night: Set a reminder on your phone or computer to take RESTASIS®—one drop in each eye every morning, another drop in each eye at night.

- 2 trays in 30 days: Make sure to throw away each vial after use. It’s important to use a 30-day supply of RESTASIS® (2 trays—60 vials total) in 30 days.

Talk to your eye doctor today to see if RESTASIS® is right for you.

Important 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. Please see additional important safety information on last page.
Step 3
Join the My Tears, My Rewards® Program
Reward Yourself for Rewarding Your Eyes

The My Tears, My Rewards® (MTMR) Program is a FREE rewards program. It can save you money, earn you rewards, and keep you up-to-date with important eye care information.*

THE SAVINGS

• Instant savings of $15 for a 30-day prescription or $45 for a 90-day prescription each month on RESTASIS®†
• FREE RESTASIS® (cyclosporine ophthalmic emulsion) 0.05%

THE REWARDS

• A free subscription to Your Health In Sight®, Allergan’s quarterly newsletter
• AMC Theatres® movie vouchers
• Gift cards to Barnes & Noble®, Target®, or CVS®

*Limitations may apply.
†$15 for a 30-day program upon filling the second through sixth prescriptions; $45 for a 90-day program for the first and second 90-day prescriptions of RESTASIS®.

AMC Theatres is a registered trademark of AMC Entertainment, Inc. Barnes & Noble is a registered trademark of Barnes & Noble, Inc. Target is a registered trademark of Target Brands, Inc. CVS is a registered trademark of CVS Pharmacy, Inc.
JOIN TODAY!
If your doctor didn’t give you a RESTASIS® Advantage Patient Support Pack and you’d like to obtain one to join the My Tears, My Rewards® Program, please fill out the card below, put it in a stamped envelope, and mail it to RESTASIS® My Tears, My Rewards® Program – Quality Health, P.O. Box 6513, West Caldwell, NJ 07007-9826.

Indication:
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:
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. RESTASIS® should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to use.

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.

Please see full Product Information on last page.

Reward Yourself for Rewarding Your Eyes
Please fill out the card below and mail it back to us.

☑ YES! Please send me more information on the My Tears, My Rewards® Program.

☐ Yes, Allergan, Inc. may use my information to help develop new products, services, programs, and materials, and may contact me to invite my participation in research on RESTASIS® Ophthalmic Emulsion promotional materials.

☑ I certify that I am not a resident of Massachusetts or covered by Medicare, Medicaid, or any other federal or state healthcare pharmacy benefit program.
RESTASIS® should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to use.

Please see additional Important Safety Information on last page.

For more MTMR Program information, visit MyTearsMyRewards.com

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

AND ASK YOUR DOCTOR IF RESTASIS® OPHTHALMIC EMULSION IS RIGHT FOR YOU.
Follow these 3 steps:

1. Have your prescription for RESTASIS® filled at your pharmacy.
2. Circle your out-of-pocket purchase price on the receipt.
3. Mail this certificate, along with your original pharmacy receipt (proof of purchase), to Allergan RESTASIS® Ophthalmic Emulsion $20 Rebate Program – Quality Health P.O. Box 6541, West Caldwell, NJ 07007

Enroll me in the My Tears, My Rewards® Program to save more!

I am not a patient enrolled in Medicare, Medicaid, any similar federal or state healthcare program, or a resident of Massachusetts.


*RESTASIS® Rebate Terms and Conditions: To receive a rebate for the amount of your prescription co-pay (up to $20), enclose this certificate and the ORIGINAL pharmacy receipt in an envelope and mail to Allergan RESTASIS® Ophthalmic Emulsion $20 Rebate Program – Quality Health, P.O. Box 6541, West Caldwell, NJ 07007. Please allow 8 weeks for receipt of rebate check. Receipts prior to April 1, 2011 will not be accepted. Offer only one rebate per consumer. Duplicates will not be accepted. See rebate certificate for expiration date. Eligibility: Offer not valid for prescriptions reimbursed or paid under Medicare, Medicaid, or any similar federal or state healthcare program including any state medical or pharmaceutical assistance programs. Void in the following state(s) if any third-party payer reimburses you or pays for any part of the prescription price: Massachusetts. Offer void where prohibited by law, taxed, or restricted. Amount of rebate not to exceed $20 or co-pay, whichever is less. This certificate may not be reproduced and must accompany your request for a rebate. Offer good only for one prescription of RESTASIS® Ophthalmic Emulsion and only in the USA and Puerto Rico. Allergan, Inc. reserves the right to rescind, revoke, and amend this offer without notice. You are responsible for reporting receipt of a rebate to any private insurer that pays for, or reimburses you for, any part of the prescription filled, using this certificate.

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Certificate expires 1/15/2012
Please allow 8 weeks for delivery of your rebate check.
RESTASIS®
(cyclosporine ophthalmic emulsion) 0.05%
Sterile, Preservative-Free

DESCRIPTION
RESTASIS® (cyclosporine ophthalmic emulsion) 0.05% contains a topical immunomodulator with anti-inflammatory effects. Cyclosporine's chemical name is Cyclo[cal(3R,4R)-3-hydroxy-4-methyl-2-(methylamino)-6-octenoyl]-L-2-aminobutyryl-N-methylglycyl-N-methyl-L-leucyl-L-valyl-N-methyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl] and it has the following structure:

![Structural Formula](image)

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 mOsm/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 1542; purified water and sodium hydroxide to adjust the 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 the all 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. 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®.

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.

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® 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, 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. 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.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
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 1000 and 500 times greater, respectively, than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Cyclosporine has not been found mutagenic/genotoxic in the Ames Test, the V79-HGPRT 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).

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 15,000 times the human daily dose of 0.001 mg/kg/day) for 9 weeks (male) and 2 weeks (female) prior to mating.

Pregnancy-Teratogenic effects
Pregnancy category C.

TERATOGENIC EFFECTS: No evidence of teratogenicity was observed in rats or rabbits receiving oral doses of cyclosporine up to 300 mg/kg/day during organogenesis. These doses in rats and rabbits are approximately 300,000 times greater than the daily human dose of one drop (28 µL) 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Non-Teratogenic Effects: 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 30,000 and 100,000 times greater, respectively, than the daily human dose of one-drop (28 µL) of 0.05% RESTASIS® BID 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 17,000 and 30,000 times greater, 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 post partum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 45,000 times greater than the daily human topical dose, 0.001 mg/kg/day, assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (15,000 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.

Nursing Mothers
Cyclosporine is known to be excreted in human milk following systemic administration but not 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.

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

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

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 burning).

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, 12 hours apart. RESTASIS® can be used concomitantly with artificial tears, allowing a 15 minute interval between products. Discard vial immediately after use.

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 this 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.

30 Vials 0.4 mL each - NDC 0023-9163-30
60 (2 x 30) Vials 0.4 mL each - NDC 0023-9163-60


KEEP OUT OF THE REACH OF CHILDREN.
Rx Only
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PAC76FT10
U.S. Patent 5,474,979
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