For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rebamipide Eye Drops

Composition:

Rebamipide I.P 2% w/v Stabilized Oxychloro Complex 0.005% w/v (As preservative) Sterile agueous vehicle a.s



Description

Ocusoothe-R is a sterile topical ophthalmic solution prepared specifically for the management of Dry eye syndrome.

Indication:

For treatment and management of:

- ✓ Dry eye syndrome
- ✓ Superior limbic keratoconjunctivitis
- ✓ Vernal/Atopic keratoconjunctivitis
- ✓ Mild lagophthalmos

Mechanism of Action:

Rebamipide is a mucin secretagogue. It increases the mucin secretion, goblet cell density, thereby, ensures the firm adhesion of tear film, improves the stabilization of tear film and relieves the symptoms of dry eye.

Contraindication:

Contraindicated in patients having allergy for the components of product.

Precautions:

Avoid operating machines and vehicles because the vision may be temporarily blurred after instillation of eye drops.

Possible adverse effects:

The most commonly reported adverse reactions include bitter taste, eye pruritus and blurred vision.

Warnings

NOT FOR INJECTION. FOR EXTERNAL USE ONLY. If irritation persists or increases, discontinue the use and consult the Physician. Do not touch the nozzle tip to any surface since this may contaminate the solution. Use the solution within one month after opening the vial If the solution becomes dark brown, it should be discarded. **SHAKE WELL BEFORE USE.**

Safety:

In the evaluation of safety, no life threatening or serious adverse events were noted. The most frequent adverse event in Rebamipide ophthalmic treatment was dysgeusia (9% of patients), otherwise the treatment was generally well tolerated.

Application and Administration:

Instill 1 drop at a time, 4 times daily for 4 weeks or as directed by physician.

 $\textbf{Storage:} Store\ below\ 30^{\circ}\text{C.}\ Protect\ from\ light\ and\ moisture.}\ Do\ not\ freeze.\ Keep\ medicine\ out\ of\ reach\ of\ children.$

Presentation: Ocusoothe-R Eye Drops is available in 10 ml vial.

Instructions for patients for administration of eye drops

- 1. Wash hands thoroughly before administration.
- 2. Tilt head backward or lie down and look upward.
- 3. Gently pull down your eye lid to make a pouch.
- 4. Hold the nozzle of the vial just above the eye and squeeze one drop inside the pouch. Try not to touch your eye, eyelashes, or any surface with the nozzle tip.
- 5. Look upward and continue to hold the eyelid for a moment while the medication spreads evenly on the surface of the eye.
- Release the eye lid slowly and close the eye. Blink gently a few times. This will further help to spread the drop over the entire eye surface.
- 7. Place one finger at the corner of the eye near the nose and apply gentle pressure. This will prevent the medication from draining away from the eye.
- 8. Wipe away any liquid that falls onto your cheek with a tissue.
- 9. Repeat the other eye if the drop is prescribed for both eyes.
- 10. Close the cap of the vial immediately after use.
- 11. If more than one type of ophthalmic drop (eye drop) is to be used, wait for at least 5 minutes before administering the second medication (eye drop) to avoid washout of the previous drug.









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