

## OCUPOL Eye/Ear Drops & Ointments

### Composition

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

Polymyxin-B sulfat	5000 IU
Chloramphenicol	4 mg

Each gm of **OCUPOL Ointment** contains:

Polymyxin-B sulfate	10000 IU
Chloramphenicol	10 mg

### Pharmacology

The anti-infective components of **OCUPOL** 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.

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

### Indications

**OCUPOL** 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.

### **Contraindications**

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

The use of **OCUPOL** 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** should be supplemented by appropriate systemic medication.

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

### **Pregnancy & Lactation**

There are no adequate and well-controlled studies in pregnant women & nursing mothers.

### **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.

Chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure. Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of chloramphenicol. Whilst the hazard is rare, it should be borne in mind when assessing the benefits expected from the use of the compound.

Transient burning or stinging sensations may occur with the use of Chloromytol Eye Drops. More serious side effects include hypersensitivity reactions that may present as angioneurotic oedema, urticaria, anaphylaxis, fever, and vesicular and maculopapular dermatitis. If this happens treatment must be discontinued immediately.

### **Dosage & Administration**

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

### **Presentation**

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

**OCUPOL Ointment** is available in a tube of 5 g.