FRONT

1 cm
Barcode

hovid

hovid Ciprofloxacin Ophthalmic Solution 0.3% w/v

VICIPSC-M

DESCRIPTION
Clear, colourless to pale yellow solution.

COMPOSITION
Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin 0.3% w/v.

ACTIONS AND PHARMACOLOGY
Ciprofloxacin eye drops contains 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.

Commonly susceptible species
Gram-positive aerobes: *Corynebacterium accolens, Corynebacterium auris, Corynebacterium propinquum, Corynebacterium psudodiphtheriticum, Corynebacterium striatum, Staphylococcus aureus (methicillin susceptible-MSSA), Staphylococcus capitis, Staphylococcus epidermidis (methicillin susceptible-MSSE), Staphylococcus hominis, Staphylococcus saprophyticus, Staphylococcus warneri, Streptococcus pneumonia, Streptococcus viridans* Group

Gram-negative aerobes: *Acinetobacter species, Haemophilus influenza, Moraxella catarrhalis, Pseudomonas aeruginosa, Serratia marcescens*

Species for which acquired resistance may be a problem
Gram-positive aerobes: *Staphylococcus aureus (methicillin resistant-MRSA), Staphylococcus epidermidis (methicillin resistant-MRSE), Staphylococcus lugdunensis*

Inherently resistant organisms
Gram-positive aerobes: *Corynebacterium jeikium*

PHARMACOKINETICS
hovid Ciprofloxacin Eye Drops 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. The mean peak ciprofloxacin plasma level obtained is approximately 450-fold less than that seen following a single oral dose of 250 mg ciprofloxacin. The systemic pharmacokinetic properties of ciprofloxacin have been well studied. 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 extrarenal routes of elimination. Similarly, in patients with severely reduced liver function the elimination half-life is only slightly longer.

INDICATION
hovid Ciprofloxacin Eye Drops Solution is indicated for the treatment of infection caused by susceptible strains of the designated microorganisms in the condition listed below:

Corneal Ulcers
Pseudomonas aeruginosa, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus* (*viridans* group)

Conjunctivitis
Haemophilus influenza, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*

CONTRAINDICATIONS
- Hypersensitivity to ciprofloxacin hydrochloride
- Hypersensitivity to quinolones

WARNINGS AND PRECAUTIONS
- After cap is removed, if tamper evident snap collar is loose, remove before using product.
- The clinical experience in children less than one year old, particularly in neonates is very limited. The use of ciprofloxacin eye drops in neonates with ophthalmia neonatorum of gonococcal or chalamydial origin is not recommended as it has not been evaluated in such patients.
- When using ciprofloxacin eye drops one should take into account the risk of rhinopharyngeal passage which can contribute to the occurrence and the diffusion of bacterial resistance.
- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, were observed in patients receiving treatment based on systematically administered quinolones. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial oedema, dyspnoea, urticaria and itching. Only a few patients had a history of hypersensitivity reactions.
- Serious acute hypersensitivity reactions to ciprofloxacin may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated.
- Discontinue use at the first appearance of skin rash or any other sign of hypersensitivity.
- As with all antibacterial preparations prolonged use may lead to overgrowth of non-susceptible bacterial strains or fungi. If superinfection occurs, appropriate therapy should be initiated.
- Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including ciprofloxacin, particularly in elderly patients and those treated concurrently with corticosteroids. Therefore, treatment with ciprofloxacin eye drops should be discontinued at the first sign of tendon inflammation.
- In patients with corneal ulcer and frequent administration of ciprofloxacin eye drops, white topical ocular precipitates (medication residue) have been observed which resolved after continued application of ciprofloxacin eye drops. The precipitate does not preclude the continued application of ciprofloxacin eye drops nor does it adversely affect the clinical course of the recovery process. The onset of the precipitate was within 24 hours to 7 days after starting therapy. Resolution of the precipitate varied from immediately to 13 days after therapy commencing.

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