

OtifloxTM Ear drops

Composition:

Neomycin	0.5% w/v
Beclomethasone	0.025%
Clotrimazole	1%w/v
Lignocaine	2%w/v

Pharmacokinetic properties:

Neomycin is poorly absorbed from the gastrointestinal tract, about 97% of an oral dose being excreted unchanged in the faeces. Doses of 3 g orally produce peak plasma concentrations of up to 4 micrograms/mL and absorption is similar after an enema. Absorption may be increased in conditions which damage or inflame the mucosa. Absorption has also been reported to occur from the peritoneum, respiratory tract, bladder, wounds, and inflamed skin. Once neomycin is absorbed it is rapidly excreted by the kidneys in active form. It has been reported to have a half-life of 2 to 3 hours

Beclometasone is stated to be readily absorbed from sites of local application, and rapidly distributed to all body tissues. It is metabolised principally in the liver, but also in other tissues including gastrointestinal tract and lung; enzymatic hydrolysis rapidly produces the monopropionate (which has some glucocorticoid activity), and, more slowly, the free alcohol, which is virtually devoid of activity. Only a small proportion of an absorbed dose is excreted in urine, the remainder being excreted in the faeces mainly as metabolites.

When applied topically clotrimazole penetrates the epidermis but there is little if any systemic absorption. Absorption of 3 to 10% of a dose has been reported after vaginal use. Clotrimazole is metabolised in the liver to inactive compounds and excreted in the faeces and urine

Mechanism of Action:

Aminoglycosides like neomycin "irreversibly" bind to specific 30S-subunit proteins and 16S rRNA. specifically neomycin binds to four nucleotides of 16S rRNA and a single amino acid of protein S12. This interferes with decoding site in the vicinity of nucleotide 1400 in 16S rRNA of 30S subunit. This region interacts with the wobble base in the anticodon of tRNA. This leads to interference with the initiation complex, misreading of mRNA so incorrect amino acids are inserted into the polypeptide leading to nonfunctional or toxic peptides and the breakup of polysomes into nonfunctional monosomes.

Beclomethasone is a steroid which promptly blocks inflammation & allergy.



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Clotrimazole works to kill individual Candida or fungal cells by altering the permeability of the fungal cell wall. It binds to phospholipids in the cell membrane and inhibits the biosynthesis of ergosterol and other sterols required for cell membrane production. This leads to the cell's death via loss of intracellular elements.

Lignocaine HCl blocks sensation of pain.

Indication:

Indication Otiflox ear drops are indicated for treatment:

- Mixed Ear Infections
- Otitis Externa
- Chronic suppurative otitis media

Contraindication:

Otiflox ear drops are contraindicated in patients with:

- Hypersensitivity to any of the ingredients
- Psychiatric illnesses and in patients with epilepsy or other seizure disorders.
- Severe systemic infections

Drug Interaction:

No specific drug interactions noted.

Adverse effects:

Otiflox ear drops can give mild irritation, burning or stinging sensation in the ear after application.

Warnings and Precautions:

Use in special population:

1. **Pediatric:** Not recommended in children.
2. **Geriatric:** Safety and effectiveness of Otiflox ear drops in geriatric patients have not been established.
3. **Liver impairment:** Use with caution.
4. **Renal failure:** Use with caution.
5. **Pregnancy and lactation:** Use with caution.

Dosage:

As directed by physician.

Presentation:

Available in 5 ml bottle with in-built dropper



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Storage and handling:

Store in a dry, well-ventilated place at a temperature not exceeding 30°C. Do not freeze.



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