Summary of Product Characteristics

1. Name of the medicinal product:

DEXATROL

2. Qualitative and quantitative composition

Each 1 gm or 1 ml contains:

Dexamethasone.....1 mg

Neomycin (as sulphate).....3.5 mg

Polymyxin B sulphate.....6000 Units

For a list of excipients, see Section 6.1.

3. Pharmaceutical form

DEXATROL EYE DROPS:

A white microfine suspension preserved in tight, light-resistant plastic dropper bottles, and its sterility is assured at the time of first use.

DEXATROL EYE OINTMENT:

A homogeneous, spreadable, yellow to yellowish white unctuous semisolid preparation filled in collapsible ophthalmic ointment tubes.

4. Clinical particulars

4.1 Therapeutic indications

DEXATROL is indicated for the short-term treatment of steroid-responsive conditions of the eye when prophylactic antibiotic treatment is also required, after excluding the presence of fungal and viral disease.
DEXATROL is indicated for Infections of the external ear canal caused by susceptible organisms. Mastoidectomy cavity infections or chronic suppurative otitis media.

4.2 Posology and method of administration

Eye Drops: Apply one or two drops to each affected eye up to six times daily or, more frequently if required.

Ear Drops: In external ear canal infection: Before administration, the external ear should be thoroughly cleaned. Drops 3-4 times daily

Topical to Mastoidectomy cavity or Ear canal:4-10 drops 3-4times daily

Ointment: Apply a small amount into the conjunctival sac(s) up to three to four times daily or, may be used adjunctively with drops at bedtime.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.
Herpes simplex keratitis.
Vaccinia, varicella, and other viral infection of cornea or conjunctiva.
Fungal diseases of ocular structures.
Mycobacterial ocular infections

4.4 Special warnings and precautions for use

Not for injection or ingestion.

After cap is removed, if tamper evident snap collar is loose, remove before using product.

As with all antibacterial preparation prolonged use may lead to overgrowth of non-susceptible bacterial strains or fungi. If superinfection occurs, appropriate therapy should be initiated.

Sensitivity to topically applied aminoglycosides may occur in some patients. Cross-sensitivity to other aminoglycosides may also occur. If signs of serious reactions or hypersensitivity occur, discontinue use of DEXATROL. Patients using ophthalmic preparations containing neomycin sulphate should be advised to consult a physician if ocular pain, redness, swelling, or irritation worsens or persists.

Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic neomycin or when applied topically to open wounds or damaged skin. Nephrotoxic and neurotoxic reactions have also occurred with systemic polymyxin B. Although these effects have not been reported following topical ocular use of this product, caution is advised when used concomitantly with systemic aminoglycoside or polymyxin B therapy.

Prolonged use of ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, reduced visual acuity and visual field defects, and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and frequently. This is especially important in paediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults.

The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.

Corticosteroids may reduce resistance to and aid in the establishment of bacterial, viral, or fungal infections and mask the clinical signs of infection, preventing recognition of ineffectiveness of the antibiotic, or may suppress hypersensitivity reactions to substances in the product. Fungal infection should be suspected in patients with persistent corneal ulceration who have been or are receiving these drugs and corticosteroid therapy should be discontinued if fungal infection occurs.

To avoid the risk of enhancement of herpetic corneal disease, frequent slip lamp examination is essential.

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. (See section 4.5).

Contact lens wear is not recommended during treatment of an ocular infection. Therefore, patients should be advised not to wear contact lenses during treatment with DEXATROL.

DEXATROL ophthalmic suspension contains benzalkonium chloride as a preservative which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

DEXATROL ointment also contains lanolin which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems.

Concomitant and/or sequential use of an aminoglycoside (neomycin) and other systemic, oral, or topical drugs that have neurotoxic, ototoxic, or nephrotoxic effects may result in additive toxicity and should be avoided, whenever possible.

If more than one ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart.

4.6 Pregnancy and Lactation

Fertility:

There are no available data on the use of this medicine affecting male or female fertility.

Pregnancy:

There are no or limited amount of data from the use of DEXATROL in pregnant women. Studies in animals with some active components of DEXATROL have shown reproductive toxicity .

DEXATROL is not recommended during pregnancy.

Lactation:

It is unknown whether topical ophthalmic dexamethasone, neomycin or polymyxin B are excreted in human milk. Because systemic corticosteroids and aminoglycosides may be distributed into milk, a risk to the suckling child cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue therapy with DEXATROL taking into account the benefit of breast-feeding for the child and the benefit of the product to the woman.

4.7 Effects on ability to drive and use machines

DEXATROL has no or negligible influence on the ability to drive and use machines. As with any other eye drop, temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If transient blurred vision occurs upon instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

the most common adverse reactions of DEXATROL were ocular discomfort, keratitis, and eye irritation, occurring in 0.7% to 0.9% of patients.

The following adverse effects are classified according to the following convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥ 1/10,000 to <1/1000), very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in decreasing order of seriousness. The adverse reactions were obtained from clinical trials and postmarketing spontaneous reports.

Immune system disorders:

Uncommon: hypersensitivity (systemic or ocular) Nervous system disorders: Not known: headache Eye disorders:

Uncommon: keratitis, intraocular pressure increased, vision-blurred, photophobia, mydriasis, eyelid ptosis, eye pain, eye swelling, eye pruritus, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, increased lacrimation

Not known: corneal thinning

Description of selected adverse event:

Due to the steroid component, in diseases causing thinning of the cornea or sclera there is a higher risk for perforation especially after long treatments (See Section Special warnings and precautions for use).

Topical ophthalmic steroid use may result in increased intraocular pressure with damage to the optic nerve, reduced visual acuity and visual field defects. Also it may lead to posterior subcapsular cataract formation (See Section Special warnings and precautions for use).

Sensitivity to topically administered aminoglycosides may occur in some patients (See Section Special warnings and precautions for use). Systemic side effects may occur with extensive use.

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 the national pharmacovigilance reporting system.

4.9 Overdose

No case of overdose has been reported.

Signs and symptoms of an overdosage of DEXATROL may be similar to adverse reaction effects seen in some patients (punctuate keratitis, erythema, increased lacrimation, oedema and lid itching).

Due to the characteristics of this preparation, intended for topical use, no toxic effects are expected when administered to the eye neither at the recommended dose nor in the event of accidental ingestion of the contents of a bottle.

A topical ophthalmic overdose of DEXATROL may be flushed from the eye(s) with lukewarm water.

5. Pharmacological properties

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: ophthalmologicals; anti-infectives
Mechanism of Action:

DEXATROL has a dual effect: suppression of inflammation symptoms by the corticosteroidal component dexamethasone, and an anti-infective effect due to the presence of two antibiotics, polymyxin B and neomycin. Dexamethasone is a synthetic glucorticoid with potent anti-inflammatory activity. Polymyxin B is a cyclic lipopeptide that penetrates the cell wall of gram-negative bacilli to destabilize the cytoplasmic membrane. It is generally less active against gram-positive bacteria. Neomycin is an aminoglycoside antibiotic that primarily exerts its effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

Mechanism of Resistance:

Resistance of bacteria to polymyxin B is of chromosomal origin and is uncommon. A modification of the phospholipids of the cytoplasmic membrane appears to play a role.

Resistance to neomycin occurs by several different mechanisms including (1) alterations of the ribosomal subunit within the bacterial cell; (2) interference with the transport of neomycin into the cell, and (3) inactivation by an array of adenylating, phosphorylating, and acetylating enzymes. Genetic information for production of inactivating enzymes may be carried on the bacterial chromosome or on plasmids.

Breakpoints:

Each gram of DEXATROL contains 6000 IU polymyxin B sulphate and 3500 IU neomycin sulphate. The breakpoints and the in vitro spectrum as mentioned below are based on the dual activity of either polymyxin B or neomycin. The breakpoints listed here are based upon acquired resistance for specific species found in ocular infections and the ratio in International Units of polymyxin B to neomycin in DEXATROL:

Resistance breakpoints:>5:2.5 to>40:20 depending upon the bacterial species Susceptibility:

The information listed below provides guidance on the approximate probabilities on the susceptibility of microorganisms to polymyxin B or neomycin in DEXATROL. The presentation below lists bacterial species recovered from external ocular infections of the eye.

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the combination of polymyxin B or neomycin as in DEXATROL in at least some types of infections is questionable.

Commonly Susceptible Species:

Aerobic Gram-positive microorganisms:

Bacillus cereus

Bacillus megaterium

Bacillus pumilus

Bacillus simplex

Corynebacterium accolens

Corynebacterium bovis

Corynebacterium macginleyi

Corynebacterium propinquum

Corynebacterium pseudodiphtheriticum

Staphylococcus aureus (methicillin susceptible - MSSA)

Staphylococcus capitis

Staphylococcus epidermidis (methicillin susceptible - MSSE)

Staphylococcus pasteuri

Staphylococcus warneri

Streptococcus mutans

Aerobic Gram-negative microorganisms:

Haemophilus influenzae

Klebsiella pneumoniae

Moraxella catarrhalis

Moraxella lacunata

Pseudomonas aeruginosa Serratia species

Species for which acquired resistance might be a problem:

Staphylococcus epidermidis (methicillin resistant - MRSE)

Staphylococcus hominis Staphylococcus lugdunensis

Inherently resistant organisms:

Aerobic Gram-positive microorganisms:

Enterococci faecalis

Staphylococcus aureus (methicillin resistant - MRSA)

Streptococcus mitis

Streptococcus pneumoniae

Anaerobic Bacteria:

Propionibacterium acnes

Dexamethasone is a moderately powerful corticosteroid having good penetration in ocular tissue. Corticosteroids have an anti-inflammatory as well as a vasoconstrictive effect. They suppress the inflammatory response and symptoms in various disorders without basically curing these disorders.

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 requested to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

5.2 Pharmacokinetic properties

Dexamethasone, like other corticosteroids, is absorbed rapidly after oral administration and has a biological half-life of about 190 minutes. Sufficient absorption may occur after topical application to the skin and eye to produce systemic effects. Intraocular penetration of dexamethasone occurs in significant amounts and contributes to the effectiveness of dexamethasone in anterior segment inflammatory disease.

Polymyxin B sulphate is not absorbed from the gastrointestinal tract or through intact skin, although the intact corneal epithelium prevents penetration into the corneal stroma, therapeutic concentrations do enter the stroma after epithelial damage. Good stromal penetration occurs after epithelial abrasion following topical instillation, subconjunctival injection, or corneal bath. No significant polymyxin B penetration into the vitreous is demonstrable after parenteral or local administration of the drug.

Neomycin is poorly absorbed from the gastrointestinal tract and after topical administration an insufficient amount is absorbed to produce systemic effects. Absorption has been reported to occur from wounds and inflamed skin. After absorption neomycin is rapidly excreted by the kidneys in active form.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Ointment: Anhydrous lanolin, chlorobutanol, yellow soft paraffin.
Drops: Hydroxypropyl Methylcellulose, benzalkonium Chloride 10 % solution, disodium edentate, sodium Chloride, polysorbate 80, sodium hydroxide or hydrochloric Acid, water for injection

6.2 Incompatibilities
Not known.

6.3 Shelf-Life
Dexatrol ophthalmic Ointment: Ophthalmic tube 5 g.
Dexatrol ophthalmic & otic suspension: 5 ml Plastic dropper bottle.

6.4 Special Precautions for Storage
Do not store above 30°C. After opening, to be used within 28 days at room temperature.

Keep away from direct sunlight.

Do not refrigerate.

Keep the container tightly closed.

6.5 Nature and Content of container
Dexatrol ophthalmic Ointment: Ophthalmic tube 5 g.
Dexatrol ophthalmic & otic suspension: 5 ml Plastic dropper bottle.

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

7. Marketing Authorization Holder
Egyptian International Pharmaceutical Industries Co. (EIPICO),
10th of Ramadan City-first industrial area B1,
Egypt

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H2025/CTD11078/22640

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