VEGATROL EYE OINTMENT

Neomycin + Polymyxin B + Dexamethasone
Sterile ophthalmic ointment | 3.5 g tube

COMPOSITION

Each 1 g contains:
Neomycin ..... **3,500 IU**
Polymyxin B ..... **10,000 units**
Dexamethasone ..... **1 mg (0.1%)**
As supplied in the product specification; salt forms and potency equivalence must be confirmed.

THERAPEUTIC CLASS

Ophthalmic aminoglycoside antibiotic + polypeptide antibiotic + corticosteroid. Primary medical segment: Ophthalmology.

PHARMACOLOGY

Neomycin inhibits bacterial protein synthesis; polymyxin B disrupts susceptible Gram-negative bacterial cell membranes. Dexamethasone suppresses ocular inflammatory responses. Corticosteroids may mask or aggravate infection and delay healing.

INDICATIONS

Steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a significant risk of infection exists, as assessed by an ophthalmologist. Use only for locally approved indications.

DOSAGE AND ADMINISTRATION

Apply a small amount (approximately 1/2 inch or 1.25 cm ribbon) into the conjunctival sac of the affected eye(s) up to three or four times daily, or as directed by the prescriber. Duration should be limited to clinical need. Do not continue or refill without reassessment.

HOW TO APPLY

Wash hands. Tilt head back, gently pull lower eyelid down to form a pocket, and place the prescribed ribbon inside without touching the tube tip to the eye, eyelids or fingers. Look down and close eye gently. Replace cap immediately. Temporary blurred vision is expected.

CONTRAINDICATIONS

Hypersensitivity to neomycin, polymyxin B, dexamethasone or any ingredient. Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, other viral diseases of cornea or conjunctiva, mycobacterial ocular infection and fungal diseases of ocular structures.

WARNINGS: OCULAR STEROID

Prolonged use may increase intraocular pressure and cause glaucoma, optic nerve damage, visual-field defects, posterior subcapsular cataract or delayed corneal healing. Steroids can worsen undiagnosed infection and may contribute to corneal or scleral perforation where tissue is thin.

MONITORING AND PRECAUTIONS

If used for 10 days or longer, intraocular pressure should be monitored. Persistent corneal ulceration warrants investigation for fungal infection. Reassess if symptoms fail to improve promptly. Avoid contamination of the tube tip. Do not use while wearing contact lenses unless specifically advised.

ALLERGY AND CROSS-SENSITIVITY

Neomycin may cause cutaneous or ocular sensitization. Stop use if itching, rash, lid swelling or other hypersensitivity develops. Cross-sensitivity with other aminoglycosides may occur.

DRUG INTERACTIONS

Systemic interactions are generally limited by topical exposure, but prolonged or excessive corticosteroid use, particularly with strong CYP3A4 inhibitors, may increase systemic steroid effects. Separate different ophthalmic products as instructed; apply ointment last.

PREGNANCY AND LACTATION

Use only if the expected benefit justifies potential risk. Safety data for the combination during pregnancy and breastfeeding are limited. The clinician should consider the lowest effective exposure and duration.

PAEDIATRIC USE

Safety and efficacy depend on the locally approved product information. Children may be more susceptible to systemic corticosteroid effects with excessive or prolonged use; use under specialist supervision.

ADVERSE REACTIONS

Local burning, stinging, itching, redness, irritation, lid swelling and transient blurred vision may occur. Serious effects include hypersensitivity, increased intraocular pressure, glaucoma, cataract, secondary infection, delayed healing and corneal injury.

OVERDOSAGE

Excess ophthalmic application may increase local irritation or steroid exposure. Wipe away excess ointment; seek medical advice if symptoms persist. Accidental ingestion, especially by a child, requires medical assessment.

STORAGE

Store in the original, tightly closed tube under the conditions approved for Vegatrol. Protect from contamination and excessive heat. Keep out of reach of children. Observe the approved discard period after opening.

PRESENTATION

Vegatrol Eye Ointment: sterile ophthalmic ointment in a 3.5 g tube. For ophthalmic use only.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.