

**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 and its quantity:

ciclosporin 0.05% w/v

For the list of 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/for you. Do not pass it on to others.

It may harm them, even if it seems to you that their illness/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 associated with dry eye syndrome. 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 ciclosporin or to any of the other ingredients that this medicine contains (see section 6 'Additional Information').

Special warnings about using this medicine

Possible eye injury and contamination of the emulsion:

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

Use with contact lenses:

Do not use Restasis while you are wearing contact lenses. Usually, wearing contact lenses is not recommended for patients with reduced tear production. If you wear contact lenses, remove them before using this medicine. You may reinsert your lenses 15 minutes after applying the medicine to your eye.

Children and adolescents

This medicine has not been studied in children and adolescents under the age of 16 and is not intended for use in this age group.

Interactions/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

Pregnancy

If you are pregnant or planning to have a baby, consult your doctor or pharmacist before you take this medicine.

Breastfeeding

If you are breastfeeding, consult your doctor or pharmacist before you take this medicine. It is not known if ciclosporin passes into breast milk.

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 according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about the dosage or the treatment regimen of this medicine.

Only your doctor will determine your dosage and treatment regimen. 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

- Check that the medicine packaging is intact before use.
- 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.

Adhere to 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

As with any medicine, 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.

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

Side effects of unknown frequency (the frequency of these effects has not yet been established):

allergic reaction (symptoms may include difficulty breathing or swallowing, swelling of the face, eye, tongue or throat, itchy skin 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 Drug Treatment' 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://sideeffects.health.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.
- **Storage conditions:** Do not store above 25°C. Protect from light.

6. Additional information

In addition to the active ingredient this medicine also contains:

glycerin, castor oil, polysorbate 80, sodium hydroxide, carbomer copolymer type A, 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. The entire package content is dispensed as a single unit.

Registration holder's name and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Manufacturer's name and address: Allergan Inc., USA, 2525 Dupont drive, Irvine, California, USA.

Revised in June 2023 according to MOH guidelines.

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