
SMOOTH EYE

1. Generic Name

Carboxymethylcellulose Sodium Eye Drops I.P.

2. Qualitative and quantitative Composition:

Carboxymethylcellulose Sodium I.P.0.5% w/vs

Preservative:

Stabilized

Oxychlorocomplex0.005% w/v

Sterile Aqueous Vehicle..... q.s.

The List of Excipients used are Sodium Chloride, Boric Acid, Borax, Stabilized Oxychlorocomplex, Potassium Chloride, Calcium Chloride Anhydrous, Sodium Carboxymethyl Cellulose, Magnesium chloride, Di Sodium Edatate.

3. Dosage form and strength

Dosage form: Ophthalmic solution

Strength: Carboxymethylcellulose 0.5% w/v

4. Clinical particulars

4.1. Therapeutic indication

“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.”

4.2. Posology and method of administration

Recommended Dosing

Instill one to two drops in the affected eye(s) as needed.

Use with Other Topical Ophthalmic Medications

If carboxymethyl cellulose 0.5% eye drops is concomitantly used with other ocular eye medications, there must be an interval of at least 15 minutes between the two medications (as displacement of a medication may occur).

Pediatric Population

The safety and efficacy of carboxymethyl cellulose 0.5% eye drops in children and adolescents have been established by clinical experience, but no clinical trial data are available. The dosage recommended in adults is recommended in the pediatric population.

4.3. Contraindications

- Hypersensitivity to sodium carboxymethyl cellulose or to any of the excipients.

4.4. Special warnings and precautions for use

To avoid contamination do not touch tip of container to any surface. Replace cap after using. 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.

If solution changes colour or becomes cloudy, do not use. Keep out of the reach of children. In case of accidental ingestion, seek professional assistance or consult your physician.

4.5. Drugs interactions

None

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Due to the negligible systemic exposure and the lack of pharmacological activity carboxymethyl cellulose 0.5% eye drops can be used during pregnancy.

Lactation

Due to the negligible systemic exposure and the lack of pharmacological activity carboxymethyl cellulose 0.5% eye drops can be used during breast-feeding.

4.7. Effects on ability to drive and use machines

Carboxymethylcellulose Sodium 0.5% eye drops 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.

4.8. Undesirable effects

The frequency of adverse reactions documented during clinical trials is given. The frequency is defined as follows: Very Common ($\geq 1/10$); Common ($\geq 1/100$, $< 1/10$); Uncommon ($\geq 1/1,000$, $< 1/100$); Rare ($\geq 1/10,000$, $< 1/1,000$); Very Rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Eye Disorders

Common: Eye irritation (including burning and discomfort), eye pain, eye pruritus, visual disturbance.

Reporting of 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. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

Accidental overdose will present no hazard.

5. Pharmacological properties

5.1. Mechanism of Action

Carboxymethylcellulose 0.5% eye drops act as a lubricating artificial tear by increasing the viscosity of the tear film and stabilizing it on the ocular surface. As a viscoelastic, mucoadhesive polymer, carboxymethylcellulose adheres to the corneal and conjunctival epithelium, allowing prolonged retention on the eye and reducing tear evaporation. It forms a protective lubricating layer that decreases friction during blinking and protects the ocular surface from dryness and irritation. Through these physical effects, carboxymethylcellulose relieves symptoms such as burning, foreign-body sensation, and discomfort associated with dry eye conditions, without exerting any pharmacological or anti-inflammatory action.

5.2. Pharmacodynamic properties

Carboxymethylcellulose Sodium has no pharmacological effect. Carboxymethylcellulose Sodium has a high viscosity, resulting in an increased retention time on the eye.

The excipients in Carboxymethylcellulose Sodium 0.5% eye drops were chosen to mimic the electrolyte constitution of tears.

5.3. Pharmacokinetic properties

Due to the high molecular weight (approximately 90,000 Daltons), Carboxymethylcellulose Sodium is unlikely to penetrate the cornea.

6. Nonclinical properties

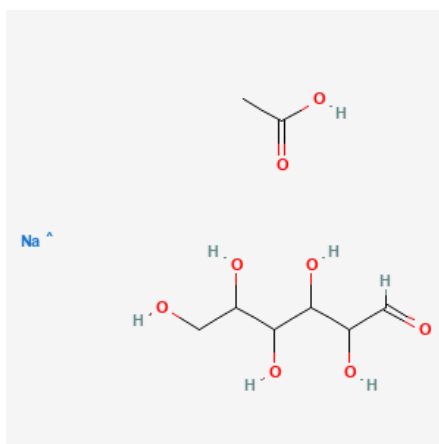
6.1. Animal Toxicology or Pharmacology

None

7. Description

Carboxymethylcellulose sodium

Carboxymethylcellulose Sodium is the Sodium salt of a partially substituted poly(carboxymethyl) ether of cellulose. The empirical formula is $C_8H_{16}NaO_8$, and its molecular weight is 263.20 g/mol. The chemical structural formula is:



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Carboxymethylcellulose Eye Drops is Clear colourless liquid. The List of Excipients used are Sodium Chloride, Boric Acid, Borax, Stabilized Oxychloro complex, Potassium Chloride, Calcium Chloride Anhydrous, Sodium Carboxymethyl Cellulose, Magnesium chloride, Di Sodium Edatate.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

SMOOTH EYE is available in pack of 10 ml.

8.4. Storage and handing instructions

Store at a temperature not exceeding 30°C, Protected from light.

For Ophthalmic use only.

Keep the medicine out of reach of children.

Use the solution within one month after opening the container.

For External use only.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies.
- Have kidney or liver problems.
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have any serious illness.
- Are taking any medicines (prescription, over the counter, vitamins, or herbal products)

10. Details of manufacturer

East African (India) overseas

Plot no. 8 & 8A

Pharmacy, selaqui,

Dehradun-248011, Uttarakhand.

11. Details of permission or licence number with date

Mfg. Licence No.: 94/UA/SC/P-2009 Issued on :10.12.2024.

12. Date of revision

N/A

MARKETED BY

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PHARMA

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IN/SMOOTH EYE/FEB-2026/01/PI**