

The content of this leaflet was revised according to Ministry of Health instructions

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

The medicine is dispensed with a doctor's prescription only

Restasis

Ophthalmic emulsion

Active ingredient: cyclosporine 0.5 mg/ml

For inactive ingredients and allergens in this medicine, see Section 6 'Additional Information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Restasis ophthalmic emulsion is intended to increase tear production in patients with reduced ability to produce tears due to eye inflammation with dryness. No increase in tear production was observed in patients taking local anti-inflammatory medicines or using tear duct plugs.

Therapeutic group: Medicines with a localized immune effect.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains.

Special warnings about using this medicine

To prevent possible injury to your eye and contamination, make sure the vial tip does not touch your eye or other surfaces.

Do not use **Restasis** while you are wearing contact lenses. Usually, patients with reduced tear production should not wear contact lenses. If you wear contact lenses, remove them before using this medicine. Wait at least 15 minutes after applying the medicine to your eye before reinserting your contact lenses.

Children and adolescents

This medicine is not intended for use in children under the age of 16.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding consult your doctor or pharmacist before you take this medicine.

Driving and using machines

Using this medicine may cause blurred vision. You are advised to avoid driving or operating dangerous machines while your vision is blurred.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine. Only your doctor will determine your dosage and treatment. The recommended dosage is usually one drop in each eye, twice a day, at intervals of about 12 hours.

Do not exceed the recommended dose.

Note: Do not swallow! This medicine is intended for external use only.

Directions for use:

Before you start using it, confirm that the container's package is closed.

Wash your hands carefully. Before you use it, turn the vial over several times until the emulsion appears white, uniform, and opaque.

Use the content of the vial immediately after you have opened it for use in one or both eyes. Discard the vial immediately after you have used it and do not reuse it because this medicine does not contain a preservative.

Tilt your head backwards and use your finger to pull the lower eyelid slightly away from your eye. Apply the medicine in the gap that you formed and close your eyes for 1-2 minutes. Do not blink.

To avoid contaminating the emulsion, make sure the vial tip does not come into contact with any surface including your finger or eye.

You may use **Restasis** concomitantly with lubricating eye drops. Wait 15 minutes between them.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Persist with the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, using **Restasis** may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Very common side effects (appear in more than one in ten users):
burning sensation in the eye while using the medicine.

Common side effects (appear in 1-10 users out of 100):
redness in the eye, discharge, burst of tears, eye pain, foreign body sensation in the eye, itching in the eye, stinging and visual disturbance (usually blurred vision).

Side effects of unknown frequency (effects whose frequency has not been established):

allergic reaction (symptoms may include difficulty breathing or swallowing, swelling of your face, eye, tongue, or throat, itchy rash and shortness of breath), superficial injury to the eye caused by contact of the eye with the tip of the vial.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by following the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

Prevent poisoning! This medicine and all other medicines must be kept in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) stated on the package/vial.

The expiry date refers to the last day of that month.

Store in the original package.

Store at 15-25°C.

Do not store different medicines in the same package.

6. Additional information

In addition to the active ingredient this medicine also contains:

glycerin, castor oil, polysorbate 80, carbomer copolymer Type A, 1-N sodium hydroxide, purified water.

What the medicine looks like and what are the contents of the package:

Restasis ophthalmic emulsion is packaged in single-use sterile vials, without preservatives. Each vial contains 0.4 ml of emulsion. Each package contains 30 vials packed in a tray sealed with removable aluminum foil. This package is dispensed as a single unit.

Registration holder name and address: Allergan Israel Ltd., 32 Shacham St.,
POB 6869, Petach Tikva.

Manufacturer name and address: Allergan Inc. California, USA.

This leaflet was reviewed and approved by the Ministry of Health in June 2014 and revised in March 2018 in accordance with Ministry of Health instructions.

Registration number of the medicine in the Ministry of Health National Drug Registry:
136 03 31306.