

OCUPOL/OCUPOL-D

Composition

Each ml of **OCUPOL Eye/Ear Drops** contains:

Polymyxin-B sulfate	5000 IU
Chloramphenicol	4 mg

Each gm of **OCUPOL Ointment** contains:

Polymyxin-B sulfate	10000 IU
Chloramphenicol	10 mg

Each ml of **OCUPOL-D Eye/Ear Drops** contains:

Polymyxin-B sulfate	5000 IU
Chloramphenicol	4 mg
Dexamethasone sodium phosphate	1 mg

Each gm of **OCUPOL-D Ointment** contains:

Polymyxin-B sulfate	10000 IU
Chloramphenicol	10 mg
Dexamethasone sodium phosphate	1 mg

In a sterile base

Pharmacology

The anti-infective components of **OCUPOL/OCUPOL-D** are intended to provide action against specific organisms susceptible to them. Polymyxin-B, a cyclic lipopeptide antibiotic, is bactericidal for a variety of Gram-negative organisms, especially *Pseudomonas aeruginosa*. It increases the permeability of the bacterial cell membrane by interacting with the phospholipid components.

Chloramphenicol is a broad-spectrum antibiotic originally isolated from *Streptomyces venezuelae*. It is primarily bacteriostatic and acts by inhibition of protein synthesis. It has been noted that chloramphenicol is found in measurable amounts in the aqueous humor following local application to the eye.

Development of resistance to chloramphenicol can be regarded as minimal for *Staphylococci* and many other species of bacteria.

Corticosteroids suppress the inflammatory response to a variety of agents. Since they may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be warranted

The combination of **OCUPOL/OCUPOL-D** is rarely irritating, and its absorption from the intact skin or mucous membrane is insignificant. The incidence of skin sensitization to this combination has been shown to be low on normal skin.

Polymyxin-B sulfate and chloramphenicol together are considered active against *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Haemophilus influenzae*, *Staphylococcus aureus*,

Streptococcus species, *Moraxella lacunata* and *Neisseria* species,

The combination of **OCUPOL/OCUPOL-D** has the advantage of greater patient compliance in terms of both the dosage and convenience.

Indications

OCUPOL/OCUPOL-D is indicated for,

- The treatment of, surface ocular infections involving the conjunctiva and/or cornea caused by susceptible organisms.
- For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics, and for the treatment of infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotics.
- For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use uncertain infective conjunctivitis's is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

Contraindications

The use of **OCUPOL/OCUPOL-D** is contraindicated in patients with hypersensitivity to any ingredient of the formulations.

The use of **OCUPOL/OCUPOL-D** is also contraindicated in epithelial herpes keratitis (dendritic keratitis), vaccinia, varicella other viral diseases of the cornea and conjunctiva, mycobacterial infections of the eye and fungal diseases of ocular structures.

Precautions

The prolonged use of antibiotics may occasionally result in overgrowth of nonsusceptible organisms, including fungi. If new infections appear the drug should be discontinued and appropriate measures instituted.

In all serious infections the topical use of **OCUPOL/OCUPOL-D** should be supplemented by appropriate systemic medication.

OCUPOL/OCUPOL-D should be used with care in cases of perforated eardrum and in longstanding cases of chronic otitis media due to the possibility of ototoxicity.

Prolonged use of **OCUPOL-D** may result in glaucoma and posterior subcapsular

cataract formation. If these products are used for 10 days or longer, intra-ocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Pregnancy & Lactation

There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Steroids appear in human milk following oral administration of the drug. Since systemic absorption may occur on topical application, caution should be exercised when **OCUPOL/OCUPOL-D** is used by a nursing woman.

Adverse Reactions

The adverse reactions reported with topical corticosteroids especially under occlusive dressings include burning sensation, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Blood dyscrasias have been reported in association with the use of chloramphenicol.

Dosage & Administration

The usual recommended dose of **OCUPOL/OCUPOL-D Eye Drops** is 2 drops to be instilled in the affected eye every 3 hours. Administration should be continued day and night for the first 48 hours, after which the interval between applications may be increased. Treatment should be continued for at least 48 hours after the eye appears normal.

The usual recommended dose of **OCUPOL/OCUPOL-D Ear Drops** in adults is 4 drops of the suspension to be instilled into the affected ear *tid* or *qid*. The dose in infants and children is 3 drops to be instilled into the affected ear *tid* or *qid*.

The usual recommended dose of **OCUPOL/OCUPOL-D Ointment** is half an inch ribbon, *bid* to *tid*.

Presentation

OCUPOL/OCUPOL-D Eye/Ear Drops is available in 5 ml lupolen vial

OCUPOL/OCUPOL-D Ointment is available in a tube of 5 g.