Cipro-Cent™

Eye Drops

1. Composition

Each ml of CIPRO-CENT Eye Drops contains:

Ciprofloxacin hydrochloride equivalent to ciprofloxacin	0.3% w/v

2. Dosage form and strength

CIPROCENT Eye Drops are available in a 5 ml lupolen vial.

3. Clinical particulars

3.1 Therapeutic indication

CIPRO-CENT Eye Drops are indicated for the treatment of: ·

- Conjunctivitis
- Corneal ulcers
- Hypopyon ulcer
- Superficial and deeper eye infections
- Pre and post-operative care

3.2 Posology and method of administration

As directed by physician.

3.3 Contraindication

A history of hypersensitivity to ciprofloxacin or any other component of the medication is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of CIPRO-CENT.

3.4 Special warnings and precautions for use

- As with other antibacterial preparations, prolonged use of CIPRO-CENT may result in overgrowth of non-susceptible organisms, including fungi.
- If superinfection occurs, appropriate therapy should be initiated.
- Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.
- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolone therapy.

3.5 Drug interactions

Specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, enhance the effects of the oral anticoagulant, warfarin, and its derivatives and has been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

3.6 Use in special population

- Paediatric: No serious adverse drug reaction was reported in this group of patients.
- Geriatric: No data available.
- Liver impairment: No studies have been performed using Cipro-cent eye drops in patients with liver problems.
- Renal failure: No data available.
- Pregnancy and lactation: There are no adequate and well-controlled studies in pregnant women. CIPROCENT should be used during pregnancy only if clearly needed and if the potential benefit justifies the potential risk to the foetus. It is not known whether topically applied ciprofloxacin is secreted in milk. Therefore, caution should be exercised when CIPRO-CENT is administered to a nursing mother.

3.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to CIPRO-CENT eye drops is known.

3.8 Undesirable effects

The most frequently reported drug related adverse reaction with ciprofloxacin is local burning or discomfort. Other reactions occurring in less than 10% of patients include lid margin crusting, crystals/scales, foreign body sensation, itching, conjunctival hyperaemia and taste disturbances following instillation.

3.9 Overdose

There is limited experience of overdose with CIPRO-CENT eye drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

4. Pharmacological properties

4.1 Mechanism of action

Cipro-cent eye drops contain the fluoroquinolone ciprofloxacin. The cidal and inhibitory activity of ciprofloxacin against bacteria results from an interference with the DNA gyrase, an enzyme needed by the bacterium for the synthesis of DNA. Thus the vital information from the bacterial chromosomes cannot be transcribed which causes a breakdown of the bacterial metabolism. Ciprofloxacin has in vitro activity against a wide range of Gram-positive and Gram-negative bacteria.

4.2 Pharmacodynamic properties

Ciprofloxacin is a second generation fluoroquinolone that is active against many Gram negative and Gram positive bacteria. It produces its action through inhibition of bacterial DNA gyrase and topoisomerase IV. Ciprofloxacin binds to bacterial DNA gyrase with 100 times the affinity of mammalian DNA gryase. There is no cross resistance between fluoroquinolones and other classes of antibiotics, so it may be of clinical value when other antibiotics are no longer effective. Ciprofloxacin and its derivatives are also being investigated for its action against malaria, cancers, and AIDS.

4.3 Pharmacokinetic properties

A CIPRO-CENT eye drop is rapidly absorbed into the eye following topical ocular administration. Systemic levels are low following topical administration. Plasma levels of ciprofloxacin in human subjects following 2 drops of 0.3% ciprofloxacin solution every 2 hours for two days and then every four hours for 5 days ranged from non-quantifiable (<1.0 ng/mL) to 4.7 ng/mL. Ciprofloxacin widely distributes to tissues of the body. The apparent volume of distribution at steady state is 1.7 to 5.0 l/kg. Serum protein binding is 20-40%. The half-life of ciprofloxacin in serum is 3-5 hours. Both ciprofloxacin and its four primary metabolites are excreted in urine and faeces. Renal clearance accounts for approximately two-thirds of the total serum clearance with biliary and faecal routes accounting for the remaining percentages. In patients with impaired renal function, the elimination half-life of ciprofloxacin is only moderately increased due to extra renal routes of elimination. Similarly, in patients with severely reduced liver function the elimination half-life is only slightly longer.

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

36 months.

7.3 Storage and handling instructions

Store in cool and dry place.