# Dexamethasone Sodium Phosphate and Neomycin Sulfate Drops

**COMPOSITION:**
Each 10 mL contains:
Dexamethasone sodium phosphate BP...0.125% w/v
Eq. to dexamethasone phosphate..... 0.1% w/v
Neomycin sulfate BP..... 0.65% w/v
Phenylmercuric nitrate BP..... 0.001% w/v
(As a preservative)
Sterile aqueous vehicle..... q.s.

**PHARMACOLOGICAL ACTION:**
Neomycin sulfate is a broad-spectrum antibiotic. Highly sensitive Gram-negative species include *E. coli*, *Enterobacter*, *Aerobacter aerogenes*, *K. pneumoniae*, *Pasteurella*, *Pr. vulgaris*, *Salmonella*, *Shigella*, *H. influenzae*, *N. meningitidis*, *V. cholerae*, and *B. pertussis*. Gram-positive microorganisms that are inhibited include *Bacillus anthracis*, *C. diphtheriae*, *Staph. aureus*, *Strep. faecalis*, *List. monocytogenes*, and *M. tuberculosis*. *Borrelia* and *Leptospira interrogans* are also suppressed. Sensitivity of *Pseud. aeruginosa* is variable. Neomycin is active against tuberculosis bacilli, regardless of their susceptibility to streptomycin. Dexamethasone is a 16-methyl-substituted hydrocortisone analogue with the highest anti-inflammatory potency and readily penetrates the cornea.

**INDICATIONS:**
For the treatment of infectious ocular inflammations caused by organisms sensitive to the antibiotic neomycin sulfate. Acute or chronic non-purulent conjunctivitis, blepharoconjunctivitis, and keratoconjunctivitis; nonspecific superficial keratitis; deep keratitis; acne rosacea keratitis; iridocyclitis; mild acute iritis, recurrent marginal ulceration, and corneal ulcer (use with caution in conditions causing corneal thinning due to the risk of perforation); non-purulent blepharitis; scleritis; episcleritis; conjunctivitis; ophthalmic herpes zoster (do not use for herpes simplex); and post-operatively to help prevent infections.

**WARNINGS:**
Since the possibility of adverse effects on corneal permeability and the risk of corneal epithelial breakdown associated with prolonged or repeated use of benzalkonium chloride-preserved preparations cannot be ruled out, regular ophthalmological examination is required. Caution should be exercised when using topical medication preserved with benzalkonium chloride for extended periods in patients with extensive ocular surface disease.

**CONTRAINDICATIONS:**
Contraindicated in cases of tuberculous, fungal, and most viral lesions of the eye (herpes simplex—dendritic keratitis); vaccinia; varicella; acute purulent conjunctivitis; acute purulent blepharitis; and in individuals who have demonstrated hypersensitivity to any of its components. Mechanical lacerations and abrasions.

**DOSAGE AND INSTRUCTIONS FOR USE:**
Instill one or two drops of LINODEX into the conjunctival sac every hour during the day and every two hours at night as initial therapy. When a favorable response is observed, reduce the dosage to one drop every four hours. Subsequently, a further reduction in dosage to one drop three or four times daily may be sufficient to control symptoms. No more than 20 milliliters should be prescribed initially, or as directed by the physician.
Adults: 2–3 drops in the affected ear/eye, 3–4 times daily.
Children: 1–2 drops in the affected ear/eye, 3–4 times daily.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**
Corticosteroids delay wound healing, promote the development and spread of infection, and may mask evidence of its progression, potentially leading to vision loss. Perforation is known to occur with the use of topical steroids in eye diseases that cause thinning of the cornea or sclera.
Prolonged use may result in glaucoma, optic nerve damage, defects in visual acuity and visual fields, and posterior subcapsular cataract formation, or may facilitate the establishment of secondary ocular infections caused by pathogens released from ocular tissue.
Since fungal infections of the cornea are particularly prone to developing concurrently with long-term topical steroid use, fungal invasion should be suspected in any persistent corneal ulceration where a steroid has been or is currently being used.
Do not touch the dropper tip to any surface, as this may contaminate the solution. Discontinue use if sensitization or irritation occurs.

**KNOWN SYMPTOMS OF OVERDOSE AND TREATMENT INDICATIONS:**
Prolonged topical use of neomycin should be avoided, as it may cause sensitization. Hypersensitivity reactions—usually of the delayed type—have occurred during topical treatment with neomycin but may be masked by dexamethasone. Treatment is symptomatic.

**STORAGE:**
Store below 30°C. Protect from light.

**Keep the medication out of the reach of children.**

Do not use more than 30 days after opening.

**PRESENTATION:** 10 mL bottle packaged in a carton.

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