

Audicom Ear Drops

Ofloxacin + Clotrimazole + Beclomethasone + Lidocaine

Compositions:

This ear drop Clear, pyrogen free, preservative free otic solution. Each ml contains- Ofloxacin BP 3 mg Clotrimazole BP 10 mg Beclomethasone Dipropionate BP 0.25 mg Lidocaine Hydrochloride BP 20 mg.

Pharmacology:

It is a combination of an antibacterial, an antifungal, an anti-inflammatory and a topical local anesthetic agent. This ear drop has been specially formulated to maintain the natural environment of the external ear canal. Ofloxacin is a fluoroquinolone that has a broad spectrum of activity against otic pathogens without ototoxicity. Hence Ofloxacin is preferred to Aminoglycosides for any application within the middle ear space. Ofloxacin exerts antibacterial activity by inhibiting DNA gyrase of bacteria. Ofloxacin has been shown to be active against the following organisms responsible for otic infections: Gram-positive: Staphylococcus aureus, Streptococcus pneumoniae. Gram-negative: Escherichia coli, Haemophilus influenzae, Moraxella catarrhalis, Proteus mirabilis, Pseudomonas aeruginosa. Clotrimazole is a synthetic imidazole derivative, which is a broad-spectrum antifungal agent that exerts fungicidal activity against fungi responsible for superficial mycotic infections affecting the outer or middle ear including Candida, Microsporum & Trichophyton. Clotrimazole inhibits Cytochrome P-450 synthesis of Ergosterol, which decreases fungal cell wall integrity thus inhibits fungal growth. Clotrimazole also has activity against certain bacteria such as Streptococci and Staphylococci. The antibacterial effect of Clotrimazole is advantageous to treat mixed bacterial-fungal infections. Beclomethasone Dipropionate is a potent steroid as compared with other topical corticosteroids. Beclomethasone like other topical corticosteroids, has anti-inflammatory, antipruritic, and vasoconstrictive properties. It induces phospholipase A2 and sequentially inhibits the release of arachidonic acid, thereby depressing the formation, release, and activity of prostaglandins, leukotrienes, and other inflammatory mediators. Lidocaine Hydrochloride is a topical local anesthetic which helps to reduce pain and stinging in the ear.

Dosage And Administration:

 Adults & Children: Instill 2-5 drops three to four times daily into the affected ear for 7-14 days. Otitis Externa with intact tympanic membrane: From age 06 months & older. Chronic Suppurative Otitis Media with perforated tympanic membrane: 12 years & older. Instruction to use: To apply, tilt head to one side so that the ear is facing up. Then gently pull the ear lobe up & backward in case of adults and children older than 3 years. In case of pediatric patients gently pull the ear lobe down & backward

Contraindications:

undefined

Warning And Precaution:

If a favorable response does not occur in one week, discontinue the use of Audicom and obtain cultures to guide further treatment. As with other anti-infective preparations, prolonged use may result in overgrowth of nonsusceptible organisms. If local irritation or sensitization occurs, discontinue Audicom and institute appropriate therapy. If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor. Not for Ophthalmic use. Not for injection.

Side Effects:

The systemic side-effects are not common with this ear drops. The following adverse reactions may be observed when using Audicom: itching, burning, irritation, dryness, earache, headache, vertigo, dizziness, redness, folliculitis, hypertrichosis, acne form eruptions and hypopigmentation.

Use in Pregnancy and Lactation:

Safety during pregnancy or lactation has not been established. It is not known whether the active substances pass into breast milk when applied topically. Therefore, the potential benefit of this product during pregnancy or lactation, should be weighed against possible hazard to the fetus or the nursing infant.

Drug Interaction:

undefined

Overdosage:

If overdose is suspected, contact a poison control center or emergency room immediately. Symptoms of overdose may include: dizziness, headache, and shortness of breath, difficulty breathing or swallowing, chest pain, confusion.

Storage:

Keep away from light and moisture, store below 25°C.

Packing:

Audicom Ear Drops :Each plastic dropper bottle contains 10 ml sterile ear drops.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.