

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrRESTASIS®

Cyclosporine Ophthalmic Emulsion

Read this carefully before you start taking **RESTASIS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RESTASIS**.

What is RESTASIS used for?

RESTASIS is used to treat certain patients who have a condition called aqueous deficient dry eye disease. If you have this condition your eyes do not produce enough tears to keep the eyes moist and comfortable. Your healthcare professional will decide if RESTASIS is right for you.

How does RESTASIS work?

RESTASIS contains cyclosporine. Cyclosporine is a medicine that changes your immune system. It reduces inflammation in the eye.

What are the ingredients in RESTASIS?

Medicinal ingredients: cyclosporine

Non-medicinal ingredients: carbomer copolymer type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide.

RESTASIS comes in the following dosage forms:

Ophthalmic emulsion, 0.05% w/v

Do not use RESTASIS if:

- you have an eye infection
- you are allergic to cyclosporine or any of the other ingredients in RESTASIS (see **What are the ingredients in RESTASIS?**).
- you are allergic to any component of the RESTASIS container

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RESTASIS. Talk about any health conditions or problems you may have, including if you:

- have a history of herpes keratitis (infection of the cornea). RESTASIS has not been tested for use in people with this condition.
- You have been told that you have a condition where you are not producing enough tears (called end stage lacrimal gland disease).
- have dry eyes (also known as keratoconjunctivitis sicca) that are the result of Vitamin A deficiency or scarring (which could occur as a result of a blistering disorder, chemical burns, skin disorders, eye infections, or being exposed to radiation). RESTASIS has not been studied in people with these causes of dry eyes.
- drive or operate machinery. RESTASIS may cause your vision to blur right after you put the drops in. Wait a few minutes until your vision clears before you try to drive or operate a machine.
- are breast feeding a baby. It is not known if cyclosporine passes into breast milk.
- are pregnant or planning to become pregnant.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RESTASIS:

No drug interaction studies have been performed with RESTASIS. Concomitant use with other eye products should be discussed with your healthcare professional beforehand.

How to take RESTASIS:

- 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.
- Each vial should be used immediately after opening for use to one or both eyes, and the remaining contents discarded after use.
- You should also avoid touching the tip of the vial to the eye or any surface as this may contaminate the emulsion, and touching the eye may cause injury.
- RESTASIS may be used together with artificial tears. Wait 15 minutes between using RESTASIS and the artificial tear product.
- Do not use RESTASIS while you wear contact lenses. If you must wear contact lenses, remove the lenses before applying RESTASIS. Wait for 15 minutes after applying RESTASIS before you put your contact lenses back in.

Usual Dose:

The usual adult dose of RESTASIS is one drop into each affected eye. This dose should be applied twice a day, about 12 hours apart.

Overdose:

If you think you, or a person you are caring for, have taken too much RESTASIS contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double your dose.

What are possible side effects from using RESTASIS:

These are not all the possible side effects you may have when taking RESTASIS. If you experience any side effects not listed here, tell your healthcare professional.

Eye Disorders

- burning sensation in the eye
- dry eye
- eye discharge
- eye irritation
- eye itching
- eye pain
- eye redness
- blurred vision
- eye swelling
- feeling of grittiness or having something in the eye
- eye sensitivity to light
- accidental injury to the surface of the eye caused by the tip of bottle touching the eye

Nervous System Disorders

- headache

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reactions: difficulty breathing, hives, shortness of breath, tongue swelling, throat swelling, face swelling.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

RESTASIS should be stored between 15 to 25°C. Keep unused vials within the resealable tray.

Keep out of reach and sight of children.

If you want more information about RESTASIS:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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