

## CIPROZID-DX Sterile Eye & Ear Drops

Ciprofloxacin USP 0.3% w/v  
Dexamethasone USP 0.1% w/v

**Composition:** Each ml of Ciprozid-DX Sterile eye & ear drops contains: Ciprofloxacin USP 3mg & Dexamethasone USP 1 mg.

**Pharmacology:** Dexamethasone is glucocorticoid. It has an anti-inflammatory and anti-allergic action. It is used topically in the treatment of inflammatory conditions of the anterior segment of the eye. It reduces prostaglandin synthesis by inhibiting the enzymes phospholipase A2. Also, Dexamethasone inhibits the chemotactic infiltration of neutrophils into the site of inflammation. Ciprofloxacin has in-vitro activity against a wide range of gram-negative and gram-positive organisms, possessing the greatest antibacterial activity of all quinolones. The bactericidal action of Ciprofloxacin results from interference with the enzyme DNA gyrase which is needed for the synthesis of bacterial DNA.

**Indications: Eye:** Ciprozid-DX drop is indicated for the treatment of inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or risk of bacterial infection exists. The combination can also be used for postoperative inflammation and any other ocular inflammation associated with infection.

**Ear:** Ciprozid-DX is also indicated for the treatment of ear infections accompanied by inflammation such as otitis externa, acute and chronic otitis media etc. The combination may also be used postoperatively in the ear.

**Dosage and administration : Eye:** One or two drops to be instilled into conjunctivalsac (s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to one to two drops every two hours.

**Ear :** Instill 2-4 drops 3-4 times daily. Or, as directed by the registered physician.

**Contraindication :** Known hypersensitivity to any ingredient of the product. Herpes simplex and other viral conditions, mycosis, glaucoma, newborn babies fungal diseases of ocular or auricular structures.

**Precautions :** Prolonged use may result in overgrowth of non susceptible organism including fungi; ocular hypertension and / or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. If the sign of hypersensitivity occurs this combination should be discontinued.

**Side effects : Eye :** The most frequently reported drug-related adverse reactions seen with Ciprofloxacin are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, periocular/ facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness and eye pain. Rare reports of dizziness have been received. The reactions due to the steroid component are; elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing.

**Ear :** The most common adverse effects are discomfort and ear pain.

**Use in pregnancy and lactation :** Ciprozid-DX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Use in child :** Safety and efficacy of this drop have not been established in pediatric patients below the age 1 years.

**Drug Interactions:** Specific drug interaction studies have not been conducted with ophthalmic Ciprofloxacin and Dexamethasone. 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 have been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

**Overdose:** There is no data available.

**Storage:** Store below 30° C in a dry place. Keep out of reach of children.

**Packing :** Ciprozid-DX Sterile Eye & Ear Drops : 5 ml plastic dropper bottle.

Manufactured by



**DRUG INTERNATIONAL LTD.**

Tongi, Gazipur, Bangladesh