

Dexonex-C[™] Steroidal Eye/Ear Drops

Dexamethasone Phosphate 0.1% and Chloramphenicol 0.5% Eye/Ear Drops

EPTICO-D EYE/EAR DROPS is a combination of chloramphenicol, broad spectrum antimicrobial and dexamethasone, a potent corticosteroid.

Dexamethasone is one of the most potent corticosteroids; it is 5 -14 times more potent than prednisolone and 25 - 75 times more potent than cortisone and hydrocortisone. Of paramount importance with regard to local therapy is the fact that dexamethasone is over 2000 times more soluble than hydrocortisone or prednisolone. Thanks to the addition of chloramphenicol, a broad-spectrum antibiotic, this combination yields excellent results in inflammation of the anterior uvea (iritis, iridocyclitis).

COMPOSITION

Dexonex-C[™] Eye/Ear Drops: Each ml contains Dexamethasone sodium phosphate 1 mg and Chloramphenicol 5 mg;

INDICATION

Eye:

For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. They are also indicated in chronic anterior uveitis and corneal injury from chemical radiation or thermal burns or penetration of foreign bodies. The combination can also be used for post-operative inflammation and any other ocular inflammation associated with infection.

Ear:

Otitis externa, Otitis media and chronic suppurative otitis media.

DOSAGE AND ADMINISTRATION

Eye

Corneal Ulcers: The recommended dosage regimen for the treatment of corneal ulcer is two drops into the affected eye every 15 minutes for the first six hours and then two drops into the affected eye every 30 minutes for the remainder of the first day. On the second day, instill two drops in the affected eye hourly. On the third through the fourteenth day, place two drops in the affected eye every four hours. Treatment may be continued after 14 days if corneal re-epithelialization has not occurred.

Bacterial Conjunctivitis: The recommended dosage regimen for the treatment of bacterial conjunctivitis is one or two drops instilled into the conjunctival sac(s) every two hours while awake for two days and one or two drops every four hours while awake for the next five days.

Ear:

For all infections two to three drops every two to three hours initially. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

CONTRAINDICATION

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and in many other viral diseases of the conjunctiva and cornea. Mycobacterial infections

of the eye, Fungal diseases of ocular structures.

Hypersensitivity to any of the components of the medication.

WARNING

Prolonged use may result ocular hypertension or glaucoma, with damage to the optic nerve, defects in the visual acuity and fields of vision and posterior sub-capsular cataract formation. Prolonged use may suppress the host response and thus increase the hazards of secondary ocular infections. If this product is used for 10 days or longer, intraocular pressure should be monitored routinely. Not for injection in the eye.

PRECAUTION

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.

USE IN PREGNANCY AND LACTATION

USFDA Pregnancy category C

There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Caution should be exercised when Dexamethasone ophthalmic solution is administered to a nursing woman.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

SIDE EFFECT

Adverse reactions seen with Chloramphenicol are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness and eye pain.

STORAGE

Store below 30°C in a cool and dry place protected from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 30 days of first opening.

HOW SUPPLIED

Dexonex-C[™] Eye/Ear Drops: Each plastic dropper bottle contains 5/10/15 ml of Dexamethasone Sodium Phosphate BP sterile solution.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH