

Ofloxacin USP 0.3%, Clotrimazole BP 1% Beclometasone Dipropionate BP 0.025% & Lidocaine Hydrochloride BP 2% w/v

Compositions

Oto-4 Ear Drops : Clear, pyrogen free, preservative free otic solution. Each ml contains ofloxacin USP 3 mg, Clotrimazole BP 10 mg, Beclometasone Dipropionate BP 0.25 mg and Lidocaine Hydrochloride BP 20 mg.

Pharmacology

It is a combination of an antibacterial, an antifungal, an anti-inflammatory and a topical local anesthetic agent. **Oto-4** has been specially formulated to maintain the natural environment of the external ear canal. Ofloxacin is a fluoroquinolone that has 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.

Beclometasone Dipropionate is a potent steroid as compared with other topical corticosteroids. Beclometasone like other topical corticosteroids, has anti-inflammatory, anti-pruritic 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.

Indications

Oto-4 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 and Children: Instill 2-5 drops three to four times daily into the affected ear for 7-14 days.

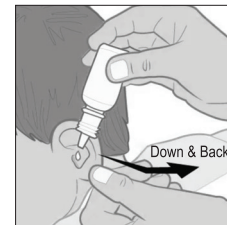
Otitis Externa with intact tympanic membrane: From age 06 months & older.

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 (Fig. 1). In case of pediatric patients gently pull the ear lobe down & backward (Fig.2).



(Fig.-1: Adult application)



(Fig.-2: Pediatric application)

Contraindications

Oto-4 is contraindicated in patients with sensitive to Ofloxacin or other quinolone, or to any of the components of this medications. It is contra-indicated in viral infections of the ear.

Warnings and Precautions

If a favorable response doesn't 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 occurs, discontinue this preparation and institute the 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 **Oto-4** ear drops. The following adverse reactions may be observed when using this product : itching, burning, irritation, dryness, earache, headache, vertigo, dizziness, redness, folliculitis, hypertrichosis, acneform 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.

Storage

Store below 25° C temperature and dry place, protected from light. Keep all medicines out of reach of children.

Packing

Oto-4 Ear Drops : Plastic container contains 10 ml pyrogen free otic solution.

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.
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