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

Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0% w/v

COMPU DROPS® 1%

Eye Drops 10mL

For the use of Registered Medical Practitioner only

Composition:

Sodium Carboxymethyl Cellulose USP ..... 1.0 % w/v

Stabilized Oxychloro Complex ..... 0.0075% w/v

(as preservative)

Water for Injection USP ..... q.s

Category

Pharmacotherapeutic group: Other ophthalmologicals.

ATC code: S01XA20

Description

A clear, colorless, slightly viscous solution filled in 10 mL Sterile Gamma irradiated Green LDPE Bottle sealed with Sterile Gamma - irradiated Green LDPE open nozzle and Sterile Gamma irradiated green HDPE tamp safe cap.

Pharmacology

Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v has no pharmacological effect. It has a high viscosity resulting in an increased retention time on the eye. The excipients in Sodium Carboxymethyl Cellulose Lubricant Eye Drops were chosen to mimic the electrolyte constitution of tears.

Pharmacokinetic

Due to the high molecular weight (approx. 90,000 Daltons), Carboxymethyl cellulose Sodium is unlikely to penetrate the cornea

Indications

Treatment of the symptoms of dry eye. It is used as tear substitute.

Dosage & Administration

Method of Administration

Instill one or two drops in the affected eye/s as needed.

The eye drop solution should be used immediately after opening the cap. 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.

If Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v 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). The eye drops may be used with contact senses.

Paediatric population

The safety and efficacy of Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v in paediatric population have not been established by clinical experience, but no data are available.

Contraindications

Hypersensitivity to Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v or to any of the excipients.

Warning and Precaution

If irritation, pain, redness or changes in vision occur or if the patient's condition is worsened treatment discontinuation should be considered and a new assessment considered. Contact lenses should be removed before each application and may be inserted after 15 minutes. Concomitant ocular medication should be administered 15 minutes prior to the instillation of Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v. To avoid contamination or possible eye injury, do not touch the tip to the bottle or vial to any surface and avoid contact with the eye.

Sodium Carboxymethyl Cellulose Lubricant Eye Drops1.0 % w/v has minor or moderate influence on the ability to drive and use machines as it may cause transient blurring of vision which may impair the ability to drive or operate machines. Do not drive or use machinery unless vision is clear.

Interactions

No interactions have been observed with Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v.

If this product is used concomitantly with other topical eye medications, there must be an interval of at least 15 minutes between the two medications.

Pregnancy & Lactation

The constituents of Sodium Carboxymethyl Cellulose Lubricant Eye Drops 1.0 % w/v have been used as pharmaceutical agents for many years with no untoward effects. No special precautions are necessary for the use of Sodium Carboxymethyl Cellulose Lubricant Eye Drops in pregnancy and lactation.

Adverse reaction

The frequency of adverse reactions documented in published literature is given. The frequency is defined as follows: Very Common (≥ 1/10); Common (≥ 1/100, <1/10); Uncommon (≥ 1/1,000, <1/100); Rare (≥ 1/10,000, <1/1,000); Very Rare (<1/10,000), not known (cannot be estimated from the available data).

Reported adverse reactions of Sodium Carboxymethyl Cellulose Lubricant Eye Drops1.0 % w/v are as follows:

Eye disorders

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

Uncommon: Lacrimation increased; vision blurred, eye discharge, eyelid margin crusting and/or medication residue, foreign body sensation in eye, ocular hyperemia, visual impairment.

Immune System Disorders

Uncommon: Hypersensitivity including eye allergy with symptoms of eye swelling or eyelid edema.

Injury, Poisons and Procedural Complications

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

Overdosage

Accidental overdose will present no hazard.

Storage

Store between 15°C - 30 °C. Protect from light

Keep out of reach of children.

Shelf life

24 Months from the date of manufacture.

Presentation

10 mL clear colourless solution filled in 10 mL Sterile Gamma-irradiated Green LDPE Bottle sealed with Sterile Gamma-irradiated LDPE Green Nozzle and Sterile Gamma-irradiated Green HDPE safe cap in printed carton along with package insert.

Directions for use :

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

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