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1. What **RESTASIS™** is used for

RESTASIS™ is used to increase tear production in patients whose eyes are not producing enough tears due to eye inflammation associated with dry eye

2. How **RESTASIS™** works

RESTASIS™ acts as a topical immunomodulator with anti-inflammatory effects.

3. 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 8 “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.

Herpes keratitis:

RESTASIS™ has not been studied in patients with a history of herpes keratitis. Therefore, before you use **RESTASIS™**, talk to your doctor or pharmacist if you have a history of herpes keratitis.

– Before you start use it

Take special care with **RESTASIS™**.

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.

– 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.

4. 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 ocular use (applied on the eye). Follow these instructions unless the pharmacist or your doctor gave you different advice.

Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else. Wash your hands before use.

Before using, gently shake the vial by tipping it up and down a few times until the emulsion is white and appears the same throughout the vial.

1. Tear one single-dose container from the strip.



2. Hold the single-dose container upright (with the cap uppermost) and twist off the cap.



3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release one drop into each eye. Blink your eyes a few times.



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

- 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)

There is no experience with over-dosage in humans using topical cyclosporine ophthalmic 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.

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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 affect your ability to drive or use machines. If the **RESTASIS™** make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Using 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™**.

6. Side effects

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

Very common (17% of patients):
burning sensation in the eyes

Common (1% to 5% of patients):
redness of the eye, discharge, watery eyes, eye pain, a feeling that something foreign is in your eye, eye itchiness, stinging, and visual disturbance (most often blurring).

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 visiting the

website nptra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of RESTASIS™

- Storage

Keep out of the reach and sight of children.

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 30°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.

4. Product Description

- What it looks like

RESTASIS™ is a sterile, preservative-free ophthalmic emulsion.

RESTASIS™ is packaged in single use vials. Each vial contains 0.4 mL fill in a 0.9 mL LDPE vial; The carton containing 30 unit-dose vials will have three sealed pouches (each containing 2 strips of 5 unit-dose vials).

- Ingredients

- Active ingredient
Cyclosporine

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

- MAL number:

MAL20071648ARZ

9. Manufacturer

Allergan Sales, LLC
8301 Mars Drive,
Waco, Texas 76712, U.S.A.

Product Registration Holder

ABBVIE SDN BHD
Level 9 Menara Lien Hoe
No.8 Persiaran Tropicana
Tropicana Golf & Country Resort
47410 Petaling Jaya Selangor, Malaysia

10. Date of revision

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