

Procin-D Sterile Eye/Ear Drops

Ciprofloxacin & Dexamethasone Sodium Phosphate

Composition:

Each ml contains Ciprofloxacin hydrochloride monohydrate USP equivalent to Ciprofloxacin 3 mg and Dexamethasone sodium phosphate BP 1mg.

Description:

Procin-D is a combination preparation of Ciprofloxacin, a synthetic fluoroquinolone antimicrobial and Dexamethasone, a potent corticosteroid. The topical combination effectively resolves inflammation and corrects anterior segment of eye or ear conditions. Ciprofloxacin has a very high antimicrobial activity against most of the gram negative microorganisms including *Pseudomonas aeruginosa*. It is also effective against gram positive bacteria such as staphylococci and streptococci.

Indications:

Eye: Procin-D is indicated for the treatment of steroid responsive inflammatory ocular conditions where bacterial infections or risk of bacterial infections co-exist. It is indicated where the risk of infection is high or where is a doubt that a potentially dangerous number of bacteria are present in the eyes. The combination can also be used for controlling the post-operative inflammation or any other ocular inflammation associated with infection.

Ear: Procin-D is also indicated in the treatment of ear infections and inflammation of otitis externa, acute and chronic otitis media. The combination may also be used for controlling the post-operative inflammation of the ear.

Dosage and Administration:

Eye: Bacterial Conjunctivitis: Instill one or two drops into conjunctival sac(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 while awake. Frequency should be decreased gradually with the improvement of clinical signs. Care should be taken not to discontinue therapy prematurely.

Corneal Ulcers: Instill two drops into the affected eye every 15 minutes for the first six hours and then two drops every 30 minutes for the remainder of the first day. On the second day, instill two drops in the affected eye one hourly. On the third through the fourteenth day, apply two drops in the affected eye every four hours. Treatment may be continued after 14 days if corneal re-epithelialization has not occurred.

Ear: For all infections, instill two to three drops every two to three hours initially. Frequency may be decreased gradually as warranted by improvement in clinical signs.

Contraindications:

Known hypersensitivity to any ingredient of the product. Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and in many other viral diseases of the conjunctiva and cornea. Mycobacterial infections of the eye. Any ear drops is contraindicated if there is a hole in ear drum.

Side-effects:

The most frequently reported drug-related adverse reactions seen with Ciprofloxacin are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, conjunctivitis or keratitis, periocular or 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 sub-capsular cataract formation and delayed wound healing.

Use in Pregnancy & Lactation

Pregnancy: Procin-D should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in human milk. It is also not known whether Ciprofloxacin is excreted in human milk following topical ophthalmic administration. Because many drugs are excreted in human milk, caution should be exercised when the combination is administered to a nursing woman.

Paediatric Use:

Safety & effectiveness for the use of this drug in children below the age of one year have not been established.

Precautions and warning:

Prolonged use may result in overgrowth of non-susceptible organisms including fungi; in ocular hypertension or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision and posterior sub-capsular cataract formation. Patients wearing contact lenses must not use the drops during the time the lenses are worn.

Overdosage

A topical overdose may be flushed from the eye(s) with warm water.

Storage

Store in a cool, dry place and protect from light. Do not use for longer than one month after first opening. Keep out of the reach of children.

How Supplied

5 ml in plastic dropper bottle.

Manufactured by :



KEMIKO PHARMACEUTICALS LTD.

Bangladesh