

Aprodex

Ciprofloxacin 0.3% & Dexamethasone 0.1%
Sterile Eye & Ear Drops

Composition:

Aprodex Sterile Eye & Ear Drops : Each ml contains Ciprofloxacin HCl USP equivalent to Ciprofloxacin 3 mg and Dexamethasone USP 1 mg.

Preservative: Benzalkonium Chloride Solution BP 0.02%.

Vehicle: Polyvinyl Alcohol USP 1.4%.

Indications:

Eye: Aprodex is indicated for the treatment of steroid responsive inflammatory ocular conditions where bacterial infections or risk of bacterial infections co-exist. The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where is an expectation that potentially dangerous numbers of bacteria will be present in the eyes. The combination can also be used for postoperative inflammation and any other ocular inflammation associated with infection.

Ear: Aprodex is also indicated in 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 drop to be instilled into conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to one drop every two hours. Frequency should be decreased gradually or warranted in clinical signs. Care should be taken not to discontinue therapy prematurely.

Ear: Instill 2-4 drops 3-4 times daily.

Contraindications:

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

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. Other reported reactions are irritability, dizziness, erythema etc.

Precautions and warning:

● Prolonged use may result in overgrowth of nonsusceptible organisms including fungi; in ocular hypertension and/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.

● If the sign of hypersensitivity occurs the otic combination should be discontinued.

Use in paediatric patients:

Eye: Safety & effectiveness for the use of Aprodex in children below the age of one year have not been established.

Ear: The safety and efficacy of Aprodex ear drops have been established in paediatric patients 6 months and older in adequate and well controlled clinical trials. Although data are available on patients less than age 6 months, there are no known safety concern or differences in this process in this population that would preclude use of this product.

Use in pregnancy:

Aprodex should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in nursing mother:

It is 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 mother.

Moreover, because of serious adverse reactions from Ciprofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother.

Storage:

● Store between 15^o-30^oC.

● Do not use longer than one month after first opening of the bottle.

● Keep out of the reach of children.

Packing:

Aprodex Sterile Eye & Ear Drops : Each plastic dropper bottle contains 5 ml/10 ml sterile eye & ear drops.

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Manufactured by:
ARISTOPHARMA LTD.
SHAMPUR-DHAKA-BANGLADESH