SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lubrex Eye drops

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Carmellose Sodium BP 0.5 %
w/v (Carboxymethyl Cellulose
Sodium)
Stabilized Oxychloro Complex 0.005% w/v (As
preservative) Water for Injections BP … q s
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ophthalmic Solution
A clear colorless 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 Carboxymethylcellulose Sodium 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).
The eye drops may be used with contact lenses.

Paediatric population
The safety and efficacy of Carboxymethylcellulose Sodium eye drops 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 Carboxymethylcellulose Sodium eye drops 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.

4.5 Interaction with other medicinal products and other forms of interaction. None known
For the use of concomitant ocular products, see section 4.2.

4.6 Pregnancy and lactation
Pregnancy and Breast-feeding
Due to the negligible systemic exposure and the lack of pharmacological activity Carboxymethylcellulose Sodium eye drops can be used during

pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machines

Carboxymethylcellulose Sodium 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 (≥ 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 Carboxymethylcellulose Sodium eye drops 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 Pharmacodynamic properties:

Pharmacotherapeutic group: Other

Ophthalmologicals ATC code: S01XA20

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

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

5.2 Pharmacokinetic properties*:*

Due to the high molecular weight (approx. 90,000 Daltons) Carboxymethylcellulose Sodium eye drops 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 Hex
hydrate Sodium Hydroxide
Water for injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months from the date of manufacture
Discard unused solution after 28 days of first opening.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

10 ml in 10 ml three piece natural sterile bottle with natural sterile open nozzle and Sterile HDPE cap packed in a carton.

6.6 Special precautions for disposal and other handling

Discard any unused solution in opened container i.e. do not re-use container for subsequent doses.

7. Marketing Authorization

Holder MICRO LABS
LIMITED
31, Race course

road BANGALORE -

560001 INDIA

8. Marketing Authorization Number

CTD10918

9. Date of first authorization/renewal of authorization

22/01/2026

10. Date of publication

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