

Otic-4TM



Ofloxacin USP, Clotrimazole BP, Beclometasone Dipropionate BP, Lidocaine Hydrochloride USP

COMPOSITION

Otic-4 Ear Drops: Each ml contains Ofloxacin USP 3 mg, Clotrimazole BP 10 mg, Beclometasone Dipropionate BP 0.25 mg and Lidocaine Hydrochloride USP 20 mg sterile otic solution.

PHARMACOLOGY

It is a combination of an antibacterial, an antifungal, an anti-inflammatory and a topical local anesthetic agent. **Otic-4** 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 the otic pathogens without ototoxicity. Hence, Ofloxacin is preferred to Aminoglycosides for any application within the middle ear space. Ofloxacin exerts antibacterial activity by inhibiting the DNA gyrase of bacteria. It has been shown that Ofloxacin is active against the following responsible organisms of otic infection: 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, Microsporium and Trichophyton. Clotrimazole inhibits the Cytochrome P-450 synthesis of Ergosterol and decreases fungal cell wall integrity, consequently inhibiting 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. Beclometasone Dipropionate is a potent steroid compared to other topical corticosteroids. Beclometasone, 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.

INDICATION

Otic-4 Ear Drops is indicated for the treatment of superficial bacterial and fungal infections of the external auditory canal and the middle ear, caused by organisms susceptible to the action of Ofloxacin and Clotrimazole.

DOSAGE AND ADMINISTRATION

Adults & Children: Instill 2-5 drops into the affected ear 3-4 times daily for 7-14 days. * In case of otitis externa with intact tympanic membrane, it can be used from the age of 06 months & older. *In case of chronic suppurative otitis media with perforated tympanic membrane, it can be used from the age of 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.

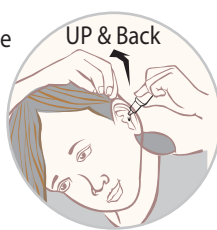


Figure 1: Adult application

In case of pediatric patients gently pull the ear lobe down & backward.

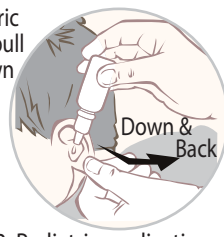


Figure 2: Pediatric application

CONTRAINDICATION

This preparation is contraindicated in patients sensitive to Ofloxacin or other quinolone, or to any of the components of this medication. It is contraindicated in viral infections of the ear.

WARNINGS AND PRECAUTION

If a favorable response does not occur in one week, discontinue the use of this preparation 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 occur, discontinue this preparation 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-EFFECT

The systemic side-effects are not common with this ear drops preparation. The following adverse reactions may be observed while using this product: 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 the 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.

STORAGE

Protect from light. Store below 25° C. Keep out of reach of children.

HOW SUPPLIED

Otic-4 Ear Drops: Each plastic dropper bottle contains 10 ml sterile otic solution of Ofloxacin, Clotrimazole, Beclometasone Dipropionate and Lidocaine Hydrochloride.

Manufactured by



SQUARE
PHARMACEUTICALS PLC.
BANGLADESH