

Aprocin[®]

Ciprofloxacin 0.3 %
Eye Drops & Ointment

Composition:

Aprocin[®] Eye Drops: Each ml contains Ciprofloxacin HCl USP equivalent to Ciprofloxacin 3.0 mg.

Aprocin[®] Eye Ointment: Each gram contains Ciprofloxacin HCl USP equivalent to Ciprofloxacin 3.0 mg.

Preservative:

Eye Drops: Benzalkonium Chloride Solution BP 0.006%.

Eye Ointment: Methylparaben BP 0.05% & Propylparaben BP 0.01%.

Vehicle: Eye Drops: Polyvinyl Alcohol USP 1.4%.

Indications :

Aprocin[®] Eye Drops & Eye Ointment is highly effective in the treatment of corneal ulcers and conjunctivitis caused by susceptible strains of microorganisms. It is also indicated in the treatment of keratitis, kerato-conjunctivitis, Blepharitis, Blepharo-conjunctivitis, Acute Meibomianitis, Dacryocystitis, Prophylaxis of ocular infections due to *Neisseria gonorrhoea* or *Chlamydia trachomatis*, prevention of ocular infections other removal of a corneal or physical agent before and other ocular surgery.

Dosage and administration:

Eye Drops: Corneal Ulcers : On the first day instill 2 drops in the affected eye every 15 minutes for the first 6 hours and then 2 drops into the affected eye every 30 minutes for the remainder of the day. On the second day instill 2 drops in the affected eye hourly. On the third day through the fourteenth day, place two drops in the affected eye every four hours. If the patients needed to be treated for more than 14 days, physician should be consulted for opinion but for either indication a maximum duration of 21 days is recommended.

Superficial Ocular Infection/Conjunctivitis: The usual dose is 1 or 2 drops instilled into the conjunctival sac of the affected eye every 2 hours, while awake, for two days and 1 or 2 drops every four hours, while awake for the next five days.

Eye Ointment: A thin film of Aprocin[®] Eye Ointment should evenly be applied either directly to the affected part or inside the lower conjunctival sac at night (if eye drops used during the day) or 3-4 times daily depending on the severity of the condition (if eye ointment used alone) or as advised by the physician.

Side Effects:

Local burning or discomfort, itching, foreign body sensation, crystalline precipitates, lid margin crusting, conjunctival hyperemia and a bad taste following administration. Photophobia and nausea may be reported.

Precautions:

Prolonged use of Ciprofloxacin may result in overgrowth of nonsusceptible organisms including fungi. Ciprofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

Contraindications:

Hypersensitivity to quinolones or any component of this product

Warnings:

Not for injection into the eye. During therapy soft contact lenses should not be used.

Drug Interaction:

Specific drug interaction have not been observed with ophthalmic Ciprofloxacin.

Use in Pregnancy and Lactation:

Do not use unless the potential benefits outweigh the potential risk during pregnancy. It is not known whether excretion in human milk occurs following topical ophthalmic administration. Caution should be exercised in the nursing mothers.

Use in Children:

The safety and efficacy of Ciprofloxacin in children below 1 year have not been established.

Use in Elderly:

There are no special prescribing instructions to the elders.

Storage:

- Store in a cool, dry place and away from light.
- Do not use longer than 30 days after first opening.
- Keep out of reach of children.

Packing:

Aprocin[®] Eye Drops: Each LDPE dropper bottle contains 10 ml Sterile Eye Drops.

Aprocin[®] Eye Ointment : Each tube contains 3 g Sterile Eye Ointment.



Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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