

ADD TEARS Eye Drops (Sodium carboxymethyl cellulose 0.5%)

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

Qualitative and Quantitative Composition

Carboxymethylcellulose Sodium IP.....0.5% w/v

Stabilized Oxychloro Complex (as preservative).....0.005% w/v

Aqueous vehicle.....q.s.

Dosage Form and Strength

Ophthalmic solution of Carboxymethylcellulose 0.5%

Clinical Particulars

Therapeutic Indications

Carboxymethylcellulose Sodium 0.5% eye drops are used as a lubricant to relieve irritation and discomfort due to dryness of the eyes or due to exposure of the eyes to wind or sun, for the treatment of the symptoms of dry eye and as a protectant against further irritation.

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).

Paediatric 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 paediatric population.

Contraindications

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

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.

Drug Interactions

None known.

Use in Special Population

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.

Effects on Ability to Drive and use Machines

Carboxymethylcellulose Sodium 0.5% eye drops are 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.

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.

Postmarketing Experience

The following additional adverse reactions have been identified during postmarketing use of sodium carboxymethyl cellulose 0.5% in clinical practice. Because postmarketing 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.

Immune System Disorders:

Hypersensitivity including eye allergy.

Eye Disorders:

Blurred vision, eye discharge, lacrimation increased, ocular hyperemia.

Injury, Poisons and Procedural Complications:

Superficial injury of eye (*from the vial tip touching the eye during administration*) and/or corneal abrasion.

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024 or you can report to Cipla Ltd. on 18002677779. By reporting side effects, you can help provide more information on the safety of this product.

Overdose

Accidental overdose will present no hazard.

Pharmacological Properties

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.

Pharmacokinetic Properties

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

Pharmaceutical Particulars

Incompatibilities

Not applicable

Shelf-life

As on pack.

Packaging Information

ADD TEARS Eye Drops: Vial of 10ml

Storage and handling instructions

Do not store above 25°C.

Details of Manufacturer

Mfd. By Cipla Ltd

B-2, Dev Bhoomi Indl. Estate

Puhana Iqbalpur Road,

Roorkee, Haridwar - 247667

Uttarakhand, India

Details of Permission or Licence Number with Date

Permission number and date of issue: 66/UA/LL/SC/P-2019

Date of Revision

20/03/2020