1. Generic Name
Carboxy Methyl Cellulose Eye Drops IP 0.5% w/v.

2. Qualitative and Quantitative Composition
Carboxy Methyl Cellulose Sodium IP …0.5% w/v.
Stabilized Oxychloro Complex…….. 0.005% w/v.
(As Preservative)
Sterile Aqueous Base…… q.s.

Other Ingredients: D-panthenol with electrolytes.

3. Dosage form and strength
Topical ophthalmic solution (Eye Drops) containing Carboxy Methyl Cellulose Sodium IP 0.5% w/v.

4. Clinical particulars
4.1 Therapeutic indication
RE-LUB Kid Eye Drops are indicated for temporary relief from burning, irritation and discomfort due to dryness of the eye or due to exposure to wind or sun.

4.2 Posology and method of administration
Posology: Use the RE-LUB Kid Eye Drops exactly as directed by your doctor. The recommended dose is to Instill one to two drops in the affected eye(s) as and when needed.

Method of administration: Topical(Eye Drops).
If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 15 minutes apart.

4.3 Contraindication
RE-LUB Kid Eye Drops are contraindicated in patients with hypersensitivity to any components of this medication.

4.4 Special warnings and precautions for use
- For ocular use only.
- Do not use if solution changes color or becomes cloudy.
- To avoid contamination, do not touch tip of container on any surface.
- Replace cap immediately after use.
- Remove contact lenses before using this eye drop.
- If you experience eye pain, changes in vision, continued redness or irritation of the eye and if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.

4.5 Drug interactions

None reported.

4.6 Use in special population

- **Pediatric:** Safety in infants has not been established.
- **Geriatric:** Safety in elderly patients has not been established.
- **Liver impairment:** No data available.
- **Renal failure:** No data available.
- **Pregnancy and lactation:** Safety during pregnancy and breast feeding has not been established.

4.7 Effects on ability to drive and use machines

RE-LUB Kid Eye Drops may temporarily cause blurred vision right after being placed in the eye(s). Do not drive, use machinery or do not do activity that requires clear vision until you are sure you can perform such activities safely.

4.8 Undesirable effects

Following adverse effects may occur after administration of RE-LUB Kid Eye Drops:
Eye disorders: Eye irritation (including eye burning and discomfort); Increased tear secretion.

Post marketing experience

The following additional adverse drug reactions have been identified during post marketing use of sodium carboxymethylcellulose eye drops 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.

System/ organ	Adverse drug reactions
Eye disorders	Blurred vision, tingling sensation, a feeling that something is in your eye, eye redness, eye pruritus, increased tear secretion, eye discharge, eye pain, increase in tear production (also known as tearing), sticky eye, crusting of the eyelid and/or drug residue, visual disturbance.
Immune system disorders	Hypersensitivity including eye allergy (including eye or eyelid swelling).
Injury, poisons and procedural complications	Superficial injury of eye (from the bottle tip touching the eye during administration) and/or corneal abrasion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

There is limited experience of overdose with RE-LUB Kid Eye Drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Carboxymethylcellulose Sodium: Sodium CMC is an ocular lubricant. It binds directly to human corneal epithelial cells (HCECs) via interaction of its glucopyranose subunits with glucose transporter-1 (GluT-1) receptors on the epithelial surface. This specific binding allows CMC to adhere to the corneal epithelium and maintain prolonged residence time on the ocular surface, enhancing tear film stability and ocular lubrication.

D-Panthenol: It is precursor of vitamin B5, possesses an established positive effect on epithelium healing in general and acts as a humectant.

5.2 Pharmacodynamics properties

This product is used to wet the cornea.

Sodium CMC has no pharmacological effect. It has high viscosity resulting in an increased retention time on the eyes. It replaces the tears by forming a transient aqueous phase.

5.3 Pharmacokinetic properties

There is no pharmacokinetic study on animals or humans.

Due to high molecular weight, sodium carboxymethyl cellulose is unlikely to penetrate the cornea.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

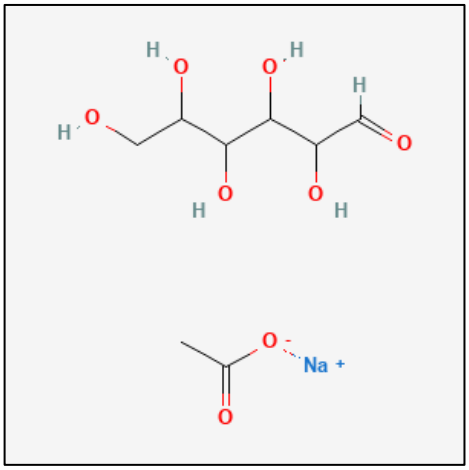
The non-clinical data from the conventional safety pharmacology, toxicology in repeated administration, genotoxicity, carcinogenicity and reproduction pre-clinical studies did not show any particular risk to human.

7. Description

Carboxy Methyl Cellulose Sodium

A cellulose derivative which is a beta-(1,4)-D-glucopyranose polymer. It is one of the most common viscous polymers used in artificial tears and has shown to be effective in the treatment of aqueous tear-deficient dry eye symptoms. The viscous and mucoadhesive properties as well as its anionic charge allow prolonged retention time in the ocular surface. The IUPAC chemical name is sodium;2,3,4,5,6-pentahydroxyhexanal; acetate. The empirical formula is $C_8H_{15}NaO_8$ and its molecular weight is approximately 262.19 g/mol.

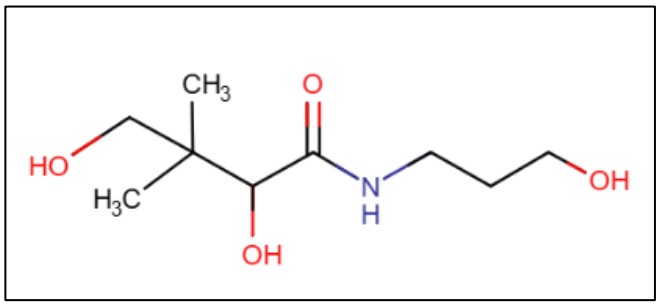
The chemical structure of carboxy methyl cellulose sodium is as follows:



D-Panthenol

Dexpanthenol is an alcohol derivative of pantothenic acid, a component of the B complex vitamins and an essential component of a normally functioning epithelium. The chemical name is (2R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide. Its empirical formula and molecular weight is $C_9H_{19}NO_4$ and 205.25 g/mol.

The chemical structure of D Panthenol is as follows:



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

RE-LUB Kid Eye Drops is available as a sterile vial of 10 ml.

8.4 Storage and handling instructions

Store in a dry, well-ventilated place at a temperature not exceeding 30°C.

Keep the medicine out of reach of children.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patients are advised to be alert for the emergence or worsening of adverse reactions and contact the prescribing ophthalmologist.

9.8 Contraindications

Refer part 4.3

10. Manufactured by

SION HEALTHCARE (SHL) LIMITED,
19, Somnath Industrial Estate, Kerala,
G.I.D.C., Bavla,
Dist. - Ahmedabad – 382 220,
Gujarat, India.

11. Details of permission or license number with date:

Mfg.Lic.No. - G/28/1536**,** Dated- 28/03/25.

12. Date of Revision: March 2026.