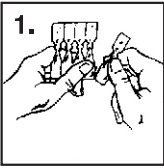
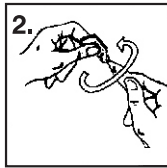


MODE OF APPLICATION



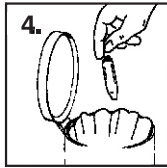
1. Detach one unidose applicap



2. To open, twist off the tab



3. Instill one or two drops into conjunctival sac



4. Dispose the unidose applicap after utilisation

For the use of a Registered Medical Practitioner or a hospital or a laboratory

CARBOXY METHYL CELLULOSE SODIUM LUBRICANT EYE DROPS 0.5% w/v

Refresh Ezee™

For dryness and irritation
Preservative Free



Many things can make your eyes feel dry, scratchy and uncomfortable like air conditioners or heaters, computer use, reading, medications & wind or a reduction in the amount of tears. Your body produces tears which help to lubricate and nourish your eyes. **Refresh Ezee™** restores the moisture of your eyes with a special formula that has some of the healthy qualities as natural tears.

COMPOSITION

Each mL contains:

Carboxy methyl cellulose sodium IP 5 mg

Purified water IP q.s.

Excipients : Sodium Chloride, Potassium Chloride, Sodium Lactate (Use 60% solution), Calcium chloride dihydrate, Magnesium Chloride Hexahydrate, Sodium hydroxide/ hydrochloric acid.

INDICATIONS

For temporary relief from burning irritation and discomfort due to dryness of the eye or due to exposure to wind or sun. May also be used as a protectant against further irritation.

CONTRAINDICATIONS

Refresh Ezee™ is contraindicated in patients with hypersensitivity to CMC or any of the excipients.

PHARMACODYNAMIC PROPERTIES

No clinical pharmacology studies were performed with **Refresh Ezee™**. CMC has no pharmacological receptor-mediated properties. The mode of action of CMC is based on its physical properties which provide a lubricant effect and prolonged residence time in the eye. CMC increases tear viscosity and has pseudo-elastic (i.e. shear thinning) properties. Since CMC is an ionic polymer containing carboxyl and hydroxyl groups, its chemical structure is similar to mucin in the tear film, and thus it has mucoadhesive properties. These properties promote prolonged residence times in the eye which alleviate the symptoms of tear deficiency.

PHARMACOKINETIC PROPERTIES

No clinical or nonclinical pharmacokinetic studies have been performed. CMC is pharmacologically inert and due to its high molecular weight is not expected to be absorbed systemically after the topical administration of **Refresh Ezee™**.

WARNINGS AND PRECAUTIONS

To avoid contamination or possible eye injury, do not touch tip of the bottle or vial to any surface and avoid contact with the eye. Discard any remaining solution in the vial immediately after use. Do not use if packaging shows evidence of tampering. Do not use if solution changes color or becomes cloudy. Discontinue use and consult a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens. Use before the expiration date marked on the container.

DRUG INTERACTIONS

No known drug interactions.

USE IN PREGNANCY AND LACTATION

There are no specific study data on the use of **Refresh Ezee™** during pregnancy and lactation in humans; however, nonclinical studies with CMC have not demonstrated any harmful effects in pregnancy. **Refresh Ezee™** has also not been studied in breast-feeding women; however, CMC is not expected to be systemically absorbed; therefore, it would not be expected to be excreted in human breast milk.

PEDIATRIC USE

Safety and effectiveness have not been demonstrated with **Refresh Ezee™** in pediatric patients.

GERIATRIC USE

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Refresh Ezee™ may cause transient blurring of vision which may impair the ability to drive or operate machines. The patient should wait until their vision has cleared before driving or using machinery.

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ADVERSE REACTIONS

CLINICAL STUDY EXPERIENCE

Allergan has conducted multiple clinical studies with CMC. Summary of Adverse Drug Reactions in Clinical Studies of **Refresh Ezee™** are described below :

Eye irritation, burning and discomfort (5.9%), Eye pain (1.8%), Eye pruritus (1.1%), Visual disturbance (2.9%).

POST MARKETING EXPERIENCE

The following additional adverse reactions have been identified during post marketing use of **Refresh Ezee™** in clinical practice. Because post marketing reporting of these reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions. Eye discharge, ocular hyperaemia, Hypersensitivity including eye allergy, Superficial injury of eye (from the vial tip touching the eye during administration) and/or corneal abrasion.

OVERDOSE

Since CMC is pharmacologically inert and not expected to be absorbed systemically, systemic effects from topical overdose are not expected from the administration of **Refresh Ezee™**. Additionally, no toxic side effects are expected should accidental systemic overdose occur

DOSAGE

Instill 1 to 2 drops in the affected eye(s) as directed. If used for post-operative care (e.g., following LASIK surgery), it is recommended for the patient to follow their eye doctor's instructions.

Concomitant ocular medications should be administered at least 5 minutes apart from the instillation of **Refresh Ezee™** to avoid washout effects.

HOW SUPPLIED

In sterile, 15 vials of 0.4 ml each along with carton & product leaflet.

STORAGE INSTRUCTIONS

Store in a cool place (below 25°C). Protect it from light.

Marketed by :

ALLERGAN INDIA PRIVATE LIMITED

Manufactured in India by :

Piramal Enterprises Limited

Plot No. 67-70, Sector 2, Pithampur-454 775,
Dist. Dhar, Madhya Pradesh.

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