For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Sencipro™

(Ciprofloxacin Eye Drops IP)
Eye / Ear Drops 10 mL

COMPOSITION:

Ciprofloxacin Hydrochloride IP equivalent to Ciprofloxacin 0.3%w/v
Benzalkonium Chloride Solution IP (as preservative).....0.02%v/v
Water for Injections IP ..... q.s.

Clinical Particulars:

Therapeutic Indications :Treatment of superficial ocular infections: Conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharo-conjunctivitis, acute melbomlanitis and dacryocystitis caused by strains susceptible to ciprofloxacin.

Prophylaxis: Infections due to Neisseria gonorrhoea or Chlamydia trachomatis Prevention of ocular infections after removal of a corneal or conjunctival foreign body after damage from chemical or physical agents, before and after ocular sugery.

EAR: Otitis externa, acute otitis media, chronic suppurative otitis media. Prophylaxis in otic surgeries such as mastoid surgery.

Dosage and administration:

EYE: Acute infections: One or two drops every 15 to 30 minutes, initially reducing the frequency of instillation with control of infection. Moderate infections: One to two drops, two to six times daily or as often as needed. Acute and chronic trachoma: Two drops in each eye, two to four times daily for one to two month or longer.

EAR: For all infections two to three drops every two to three the frequency of instillation with control of infections

Contraindications: Hypersensitivity to quinolone group of antibacterials or any of the components of the formulation.

Special Warnings and Precautions for Use

I) If irritation persists or increases, discontinue the use and consult physician.

ii) Do not touch dropper tip or other dispensing tip to any surface since this may contaminate solutions "NOT FOR INJECTION" FOR EXTERNAL USE ONLY.

iii) Prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate measures should be initiated. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving systemic quinolone therapy. Ciprofloxacin Eye / ear drops should be discontinued at the first appearance of a skin rash or any sign of other hypersensitivity reaction. The concurrent use of oral quinolones and theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life. Transient increases in serum creatinine concentrations have been observed in patients receiving cyclosporin concomitantly with systemic ciprofloxacin. As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

Interaction with other medicinal products and other forms of interaction specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin.

Fertility, pregnancy and lactation

PREGNANCY Safety in pregnant women has not been established.

NURSING MOTHERS It is not known whether topically applied ciprofloxacin is secreted in breast milk, however caution should be exercised when administering to a nursing mother.

PAEDIATRIC USE: Safety and effectiveness in children under the age of 12 have not been established. There is no evidence that the ophthalmic dosage form has any effect on the weight bearing joints.

Effects on Ability to Drive and Use Machines: This product has no or negligible influence on the ability to drive or use machines. Temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If transient blurred vision occurs upon instillation, the patient must wait until the vision clears before driving or using machinery.

Undesirable Effects Local burning and ocular discomfort may occur as well as itching and foreign body sensation, lid margin crusting, crystals/scales, conjunctival hyperaemia and bad taste following instillation. Moreover, corneal stinging, keratopathy/keratitis, allergic reactions, lid oedema, tearing, photophobia, corneal infiltrates, nausea and decreased vision may occur. Hypersensitivity reactions cannot be excluded. In patients with corneal ulcer and

frequent administration of the drug, a white precipitate may be observed which resolves spontaneously with continued application of Ciprofloxacin Eye drops. The precipitate does not preclude continued use of the solution nor does it adversely affect the clinical course of the ulcer or the visual outcome. Safety during pregnancy and lactation have not been established.

Overdose A topical overdose of Ciprolfoxacin Eye drops may be flushed from the eye(s) with warm tap water. Treatment should be symptomatic and supportive.

Mode of action: Ciprofloxacin is a broad-spectrum water-soluble fluoroquinolone antibacterial. It has cidal and inhibitory activities against bacteria which result from an interference with the DNA gyrase, an enzyme required by the bacterium for the synthesis of DNA. Thus the vital information from the bacterial chromosomes cannot be transcribed any longer which causes a break-down in the bacterial metabolism. Ciprofloxacin has an in vitro activity against a wide range of Gram negative micro-organisms including Pseudomonas aeruginosa and Serratia marcescens. It is also effective in vitro against Gram positive bacteria such as Staphylococci and Streptococci including Staphyloccus aureus (including methicillin-susceptible and methicillin-resistant strains); Staphylococcus epidermidis, Streptococcus pneumonia and Streptococcus (viridans group). Microbiology: Ciprofloxacin has in vitro activity against wide range of gram-negative and gram-positive organisms. The bactericidal action of ciprofloxacin results from interference with the enzyme DNA gyrase which is needed for the synthesis of bacterial DNA. Gram-Positive: Pseudomonas aeruginosa Serratia marcescens Ciprofloxacin has been shown to be active in vitro against most strain of the following organisms; however, the clinical significance of these data is unknown: Gram-Positive: Enterococcus faecalis (many strains are only moderately susceptible) Staphylococcus haemolyticus Staphylococcus hominis Staphylococcus saprophyticus Streptococcus pyogenes Gram-Negative: Acinetobacter calcoaceticus Escherichia coli Proteus mirabilis Subsp.Anitratus Haemophilus ducreyi Proteus vulgaris Aeromonas caviae Haemophilus influenza Providencia rettgeri Aeromonas hydrophila Haemophilus parainfluenzae Providencia stuatii Brucella melitensis kiebsiella pneumoniae Salmonella enteritidis Campylobacter coli Klebsiella oxytoca Salmonella typhi Campylobacter jujuni Legionella pneumophila Shigella sonnеii Citrobacter freundii Moraxella morganii Vibrio cholera Edwarsiella tarda Neisseria gonorrheae Vibro parahaemolyticus Enterobacter aerogenes Neisseria meningitides Vibro vulnificus Enterobacter cloacae Pasteurella multicoda Yersinia enterocolitica

Pharmacokinetic properties: Ciprofloxacin is absorbed systemically after topical ocular administration. Plasma levels range from nonquantifiable to 4,7 ng/mL (some 450-fold less than levels observed following simple 250 mg oral administration)

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long term carcinogenicity studies in mice and rats have been completed, after daily oral dosing for up to two years, there is no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species.

Storage and handling instructions:
Keep in a cool place

Use the suspension within one month after opening the container.

Do not touch the tip of the container to any surface. Replace cap after using. Protect from light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

Presentation:

Sencipro is a sterile clear solution supplied in opaque plastic dropper bottle with a cap, containing 10 mL of the solution.

Directions for use:

Turn the tamper proof cap anti clockwise to break the seal and remove the cap.

Remove and discard the tamper proof ring from the container.

Eye drops tilt your head back. Gently pull your lower eyelid downwards to form a pocket between your eyelid and your eye, look up.
Ear drops lie down on your side with affected ear facing upward.

Turn the container upside down, place the dropper tip close to your eye/ear but be careful not to touch your eye/ear with it and gently press the container with thumb and index finger to dispense the drop.

Replace the cap by turning clockwise direction until it is firmly touching the bottle. Do not overtighten the cap.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,
No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

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