

RESTASIS[®] OPHTHALMIC SOLUTION

cyclosporine (0.05% w/w)

What is in this leaflet

1. What **RESTASIS[®]** is used for
2. How **RESTASIS[®]** works
3. Before you use **RESTASIS[®]**
4. How to use **RESTASIS[®]**
5. While you are using it
6. Side effects
7. Storage and Disposal of **RESTASIS[®]**
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What **RESTASIS[®]** is used for

RESTASIS[®] is used to increase tear production in people whose eyes are not producing enough tears due to eye inflammation associated with dry eye

How **RESTASIS[®]** works

RESTASIS[®] acts as a topical preparation that affects the immune system.

Before you use **RESTASIS[®]**

- When you must not use it

Do not use **RESTASIS[®]**:

- If you are allergic (hypersensitive to cyclosporine, or any of the other ingredients of **RESTASIS[®]**. (for a full list of ingredients, see section "PRODUCT DESCRIPTION").
- If you have an active eye infection

- Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not use **RESTASIS[®]** if you are pregnant unless your doctor still recommends it.

Do not use **RESTASIS[®]** if you are breast-feeding. It is not known whether or not cyclosporine is passed into breast milk. Ask your doctor for advice

before taking any medicine during breast-feeding.

- Children:

The safety and efficacy of **RESTASIS[®]** have not been studied in children below the age of 16.

- Before you start use it

Before you use **RESTASIS[®]**, talk to your doctor or pharmacist if you have a history of infection of the cornea caused by herpes simplex virus.

- Taking other medicines

RESTASIS[®] can be used concomitantly with artificial tears, allowing a 15 minute interval between products.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use **RESTASIS[®]**

- How much to use

Instill one drop of **RESTASIS[®]** twice a day in the affected eye(s) approximately 12 hours apart.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- Instructions for use

RESTASIS[®] is for application on the eye.

Wash your hands before use.

Before using, invert the unit dose vial a few times until the emulsion is white and appears the same throughout the vial.

Do not re-use the single-dose container even if there is some solution left.

To avoid eye injury and contamination, do not let the tip of the dropper touch your eye or anything else.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking **RESTASIS[®]** for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Systemic overdose is unlikely to occur using topical cyclosporine eye emulsion.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much **RESTASIS[®]** or have accidentally ingested this medicine.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking **RESTASIS[®]**.

Tell your doctor immediately if you are pregnant/ become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give **RESTASIS**[®] to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

This medicine may cause transient blurring of vision which may impair the ability to drive or operate machines. You should wait until your vision has cleared before driving or using machinery.

Using contact lenses:

RESTASIS[®] should not be administered while wearing contact lenses. People 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**[®].

Side effects

Like all medicines, **RESTASIS**[®] can cause side effects, although not everybody gets them.

Very common: burning sensation in the eyes

Common: headache, redness of the eye, discharge, dry eye, eye pain, eye irritation, a feeling that something foreign is in your eye, eye itchiness, stinging, light sensitivity and visual disturbance (most often blurring).

Not known:

Allergic reaction, eye swelling, itchy skin rash, face swelling, tongue swelling, throat swelling, shortness of

breath and superficial injury to the eye from the vial tip touching the eye during administration.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of RESTASIS[®]

- Storage

Keep out of the reach and sight of children.

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 use **RESTASIS**[®] after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Store below 25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Description

- What it looks like

RESTASIS[®] is a sterile, preservative-free white opaque to slightly translucent homogeneous eye emulsion.

RESTASIS[®] 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.

- Ingredients

- Active ingredient

Cyclosporine

- Inactive ingredients

Carbomer 1342, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide to adjust the pH.

- MAL number:

MAL20071648AZ

Manufacturer

Allergan Sales, LLC

Waco, Texas, U.S.A.

Product Registration Holder

Allergan Malaysia Sdn Bhd

Level 5-02, Block A, PJ8, No.23, Jalan Barat, Seksyen 8, 46050 Petaling Jaya, Selangor, Malaysia

Date of revision

31/05/2018

Serial Number

NPRA(R4/1)300518/00170