Cipro-Cent™

Eye Drops

1. Generic Names

Ciprofloxacin hydrochloride

2. Composition

Each ml of CIPRO-CENT Eye Drops contains:

Ciprofloxacin hydrochloride equivalent to ciprofloxacin	0.3%w/v

3. Dosage form and strength

Topical ophthalmic solution containing Ciprofloxacin hydrochloride 0.3% (0.3mg/100ml).

4. Clinical particulars

4.1 Therapeutic indication

Ciprocent is indicated for the treatment of corneal ulcers and superficial infections of the eye and adnexa caused by susceptible strains of bacteria.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

The recommended dose
This will depend on whether you are being treated for corneal ulcers or for some other bacterial infection in your eye.
Corneal Ulcers
Dosing is continued during the night time. Day 1 - 2 drops every 15 minutes for the first 6 hours and then 2 drops every 30 minutes. Day 2 - 2 drops every hour. Day 3 to Day 14 - 2 drops every 4 hours. Your doctor will tell you if treatment needs to be continued for longer than 14 days.
Other bacterial infections
1 or 2 drops 4 times a day. For severe infections the dose for the first 2 days may be increased to 1 or 2 drops every 2 hours, while you are awake.

4.3 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.

4.4 Special warnings and precautions for use

- As with other antibacterial preparations, prolonged use of Ciprofloxacin may result in over growth of non-susceptible organisms, including fungi.
- If super infection 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.

4.5 Drug interactions

Specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin. However, the systemicadministrationofsomequinoloneshasbeenshowntoelevateplasma concentrations of theophylline, interfere with the metabolism of caffeine, enhance the effects of the oral anticoagulant, warfarin, and its derivatives and has been associatedwithtransientelevationsinserumcreatinineinpatientsreceivingcyclosporineconcomitantly.

4.6 Use in special population

- Paediatric: Safety below 1 year not established.
- 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.

4.7 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.

4.8 Undesirable effects

The most frequently reported drug related adverse reaction with ciprofloxacin is local burning or discomfort. Other reactions are Visual impairment, Vision blurred, Periorbital oedema, Eyelid oedema, Eye pain, Diplopia, Photophobia, Eye irritation, Ocular hyperaemia, Dry eye, Eye swelling, Vitreous floaters, Drug Induced Stevenson Johnson Syndrome / Toxic and Epidermal Necrosis.

4.9 Overdose

There is limited experience of over dose with CIPRO-CENTeyedrops. Initiate general symptomatic and supportive measures in all cases of over dosages where necessary.

5. Pharmacological properties

5.1 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 invitro activity against a wide range of Gram-positive and Gram-negative bacteria.

5.2 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.

5.3 Pharmacokinetic properties

A CIPRO-CENT eye drop is rapidly absorbed into the eye following topical ocularadministration. Systemic levels are low following topical administration. Plasma levels of ciprofloxacin in human subjects following 2 drops of 0.3% ciprofloxacin solution every 2hours for two days and then every four hours for 5 days ranged from non-quantifiable (<1.0ng/mL) to 4.7 ng/mL. Ciprofloxacin widely distributes to tissues of the body. The apparent volume of distribution at steady state is 1.7to5.0l/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.

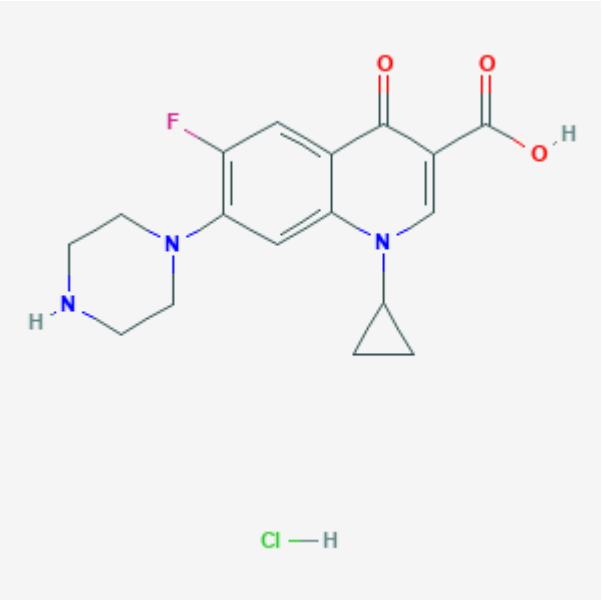
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Ciprofloxacin Hydrochloride is the hydrochloride salt form of ciprofloxacin ,a fluoroquinolone related to nalidixic acid with antibacterial activity. The chemical name is 1-cyclopropyl-6-fluoro-4-oxo-7-piperazin-1-ylquinoline-3-carboxylic acid; hydrochloride. The empirical formula and molecular weight is. $C_{17}H_{19}ClFN_3O_3$ and 367.8g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

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

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Referpart4.8

9.2 DrugInteractions

Referpart4.5

9.3 Dosage

Referpart4.2

9.4 Storage

Referpart8.4

9.5 Risk Factors

Referpart4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by CENTAUR PHARMACEUTICALS PVT.LTD.

11. Details of permission or license number with date

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