SUMMARY OF PRODUCT CHARACTERISTICS

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1. Name of drug product

Levosta Eye Drops

2. Qualitative and quantitative compositions

Each mL contains 5 mg of Levofloxacin

3. Pharmaceutical Form

Pale yellow to light yellow transparent solution in a light protected plastic container

4. Posology and method of administration

1) Before use : In use of levofloxacin, susceptibility is identified to prevent tolerant strain from inducing. Levofloxacin is used during the minimum period required for therapeutic benefit. Prolonged use may result in overgrowth of non-susceptibile organism, including fungi. If superinfection occurs, discontinue use and institute alternative therapy.

2) How to use : Instill one drop into eyes, 3 times daily.

4. Therapeutic indications

Blepharitis, Sty, Dacryocystitis, Conjunctivitis, Adenophthalmia, keratitis, Keratohelcosis, Aseptic therapy during ophthalmic operation.

5. Clinical Pharmacology

1) Pharmacokinetics : The mean levofloxacin concentration in plasma 1 hour post-dose, ranged from 0.86 ng/mL on Day 1 to 2.05 ng/mL on Day 15. The highest maximum mean levofloxacin concentration of 2.5 ng/mL was measured on Day 4 following 2 days of dosing every 2 hours for a total of 8 doses per day. Maximum mean levofloxacin concentrations increased from 0.94 ng/mL on Day 1 to 2.15 ng/mL on Day 15, which is more than 1,000 times lower than those reported after standard oral doses of levofloxacin. Levofloxacin concentration in tears was measured in 30 healthy adult volunteers at various time points following instillation of a single drop of levofloxacin ophthalmic solution. Mean levofloxacin concentrations in tears ranged from 34.9 to 221.1 mcg/mL during the 60-minute period following the single dose. The mean tear concentrations measured 4 and 6 hours postdose were 17.0 and 6.6 mcg/mL.

2) Microbiology : The mechanism of action of levofloxacin and other fluoroquinolone antimicrobials involves the inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoismerases), enzymes required for DNA replication, transcription, repair, and recombination. Levofloxacin has in vitro activity against a wide range of Gram-negative and Gram-positive microorganisms and is often bactericidal at concentrations equal to or slightly greater than inhibitory concentrations.

6. Adverse reactions

1) Shock : Rarely symptoms like shock (nausea, cold sense of limb, dyspnea) may occur. In the case that acknowledged as abnormality, therapy is discontinued and appropriate measures are taken.

2) Hypersensitivity : Rarely cardiovascular collapse, Apsychia, Angioedema (including larybgeal, pharybgeal or facial edema) , airway obstruction, dyspnea, rash, urticaria, itching, blepharal flare·edema, skin flare and conjunctival injection may occur. In the event of these symptoms, this therapy is discontinued.

3) Eye : Occasionally irritation such transient burning sense, dysphoria, occasionally stinging pain, flare, itching, chemical conjunctivitis and keratitis, circumbulbar or facial edema, foreign body sensation, dazzling, blurred vision, tears, dryness, eye pain, rarely dizziness, corneal disorder such as obesity lamellar keratitis and Stevens-Johnson syndrome that can become to be toxic epidermal necrolysis may occur. In the event of the symptom, therapy is discontinued.

7. Pharmaceutical particulars

7.1 List of excipients

Sodium chloride	KP
Hydrochloric acid	KP
Sodium hydroxide	KP
Water for injection	KP

7.2 Incompatibilities

Not applicable

7.3 Shelf-life

3 years from manufacturing date

7.4 Special precaution for storage

Preserve in tight containers. Store at room temperature not exceeding 30℃.

7.5 Nature and contents of container

Levosta Eye Drops is filled in low-density polyethylene (LDPE) bottles sealed with half-clear low-density polyethylene (LDPE) dropper applicators and opaque high-density polyethylene (HDPE) tamper-proof screw caps.

8. Manufacturer

SamChunDang Pharm.Co.,Ltd.

Address : SamChunDang Pharmaceutical Co., Ltd. 351, Hyoryeong-ro, Seocho-gu, Seoul, Korea

9. Marketing authorization holder

Rich Pharma LP. United Kingdom.

10. Marketing authorization number

Not applicable

11. Date of first authorization / renewal of authorization

Not applicable

12. Date of revision of the text

February 05, 2018