DEXAMED®
EYE & EAR DROPS

COMPOSITION
Each ml Contains: Dexamethasone Sodium Phosphate equivalent to 1 mg (0.1% w/v) Dexamethasone

INDICATIONS
For the treatment of the following conditions:
Eye: 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 penetration of foreign bodies.

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

DOSAGE AND DIRECTIONS FOR USE
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. Relapses, more common in chronic active lesions than in self-limited conditions, usually respond to retreatment.

Eye: Instill 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 favorable response is observed, reduce dosage to one drop every four hours. Later, further reduction in dosage to one drop three or four times daily may suffice to control symptoms.

Ear: Clean the aural canal thoroughly and sponge dry. Instill the solution directly into the aural canal. A suggested initial dosage is three or four drops two or three times a day. When a favorable response is obtained, reduce dosage 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 discretion of the physician.

CONTRAINDICATIONS
Dexamethasone Sodium Phosphate drops is contraindicated in:
- 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 or auricular structures.
- Hypersensitivity to any component of this product, including sulfites (see WARNINGS).
- Perforation of a drum membrane.

SPECIAL WARNINGS
Prolonged use may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroid.

In acute purulent conditions of the eye or ear, corticosteroids may mask infection or enhance existing infection. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Employment of corticosteroid medication in the treatment of herpes simplex other than epithelial herpes simplex keratitis, in which it is contraindicated, requires great caution; periodic slit-lamp microscopy is essential.

Excipients with specified warnings
The drops contain 0.02% w/v Benzalkonium chloride in each dose, which if absorbed by soft contact lenses may change the colour of the contact lenses. Contact lenses should be removed before using this medicine and reinserted 15 minutes afterwards. Benzalkonium may also cause eye irritation, especially in patients with dry eyes or disorders of the cornea. The drops contain 0.23% w/v phosphates in each dose, which in patients with severe damage to the cornea may rarely cause cloudy patches on the cornea due to calcium build-up during treatment.

PRECAUTIONS
General
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.

Information for Patients:
Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures. Patients should also be instructed that ocular preparations, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Patients should also be advised that if they develop an inter-current ocular condition (e.g., trauma, ocular surgery or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Co-treatment with CYP3A inhibitors increases the risk of systemic side-effects and should be avoided unless the benefit outweighs the increased risk, in which case patients should be monitored for systemic corticosteroid side-effects.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of dexamethasone sodium phosphate ophthalmic solution.

Pregnancy
Pregnancy Category C. Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose.

Nursing Mothers
Topically applied steroids are absorbed systemically. Therefore, because of the potential for serious adverse reactions in nursing infants from dexamethasone sodium phosphate, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
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, filtering blebs have been reported when topical steroids have been used following cataract surgery.

Rarely, stinging or burning may occur.

PHARMACOLOGY
PHARMACODYNAMIC PROPERTIES:
Dexamethasone sodium phosphate suppresses the inflammatory response to a variety of agents and it probably delays or slows healing. No generally accepted explanation of these steroid properties have been advanced.

PHARMACOKINETIC PROPERTIES:
When applied typically to the eye, dexamethasone is absorbed into the aqueous humour, cornea, iris, choroid, ciliary body and retina. Systemic absorption occurs but may be significant only at higher dosages or in extended paediatric therapy.

LEGAL CATEGORY: Prescription Only Medicine (POM)

THERAPEUTIC CATEGORY: Ophthalmological and Otological preparations, Corticosteroids. ATC code: S03BA01

STORAGE CONDITIONS: Store in a dry place below 30°C. Avoid freezing. Protect from light. Keep all medicines out of reach of children

SHELF LIFE: As per the product label. Once opened, the drops should be used within 4 weeks.

PRESENTATION: 5ml or 10ml bottle with a nozzle insert moulded from low density polyethylene and a tamper evident cap having the nozzle puncturing spike on the inside.

DATE OF LAST REVIEW: June 2022

LICENCE HOLDER: LABORATORY & ALLIED LTD

Manufactured by:
Laboratory & Allied Ltd.
Plot No. 209/10349, Mombasa Road,
P.O. Box 42875, Nairobi, Kenya

LTSD003-00