

Audicare

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

COMPOSITION: Audicare 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.

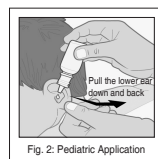
Preservative: Nil

PHARMACOLOGY: **Audicare** is a combination of four drugs: Ofloxacin (antibacterial), Clotrimazole (antifungal), Beclometasone (anti-inflammatory) and Lidocaine (local anesthetic). This ear drop has been specially formulated to maintain the natural environment of external & middle ear. **Ofloxacin** is a fluoroquinolone which exerts its antibacterial activity by inhibiting DNA gyrase enzyme of bacteria. **Clotrimazole** is a synthetic imidazole derivative which shows fungicidal activity by inhibiting the biosynthesis of ergosterol which is an important ingredient required for fungal cell wall synthesis & thus it inhibits fungal growth. **Beclometasone Dipropionate** is a potent steroid which gives anti-inflammatory effect by blocking 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 by inhibiting the pain signal conduction.

INDICATION: **Audicare** Ear Drop 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: 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 6 months and older. * In case of chronic suppurative otitis media with perforated tympanic membrane, it should be used from the age of 12 years & older.

ADMINISTRATION PROCEDURE: To administer, position the head so that the ear faces upward - **For adult and children older than 3 years:** then gently pull the upper ear up and back (Fig. 1). **For children younger than 3 years:** then gently pull the lower ear down and back (Fig. 2).



CONTRAINDICATIONS: **Audicare** Ear Drop is contraindicated in patients with sensitive to Ofloxacin or other quinolone, or to any of the components of this medications. It is contraindicated in viral infections of the ear.

SIDE EFFECTS: The systemic side effects are not common with this **Audicare** 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.

WARNING & 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 overgrowth of nonsusceptible organisms. • If local irritation or sensitization occurs, discontinue this preparation and institute appropriate therapy.

USE IN SPECIAL GROUP: Use in Pregnancy: Safety during pregnancy has not been established. Therefore, during use in pregnancy, the risk-benefit relationship should be considered carefully.

Use in Lactation: It is not known whether the active substances pass into breast milk when applied topically. Therefore, caution should be exercised when **Audicare** is administered to a nursing mother.

STORAGE: Store below 25°C, keep in dry place & protect from light. Keep out of the reach of children.

PACKAGING: **Audicare** Ear Drops: Each LDPE dropper bottle contains 10 ml ear drops.

Manufactured by:
 **ARISTOPHARMA LTD.**
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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