Dexamethasone sodium phosphate suppresses the inflammatory responses to a variety of agents. No generally accepted explanation of this steroid property has been advanced.

**COMPOSITION**

Dexonex® 0.1% Eye/Ear Drops: Each ml contains Dexamethasone Phosphate 1 mg as Dexamethasone Sodium Phosphate BP.

**INDICATION**

For the treatment of the following conditions:

**Ophthalmic:** Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical or thermal burns, or perforation of foreign bodies.

**Otic:** Steroid responsive inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and nonpurulent infective otitis externa when the hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

**DOSAGE AND ADMINISTRATION**

The duration of treatment will vary with the type of lesion and may extend from a few days to several weeks, according to therapeutic response. Relapse, more common in chronic active lesions than in self-limited conditions, usually respond to retreatment.

**Eye:** Instil one or two drops of solution into the conjunctival sac every hour during the day and every two hours during the night as initial therapy. When a favourable response is observed, reduce dosage to one drop every four hours. Later, further reduction in dosage to one drop three to four times daily may suffice to control symptoms.

**Ear:** Clean the aural canal thoroughly and sponge dry. Instil the solution directly into the aural canal. A suggested initial dosage is three or four drops two or three times a day. When a favourable response is obtained, reduce dose gradually and eventually discontinue.

If preferred, the aural canal may be packed with a gauze wick saturated with solution. Keep the wick moist with the preparation and remove from the ear after 12 to 24 hours. Treatment may be repeated as often as necessary at the direction of the physician.

**CONTRAINDICATION**

Epithelial herpetic simplex keratitis (dendritic keratitis), acute infections stages of vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva, Mycobacterial infection of the eye, Fungal diseases of ocular or auricular structures, perforation of a drum membrane. Hypersensitivity to any ingredient of this product.

**WARNING**

Prolonged use may result ocular hypertension or glaucoma, with damage to the optic nerve, defects in the visual acuity and fields of vision and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazards of secondary ocular infections. If this product is used for 10 days or longer, intraocular pressure should be monitored routinely.

**PRECAUTION**

The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing. There have been reports of bacterial keratitis associated with the use of multiple dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

**USE IN PREGNANCY AND LACTATION**

USFDA Pregnancy category C.

There is no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Dexamethasone opthalmic solution is administered to a nursing woman.

**Pediatric Use**

Safety and efficacy in pediatric patients below the age of 18 have not been established.

**SIDE EFFECT**

Glaucoma with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, perforation of the globe. Rarely, stinging and burning may occur.

**STORAGE**

Store below 30°C in a cool and dry place protected from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 30 days of first opening.

**HOW SUPPLIED**

Dexonex® 0.1% Eye/Ear Drops: Each container contains 5 ml of 0.1% Dexamethasone Phosphate sterile solution.

Manufactured by:

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