SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Carmellose sodium 0.5% w/v eye drops solution
Tearlin 0.5%

Carmellose sodium 1% w/v eye drops solution
Tearlin 1%

2. Qualitative and quantitative composition

Tearlin 0.5%
Each mL of solution contains 5 mg of carmellose sodium. One drop (≈ 0.05 ml) contains 0.25 mg of carmellose sodium.

Tearlin 1%
Each mL of solution contains 10 mg of carmellose sodium. One drop (≈ 0.05 ml) contains 0.5 mg of carmellose sodium.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops solution.

Clear, colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

Carmellose sodium is indicated for the treatment of the symptoms of dry eye.

4.2 Posology and method of administration

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

The Tearlin bottle should be used within 28 days after opening and discarded after the 28 days have elapsed.

Paediatric population
The safety and efficacy of carmellose sodium in the paediatric population have not been established. No data is available.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If irritation, pain, redness and vision changes occur or worsen, treatment should be discontinued 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 before the instillation of carmellose sodium (as displacement of medication may occur).

To avoid contamination or possible eye injury, do not touch the tip of the bottle or vial to any surface and avoid contact with the eye.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed:

1. No interactions have been observed with carmellose sodium. Given the formulation of carmellose sodium, no interactions are anticipated.
2. 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.

4.6 Pregnancy, fertility and lactation
The constituents of carmellose sodium have been used as pharmaceutical agents for many years with no untoward effects. No special precautions are necessary for the use of Tearlin in pregnancy and lactation.

4.7 Effects on the ability to drive and use machines
Carmellose sodium has a 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 your vision is clear.

4.8 Undesirable effects
The frequency of undesirable effects 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).

The following adverse reactions have been identified during clinical studies of 0.5% w/v and 1.0% w/v carmellose sodium eye drops solution (unit dose).

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

Postmarketing Experience
The following additional adverse reactions have been identified during postmarketing use of carmellose sodium eye drops 1.0% in clinical practice.

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

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

Injury, Poisons and Procedural Complications
Uncommon: Superficial injury of the eye (*from the vial tip touching the eye during administration)* and/or corneal abrasion.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose
In the case of accidental ingestion, symptomatic therapy is recommended.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacological classification: 19.10 Ophthalmic medicines.

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

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
Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients
Stabilised oxychloro complex
Sodium chloride
Sodium lactate
Potassium chloride
Calcium chloride
Water for injection

Tearlin 0.5%
Boric acid

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store below 30°C. Use the solution within 28 days after opening the container.

6.5 Nature and contents of the container
An LDPE plastic dropper bottle, closed with an HDPE cap and a white plastic cap.

Fill volume: 10 ml.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT
Lincoln Pharmaceuticals Limited
Lincoln House, Behind Satyam Complex, Science City Road, Sola
Ahmedabad – 380060
Gujarat
India

8. MANUFACTURER
Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Tal. Kalol
Dist. Gandhinagar
Gujarat
India

9. REGISTRATION DETAILS
Tearlin 0.5%
Zimbabwe registration number: 2023/19.10/6438
Zimbabwe category for distribution: Pharmacy Medicines (P.)

Tearlin 1%
Zimbabwe registration number: 2023/19.10/6439
Zimbabwe category for distribution: Pharmacy Medicines (P.)

10. DATE OF REVISION OF THE TEXT
October 2023