1.4 PRODUCT INFORMATION.
1.4.1 Prescribing information (Summary of Product Characteristics)
1. NAME OF THE MEDICINAL PRODUCT
Dexamed Eye/ear Drops.

1.1 Strength:
Dexamethasone Sodium Phosphate 0.1%w/v.

1.2 Pharmaceutical Form:
Sterile solution for ophthalmic and otic administration.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each mL contains: Dexamethasone (as Sodium Phosphate BP) 0.1%w/v. For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Sterile solution for ophthalmic and otic administration.
Clear, colourless sterile solution, free from visible particles. Filled in 10mL clear plastic droppers contained in a unit box with literature insert.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications:
Dexamed 0.1% w/v Eye/ear Drops are indicated for 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 penetration of foreign bodies.
Otic: 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.

4.2 Posology and method of 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.
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.

4.3 Method of administration:
Dexamed Eye/Ear Drops is for ophthalmic and otic administration.

4.4 Contraindications:
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
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.
Perforation of a drum membrane**.**

4.5 Special warnings and precautions for use:
For ocular and otic use only. Not for injection into the eye/ear.
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 those 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 intercurrent 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.
One of the preservatives in dexamethasone sodium phosphate ophthalmic solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling dexamethasone sodium phosphate ophthalmic solution before they insert their lenses.
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 corticosteroids. 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.

4.6 Paediatric Population:
At the discretion of the physician.

4.7 Interaction with other medicinal products and other forms of interactions.
The risk of increased intraocular pressure associated with prolonged corticosteroid therapy may be more likely to occur with concomitant use of anticholinergics, especially atropine and related compounds, in patients predisposed to acute angle closure.
The risk of corneal deposits or corneal opacity may be more likely to occur in patients presenting with compromised cornea and receiving polypharmacy with other phosphate-containing eye medications.
The following drug interactions are possible, but are unlikely to be of clinical significance, following the use of Dexamed 0.1% w/v Eye/ear Drops in the eye: The therapeutic efficacy of dexamethasone may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin.
Glucocorticoids may increase the need for salicylates as plasma salicylate clearance is increased.
CYP3A4 inhibitors (including ritanovir and cobicistat) may decrease dexamethasone clearance resulting in increased effects and adrenal suppression/Cushing's syndrome. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.
If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.8 Additional information on special populations:
No information on this section has been provided.

4.9 Paediatric Population:
At the discretion of the physician.

4.10 Fertility, Pregnancy and Lactation:
Pregnancy
There are no or limited amount of data from the use of dexamethasone eye/ear drops in pregnant women.
Studies in animals have shown that topically applied steroids can be absorbed systemically and can cause abnormalities of foetal development in pregnant animals. Although the relevance of these findings to human beings has not been established, the use of Dexamed 0.1% w/v Eye/ear Drops during pregnancy should be avoided.
Breastfeeding/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.

4.11 Effects on ability to drive and use machines:
Dexamed 0.1% w/v Eye/ear Drops have no or negligible influence on the ability to drive and use machines; however, instillation of eye/ear drops may cause transient blurring of vision. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.12 Undesirable Effects:
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.

4.13 Overdose:
This medicine may be harmful if swallowed. If someone has overdosed and has serious symptoms such as passing out or trouble breathing, he/she should seek immediate medical attention.
Overdose is unlikely to occur as Dexamed 0.1% w/v Eye/ear Drops are single-dose units. Excess Dexamed 0.1% w/v Eye/ear Drops may be wiped away with a clean tissue.

5. PHARMACOLOGICAL PROPERTIES.

5.1 Pharmacodynamic Properties.
Pharmacotherapeutic Group: Sensory Organs, Ophthalmological and Otological Preparations, Corticosteroids.
ATC code: S03BA01.
Dexamethasone is a highly potent and long-acting glucocorticoid. It has an approximately 7 times greater anti-inflammatory potency than prednisolone, another commonly prescribed corticosteroid.
The actions of corticosteroids are mediated by the binding of the corticosteroid molecules to receptor molecules located within sensitive cells. Corticosteroid receptors are present in human trabecular meshwork cells and in rabbit iris ciliary body tissue.
Corticosteroids will inhibit phospholipase A2 thereby preventing the generation of substances which mediate inflammation, for example, prostaglandins. Corticosteroids also produce a marked, though transient, lymphocytopaenia. This depletion is due to redistribution of the cells; the T lymphocytes being affected to a greater degree than the B lymphocytes. Lymphokine production is reduced, as is the sensitivity of macrophages to activation by lymphokines. Corticosteroids also retard epithelial regeneration, diminish post-inflammatory neo- vascularization and reduce towards normal levels the excessive permeability of inflamed capillaries.
The actions of corticosteroids described above are exhibited by dexamethasone and they all contribute to its anti-inflammatory effect.

5.2 Pharmacokinetic Properties:
Absorption: When given topically to the eye/ear, 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. Up to 90% of dexamethasone is absorbed when given by mouth; peak plasma levels are reached between 1 and 2 hours after ingestion and show wide individual variations.
Distribution: Tissue distribution studies in animals show a high uptake of dexamethasone by the liver, kidney and adrenal glands; a volume of distribution has been quoted as 0.58 l/kg. In man, over 60% of circulating steroids are excreted in the urine within 24 hours, largely as unconjugated steroid.
Biotransformation: Dexamethasone sodium phosphate is rapidly converted to dexamethasone within the circulation. Up to 77% of dexamethasone is bound to plasma proteins, mainly albumin. This percentage, unlike cortisol, remains practically unchanged with increasing steroid concentrations. The mean plasma half-life of dexamethasone is 3.6 ± 0.9h.
Elimination: Dexamethasone also appears to be cleared more rapidly from the circulation of the foetus and neonate than in the mother; plasma dexamethasone levels in the foetus and the mother have been found in the ratio of 0.32:1.

5.3 Preclinical safety data:
Repeat dose topical ocular safety studies with dexamethasone in rabbits have shown systemic corticosteroid effects. Such effects are considered to be unlikely when dexamethasone eye drops are used as recommended.
Dexamethasone was clastogenic in the in vitro human lymphocyte assay and in vivo in the mouse micronucleus assay at doses in excess of those obtained following topical application. Conventional carcinogenicity studies with dexamethasone have not been performed.
Dexamethasone has been found to be teratogenic in animal models. Dexamethasone induced abnormalities of foetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. There are no other preclinical data of relevance to the prescriber which are additional to that included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:
- Benzalkonium Chloride
- Disodium EDTA
- Sodium Chloride
- Disodium Hydrogen Phosphate
- Dihydrogen Sodium Phosphate
- Water for injection

6.2 Incompatibilities:
None known. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life:
24 Months.

6.4 Special precautions for storage.
Store in a dry place below 30ºC.
Protect from light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container.
Filled in 10mL clear plastic droppers contained in a unit box with literature insert.

6.6 Special precautions for disposal.
Any unused product or waste material should be disposed off in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER & MANUFACTURING SITE ADDRESS
Marketing Authorization Holder:
Company Name: Laboratory and Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.
Country: Kenya.
Telephone: +254 20 8040306.
Telefax: +254 20 8040309.
E-Mail: info@laballied.com.

Manufacturing Site Address:
Company Name: Laboratory & Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.
Country: Kenya
Telephone: +254 20 8040306.
Telefax: +254 20 8040309
E-Mail: info@laballied.com

8. MARKETING AUTHORIZATION NUMBER:
Kenya Reg No.: 9362.

9. DATE OF FIRST REGISTRATION/ RENEWAL OF THE REGISTRATION:
Registration Date: 18/06/2009.
Renewal Date: To be retained annually.

10. DATE OF REVISION OF THE TEXT:
May, 2024.

11. DOSIMETRY (IF APPLICABLE)
Not Applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable.