

ADD TEARS Eye Drops (Sodium carboxymethyl cellulose 0.5%)

Composition

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

Stabilized Oxchloro Complex.....0.005% w/v

Aqueous vehicle.....q.s.

Also contains Boric acid, Calcium chloride, Magnesium chloride, Potassium chloride and Sodium Chloride

Dosage Form

Ophthalmic solution

Pharmacology

► Pharmacodynamics

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

► Pharmacokinetics

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

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.

Dosage And Administration

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

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.

Warnings And Precautions

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.

▶ General

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.

▶ 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

▶ 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. By reporting side effects, you can help provide more information on the safety of this product.

Overdosage

Accidental overdose will present no hazard.

Incompatibility

Not applicable.

Shelf-Life

18 months.

Storage And Handling Instructions

Do not store above 25°C.

Packaging Information

ADD TEARS Eye Drops Sterile vial of 10 ml

Last updated: *April 2018*

Last reviewed: *April 2018*

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