Dexamethasone Ophthalmic/Otic

(dexamethasone sodium phosphate)

THERAPEUTIC CLASS
Glucocorticoid

DEA CLASS
RX

INDICATIONS
Treatment of 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. Treatment of corneal injury from chemical/thermal burns, or penetration of foreign bodies. Treatment of 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.

ADULT DOSAGE
Adults: Eye: Initial: Instill 1 or 2 drops into the conjunctival sac qh (daytime) and q2h (nighttime). Titrate: Reduce dose to 1 drop q4h when a favorable response is observed. Maint: 1 drop tid or qid may suffice to control symptoms. Ear: Clean the aural canal thoroughly and sponge dry. Initial: Instill 3 or 4 drops directly into the aural canal bid or tid. Titrate: Reduce dose gradually and eventually d/c when a favorable response is obtained. If preferred, the aural canal may be packed with a gauze wick saturated with sol. Keep the wick moist with the preparation and remove from the ear after 12-24 hrs. May repeat PRN. Duration will vary with type of lesion and may extend from a few days to several weeks, according to therapeutic response. Relapses usually respond to retreatment.

ADMINISTRATION
Ocular/otic route.

HOW SUPPLIED
Sol: 0.1% [5mL]

CONTRAINDICATIONS
Epithelial herpes simplex keratitis (dendritic keratitis), acute infectious stages of vaccinia/varicella and many other viral diseases of the cornea and conjunctiva, mycobacterial infection of the eye, fungal diseases of ocular/auricular structures, and perforation of a drum membrane.

WARNINGS/PRECAUTIONS
Prolonged use may result in ocular HTN and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Persistent fungal infections of the cornea or suppression of the host response and increased hazard of secondary ocular infections may occur with prolonged use. May cause perforations in diseases causing thinning of the cornea or sclera. May mask infection or enhance existing infection in acute purulent conditions of the eye or ear. Routinely monitor intraocular pressure (IOP) if used for ≥10 days. Caution with herpes simplex; periodic slit-lamp microscopy is essential. Contains sodium bisulfite; allergic-type reactions may occur. Bacterial keratitis reported with the use of multiple dose containers contaminated by patients with concurrent corneal disease or disruption of ocular epithelial surface.

ADVERSE REACTIONS
Glaucoma with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection, globe perforation.

PREGNANCY AND LACTATION
Category C, not for use in nursing.

MECHANISM OF ACTION
Glucocorticoid; not established. Suppresses the inflammatory response to a variety of agents and probably delays or slows healing.

ASSESSMENT
Assess for hypersensitivity to the drug (including sulfites), diseases causing thinning of the cornea/sclera, acute purulent conditions of the eye/ear, herpes simplex, pregnancy/nursing status, and any other conditions where treatment is cautioned or contraindicated.

MONITORING
Monitor for allergic-type reactions, ocular HTN, glaucoma, optic nerve damage, defects in visual acuity and fields of vision, cataract formation, secondary ocular infections, fungal infections of the cornea, bacterial keratitis, and other adverse reactions. Routinely monitor IOP if used for ≥10 days.

PATIENT COUNSELING

Instruct to avoid allowing tip of the dispensing container to contact the eye or surrounding structures. Inform that ocular preparations, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Inform that serious damage to the eye and subsequent loss of vision may result from using contaminated sol. Advise to seek physician's advice immediately concerning the continued use of the present multidose container if an intercurrent ocular condition (eg, trauma, ocular surgery/infection) develops. Instruct patients wearing soft contact lenses to wait at least 15 min after instilling the sol before inserting their lenses.

STORAGE

15-25°C (59-77°F).