[Instructions in this font/colour are from the World Health Organisation Public Assessment Report WHOPAR guidelines.]

1. NAME OF THE MEDICINAL PRODUCT

Carboxymethyl Cellulose Sodium Ophthalmic Solution

LUBREX EYE DROPS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Carmellose Sodium BP…… 0.5 % w/v

(Carboxymethyl cellulose Sodium)

Oxychloro Complex Stabilized

(As Preservative)..... 0.005 % w/v

Water for injections BP …… q.s

3. PHARMACEUTICAL FORM

Ophthalmic solution

4. Clinical particulars

4.1 Therapeutic indications

Tear substitute. Treatment of the symptoms of dry eye.

4.2 Posology and method of administration

Instill 1-2 drops in the affected eye/s 4 times a day or as needed.

Ensure that the single-dose container is intact before use. The eye drop solution should be used immediately after opening.

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 Carmellose sodium 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 lenses.

Paediatric population

The safety and efficacy of Carmellose sodium in children and adolescents have been established by clinical experience, but no clinical trial data are available. The posology recommended in adults is recommended in the paediatric population.

4.3 Contraindications

Hypersensitivity to carmellose sodium or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

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 made.

- For external use only.
- To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.
- Do not touch unit-dose tip to eye.
- If solution changes color, do not use.

Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours.

4.5Interaction with other medicinal products and other forms of interaction

None known

For the use of concomitant ocular products

4.6 Pregnancy and Lactation

Pregnancy and Breast-feeding

Due to the negligible systemic exposure and the lack of pharmacological activity Carmellose sodium can be used during pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machines

Carmellose sodium 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 (≥ 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).

Eye disorders:

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

Post marketing Experience

The following additional adverse reactions have been identified during post marketing use of Carmellose sodium 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.

Immune System Disorders:

Hypersensitivity including eye allergy

Eye Disorders:

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

Injury, Poisons and Procedural Complications:

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

4.9 Overdose

Accidental overdose will present no hazard.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Other Ophthalmologicals

ATC code: S01XA20

Carmellose sodium has no pharmacological effect. Carmellose sodium has a high viscosity resulting in an increased retention time on the eye.

The excipients in Carmellose sodium were chosen to mimic the electrolyte constitution of tears.

5.2 Pharmacokinetic properties

Due to the high molecular weight (approx. 90,000 Daltons) carmellose sodium is unlikely to penetrate the cornea.

5.3 Preclinical safety data

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chlorite

Boric Acid

Potassium Chloride

Sodium Chloride

Calcium Chloride Dihydrate

Magnesium Chloride Hexahydrate

Sodium Hydroxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacturing.

After first opening: Use immediately.

6.4 Special precautions for storage

Keep in cool place. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

10 ml sterile LDPE container with sterile nozzles and sterile HDPE double safe violet color screw cap pack in a carton.

6.6 Special precautions for disposal <and other handling>

Not Applicable.

7. APPLICANT/MANUFACTURER

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