Summary of Product Characteristics

1. Name of the medicinal product

DEXAMYCIN - Gentamicin Sulphate & Dexamethasone Sodium Phosphate Eye/Ear Drops

2. Qualitative and quantitative composition

Gentamicin sulphate BP
Eq to Gentamicin base .....0.3 % w/v

Dexamethasone sodium phosphate BP
Eq to dexamethasone phosphate..... %0.1. w/v

Benzalkonium chloride BP..... % w/v
(as preservative)

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Eye/ear drops, solution.
A Clear, colourless to pale yellow solution.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of infections of the external structures of the eye and its adnexa caused by susceptible bacteria. Such infections include conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis and blepharo-conjunctivitis, acute meibomiantis, episcleritis and dacryocystitis. It may be used for the prevention of ocular infection after removal of a foreign body, burns or laceration of the conjunctiva; damage from chemical or physical agents and after ocular surgery. Also indicated for the treatment of otitis externa.

4.2 Posology and method of administration Posology

For use in the eye: the normal dosage I -2 drops to be put in the affected eye up to 6 times a day or as directed by the physician.
For use in the ear: 2 or 3 drops are usually put in the ear 3-4 times a day and at night or as directed by the physician.

Method of administration

For eye and ear use

Shake the bottle well before use.

Do not let the tip of the dropper touch the eye. Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.

4.3 Contraindications

- Hypersensitivity to the dexamethasone, gentamicin and other aminoglycosides, or to any of the excipients listed in section 6.1.

- Vaccinia, varicella, or other viral diseases of cornea and conjunctiva (except herpes zoster keratitis)
- Herpes simplex keratitis
- Fungal diseases of ocular structures or untreated parasitic eye infections
- Mycobacterial ocular infections
- Acute, untreated bacterial infections

4.4 Special warnings and precautions for use Gentamicin

Avoid prolonged use. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross-sensitivity with other aminoglycoside antibiotics may occur.

In severe infections, topical use of gentamicin should be supplemented with appropriate systemic antibiotic treatment.

The condition of the ear drum must always be checked before this medicinal product is prescribed. The medicinal product must not be used if the integrity of the ear drum cannot be guaranteed.

Dexamethasone

Prolonged use of topical ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, reduced visual acuity, visual field defects and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure and the lens should be checked routinely and frequently, particularly in patients with a history or presence of glaucoma. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

Corticosteroids may reduce resistance to and aid in the establishment of bacterial, viral, fungal or parasitic infections and mask the clinical signs of infections. Fungal infection should be suspected in patients with persistent corneal ulceration and corticosteroids therapy should be discontinued if fungal infection occurs.

Topical ophthalmic corticosteroids may slow corneal wound healing. Topical NSAIDs are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may be cataract or glaucoma which have been reported after use of systemic and topical corticosteroids.

The wearing of contact lenses is discouraged during treatment of an ocular inflammation.

Because of the possibility of reduced glucose tolerance/diabetes mellitus with topical ophthalmic corticosteroids, caution is recommended when

administering Dexamycin to patients with a personal or family history of diabetes.

Additionally, this product contains benzalkonium chloride. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

Benzalkonium is known to deposit in soft contact lenses. Avoid contact with soft contact lenses. However, if the healthcare provider considers contact lenses use appropriate, patients must be instructed to remove contact lenses prior to application of Dexamycin and wait at least 15 minutes before reinsertion

4.5 Interaction with other medicinal products and other forms of interaction Gentamicin

Potent diuretics such as ethacrynic acid and frusemide are believed to enhance any risk of ototoxicity whilst amphotericin B, cisplatin and cyclosporin and cephalosporins are potential enhancers of nephrotoxicity. Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician. Neuromuscular blockade and respiratory paralysis have been reported in patients from the administration of aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia

Dexamethasone

No interaction studies have been performed.

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems. CYP3A4 inhibitors (including ritonavir 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.

4.6 Fertility, pregnancy and lactation Pregnancy

Dexamycin is not recommended during pregnancy unless the clinical condition of the woman requires treatment with dexamethasone.

Breastfeeding

Systemically administered corticosteroids appear in human milk in quantities that could affect the child being breastfed. However, when instilled topically, systemic exposure is low. It is unknown whether dexamethasone is excreted in human milk.

4.7 Effects on ability to drive and use machines

As with any topical ophthalmic medicinal product, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If

blurred vision occurs upon instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

Hypersensitivity reactions, dysgeusia, ocular discomfort, keratitis, conjunctivitis, corneal

staining, photophobia, vision, blurred, eye pruritus, foreign body sensation in eyes, lacrimation increased, abnormal sensation in eyes, eyelid margin crusting, eye irritation, ocular hyperaemia, Local sensitivity; eye irritation, burning sensation, stinging sensation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'.

4.9 Overdose

Gentamicin

Haemodialysis and peritoneal dialysis will aid the removal from blood but the former is probably more efficient.

Dexamethasone

Long-term intensive topical use may lead to systemic effects. Oral ingestion of the contents of the bottle (up to 10 mls) is unlikely to lead to any serious adverse effects. An ocular overdose of the drops can be flushed from the eye(s) with lukewarm water

5. Pharmacological properties

5.1 Pharmacodynamic properties Gentamicin

Gentamicin is a mixture of antibiotic substances produced by the growth of micromonospora purpurea. It is bactericidal with greater antibacterial activity than streptomycin, neomycin or kanamycin. Gentamicin exerts a number of effects on cells of susceptible bacteria. It affects the integrity of the plasma membrane and the metabolism of RNA, but its most important effect is inhibition of protein synthesis at the level of the 30s ribosomal subunit

Dexamethasone

Pharmacotherapeutic Group: Ophthalmologicals: Anti-inflammatory Agents. ATC Code S01B A01.

Dexamethasone has been demonstrated by animal and human studies based on oral application to possess approximately six to seven times the potency of prednisolone and at least 30 times the potency of cortisone. The potency of the compound is accomplished by the addition of a methyl radical and a fluorine atom to the prednisolone radical. it blocks the production of certain chemical messengers (prostaglandins) that cause redness, swelling and itching.

5.2 Pharmacokinetic

properties Gentamicin
Topical application of Gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µ g/ml. Gentamicin is not readily absorbed from the gastro-intestinal tract < 10% is bound to plasma protein. Following administration and is excreted >90% in the urine by glomerular filtration. The half-life for its elimination in normal patients is 2 to 3 hours, but can be increased in cases of renal insufficiency. Effective plasma concentration is 4 - 8ug/ml the volume of distribution (VD) is
0.3 1/kg

Dexamethasone
Dexamethasone is absorbed rapidly after oral administration with a half-life of about 190 minutes. Sufficient absorption may occur after topical application to the skin and eye to produce systemic effects. In plasma dexamethasone protein binding is less than for most other corticosteroids. Corticosteroids diffuse into tissue fluids and cerebrospinal fluid but transplacental diffusion in significant amounts has not been demonstrated. Corticosteroids are metabolised in the liver and excreted in the urine. Metabolism is similar to other corticosteroids. Intraocular penetration occurs in significant amounts and contributes to the effectiveness of dexamethasone in anterior segment inflammatory disease.

5.3 Preclinical safety data
Dexamethasone
Repeat dose topical ocular safety studies with dexamethasone in rabbits have shown systemic corticosteroid effects. Such effects are considered to be unlikely when the dexamethasone 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 drops have not been performed. Dexamethasone has been found to be teratogenic in animal models. Dexamethasone induced abnormalities of fetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. The ocular administration of 0.1% dexamethasone also resulted in fetal anomalies in rabbits. Dexamethasone had no adverse effects on female fertility in a chorionic gonadotropin primed rat model.

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
Hydroxy propyl B-cyclodextrin Mannitol
Disodium edetate
Sodium hydroxide
Hydrochloric acid
Water for injection

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage Do not store above 30°C.
Do not freeze.

6.5 Nature and contents of container

5 ml plastic bottle

6.6 Special precautions for disposal and other handling
Do not touch dropper tip to any surface as this may contaminate the contents.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Manufactured in India by**:**
Mercury Laboratories Limited
Unit No. 2/13-2/14, Industrial Estate, Gorwa, Vadodara-390016.
Gujarat, India

Manufactured For & Marketed by:
Krishna Chemists Ltd.
P.O. Box 3328-00506
Nairobi, Kenya.

8. Marketing authorisation number(s)

H2025/CTD9353/15538

9. Date of first authorisation/renewal of the authorization

April 2025

10. Date of revision of the text
13/12/2024