

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrRestasis MultiDose™ Cyclosporine Ophthalmic Emulsion

Read this carefully before you start taking Restasis MultiDose™ 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 MultiDose™.

What is Restasis MultiDose™ used for?

- It 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 MultiDose™ is right for you.

How does Restasis MultiDose™ work?

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

What are the ingredients in Restasis MultiDose™?

Medicinal ingredients: cyclosporine.

Non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide.

Restasis MultiDose™ comes in the following dosage forms: Emulsion, 0.05% w/w.

Do not use Restasis MultiDose™ if:

- You have an eye infection.
- You are hypersensitive to cyclosporine or any of the other ingredients in Restasis MultiDose™.
- You are allergic to any component of the Restasis MultiDose™ container.

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

- You have or have had *herpes keratitis*. Restasis MultiDose™ 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.
- Your dry eyes are the result of Vitamin A deficiency or scarring. Restasis MultiDose™ has not been studied in people with these causes of dry eyes.
- You drive or operate machinery. Restasis MultiDose™ may cause your vision to blur right after you put the drops in. Wait until your vision clears before you drive or operate a machine.

- You are breastfeeding a baby. It is not known if Restasis MultiDose™ passes into breast milk.
- You are pregnant or planning to become pregnant.

Other warnings you should know about:

Do not administer Restasis MultiDose™ while you wear contact lenses. If you must wear contact lenses, remove the lenses before applying Restasis MultiDose™. Wait for 15 minutes before you put your contact lenses back in.

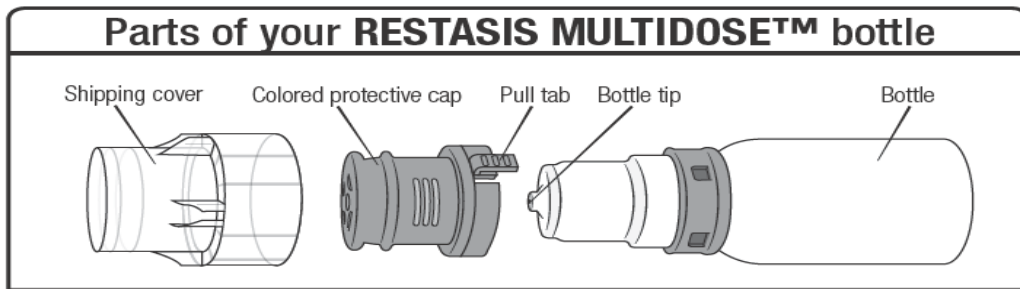
You should avoid touching the tip of the bottle to the eye or any surface. This may contaminate the emulsion, and touching the eye may cause injury.

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

How to take Restasis MultiDose™:

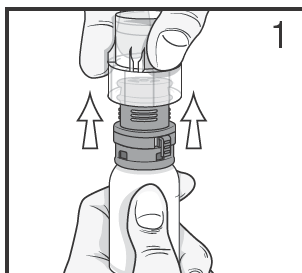
Before using, gently shake the bottle by turning it upside down a few times to make sure the emulsion is mixed well.

Restasis MultiDose™ may be used together with artificial tears. Wait 15 minutes between using Restasis MultiDose™ and the artificial tear product.

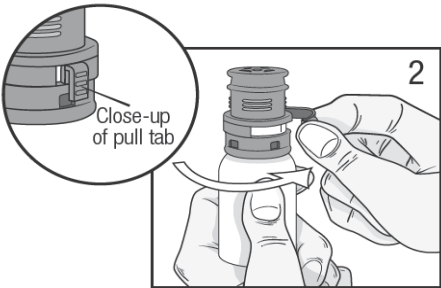


Preparation for First-Time Use

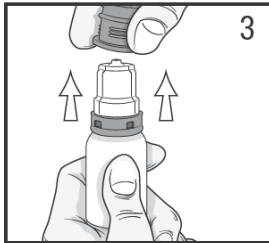
Step 1: Pull off shipping cover by pulling straight up. Throw the shipping cover away. Do not use Restasis MultiDose™ if shipping cover or pull tabs are damaged or missing.



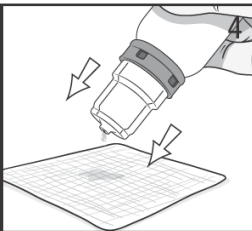
Step 2: Remove the pull tab on the olive green colored protective cap by pulling the end of the pull tab away from the bottle then winding it counterclockwise. Throw away the pull tab.



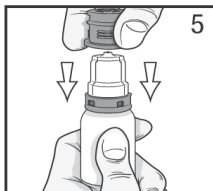
Step 3: Remove the olive green colored protective cap by pulling it straight up. Keep the colored protective cap.



Step 4: Prime the bottle for first time use by holding the bottle with the tip pointing down. Slowly squeeze the bottle to deliver one drop onto a tissue to get used to the pressure and time required to deliver one drop. Do this twice. Do not let the bottle tip touch the tissue.

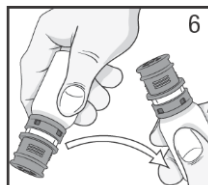


Step 5: The bottle is now ready for use. After use, recap the bottle with the olive green colored protective cap by pushing straight down onto the bottle.



Preparation for Use:

Step 6: Turn the bottle upside down a few times before giving your dose to make sure the medicine is mixed well.



Step 7: Hold the bottle with the tip pointing down and squeeze the bottle gently in the middle to let one drop fall into the eye you are treating. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze the bottle too hard to avoid releasing too many drops. Once administered, replace the olive green colored protective cap.

By design, there may be a small quantity of Restasis MultiDose™ remaining in the bottle at the end when used as directed. Do not try to use the remaining quantity in the bottle.

Usual dose:

The usual adult dose of Restasis MultiDose™ is one drop into each eye you are treating. This dose should be applied twice a day – about 12 hours apart.

Overdose:

If you think you have taken too much Restasis MultiDose™, contact your 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 take a double dose to make up for a missed dose.

What are possible side effects from using Restasis MultiDose™?

These are not all the possible side effects you may feel when taking Restasis MultiDose™. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

Eye Disorders

- burning sensation in the eye
- blurred vision
- dry eye
- eye discharge
- eye irritation
- eye itching
- eye pain

- eye redness
- 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.			X

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

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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Storage:

Restasis MultiDose™ should be stored at 15-25°C. Discard unused emulsion 30 days after opening.

Keep out of reach and sight of children.

If you want more information about Restasis MultiDose™:

- 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 (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website www.abbvie.ca, or by calling 1-888-704-8271.

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