OTIFLOX EAR DROPS

COMPOSITION

Ofloxacin	0.3% w/v
Clotrimazole IP	1% w/v
Beclomethasone Dipropionate IP	0.025 % w/v
Lignocaine Hydrochloride IP	2% w/v
Propylene Glycol IP & Glycerine IP	[Base]
Glacial Acetic Acid IP, Polyoxyethylene Castor Oil derivatives IHS, Purified Water	Excipients

PHARMACOLOGY

Otiflox Ear Drops provides an antibacterial and antifungal along with an anti-inflammatory agent. It may be used to prevent or treat ear infections. **Otiflox Ear Drops** 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 but lacks the capacity for ototoxicity. Hence ofloxacin is preferred to aminoglycosides for any application within the middle ear space.

Ofloxacin exerts its antibacterial activity by inhibiting DNA gyrase, a bacterial enzyme that is essential in DNA replication, repair, deactivation and transcription. Ofloxacin has been shown to be active against the following organisms responsible clinically 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. Clotrimazole is a broad-spectrum antifungal agent that has fungicidal activity against fungi responsible for superficial mycotic infections affecting the outer or middle ear including Candida, Microsporum, Trichophyton.

Clotrimazole inhibits fungal cytochrome P-450 synthesis of ergosterol, which decreases fungal cell wall integrity. By inhibiting the biosynthesis of ergosterol for fungal cytoplasmic membrane, clotrimazole inhibits fungal growth. Resistance to clotrimazole is very rare among the fungi that cause superficial mycoses.

Clotrimazole also has activity against certain gram-positive bacteria such as Streptococci and Staphylococci. It is the most widely used topical azole. Its antibacterial effect is advantageous in treating mixed bacterial-fungal infections.

Beclomethasone like other topical corticosteroids, has anti-inflammatory, antipruritic, and vasoconstrictive properties. Corticosteroids like Beclomethasone are thought to act by the induction of phospholipase A2 inhibitory proteins,

collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting their release from the common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Beclomethasone Dipropionate 0.025 % is a potent steroid as compared with other topical corticosteroids. Beclomethasone Dipropionate is often used in conjunction with acetic acid to reduce inflammation when infection is present.

Lignocaine Hydrochloride is a topical anesthetic with a low index of sensitization and toxicity. It helps reduce pain and stinging in the ear.

Otiflox Ear Drops by virtue of its three active ingredients, ofloxacin, clotrimazole, and beclometasone, has antibacterial, antifungal and anti-inflammatory activity. **Otiflox Ear Drops** is ideally suited to control bacterial and/or fungal infections of the ear.

Glycerin in **Otiflox Ear Drops** acts as a carrier for the other ingredients. It soothes and moisturizes the skin. Glycerin also softens cerumen due to its water-retaining and emollient properties.

The Propylene glycol is an inert, non-irritant and viscous vehicle. It softens the cerumen and ensures prolonged contact of the active ingredients with the surface of the ear canal.

INDICATIONS

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

DOSAGE & ADMINISTRATION

Adults & Children:

- Apply 3-5 drops of **Otiflox Ear Drops** into the affected ear.
- To apply, tilt head to one side so that the ear is facing up.
- Then gently pull the ear lobe backward and upward in case of adults and children older than 3 years
- For children younger than 3 years, gently pull the ear lobe backward and down
- Apply 3-5 drops of **Otiflox Ear Drops** into the ear.
- Keep head tilted for about 5 minutes to allow the drops to penetrate lower into the ear canal.
- Gently pat excess material dripping out of the ear using a clean cotton ball.
- Follow these instructions 3-4 times a day for 7 to 14 days.

If the ear canal is swollen consider inserting a wick to allow topical treatment to travel along the length of the ear canal. The wick should be saturated with the ear drops. The wick should be moistened for the first 24 hours by occasionally adding a few drops on the wick. Remove the wick after the first 24 hours and continue to instill 5 drops for Adults, and 3 drops for Children, of **Otiflox Ear Drops** 3 or 4 times daily thereafter.

To prevent infection of the other ear during treatment, **Otiflox Ear Drops** may be used in the unaffected ear 3 times daily.

CONTRAINDICATIONS

- Patients sensitive to Ofloxacin or other quinolones, or to any of the components of this medication
- Viral infections of the ear
- This preparation is not for ophthalmic use

PRECAUTIONS

- 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 over-growth of nonsusceptible organisms.
- Although systemic side effects are not common with ototopical medications, their possible occurrence must be kept in mind.
- If local irritation or sensitization occurs, 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
- Use of corticosteroids, depending on dose and duration may result in endogenous steroid production inhibition following drug withdrawal. In patients presently receiving or recently withdrawn from corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in especially stressful situations.

Pregnancy & Lactation

Safety during pregnancy or lactation has not been established. Studies have shown that corticosteroids may induce fetal abnormalities in pregnant animals. The relevance of this finding to human use has not been elucidated. 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.

Pediatric Use

Safety and efficacy of Ofloxacin as ear drops have been demonstrated in pediatric patients of the following ages for the listed indications:

• Six months and older: otitis externa with intact tympanic membranes
• One year and older: acute otitis media with tympanostomy tubes
• Twelve years and older: chronic suppurative otitis media with perforated tympanic membranes

Safety and efficacy in pediatric patients below these ages have not been established.

Although no data are available on patients less than age 6 months, there are no known safety concerns or differences in the disease process in this population that will preclude use of this product.

No changes in hearing function occurred in 30 pediatric subjects treated with ofloxacin otic and tested for audiometric parameters. Although quinolones, including ofloxacin, have been shown to cause arthropathy in immature animals after systemic administration, young growing guinea pigs dosed in the middle ear with 0.3% ofloxacin otic solution for one month showed no systemic effects,

quinolone induced lesions, erosions of the cartilage in weight-bearing joints, or other signs of arthropathy.

WARNINGS
NOT FOR OPHTHALMIC USE.
NOT FOR INJECTION.
Serious and occasionally fatal hypersensitivity reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. If an allergic reaction to **Otiflox Ear Drops** is suspected, stop the medication. Serious acute hypersensitivity reactions may require immediate emergency treatment.

ADVERSE EFFECTS
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.

PRESENTATION
Otiflox Ear Drops is available in plastic dropper bottles of 5ml.