

Sterile Eye/Ear Drops

Composition

Stedex[™]-C Sterile Eye/Ear Drops: Each ml drops contains Chloramphenicol BP 5 mg & Dexamethasone Phosphate USP 1 mg..

Pharmacology

Chloramphenicol is a bacteriostatic antibiotic with a broad spectrum of action against both Gram-positive and Gram-negative bacteria as well as some other organisms.

Dexamethasone is a glucocorticoid. It has anti-inflammatory and anti-allergic action. It is used topically in the treatment of inflammatory conditions of the anterior segment of the eye.

Indications

Eye: For steroid-responsive inflammatory ocular condition for which a corticosteriod is indicated and where bacterial infection or a risk of bacterial ocular infection exists. For inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitis is accepted to obtain a diminution in edema and inflammation. For chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies. Ear: Otitis externa, Otitis media and chronic suppurative otitis media.

Dosage & Administration

Eye: 1 or 2 drops is instilled into the affected eyes every 3 or 4 hours, or more frequently if deemed advisable by the prescribing physician. Administration should be continued day and night for the first 48 hours, after which the interval between applications may be increased. Treatment should be continued for at least 48 hours after the eye appears normal or as directed by the physician.

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 or as directed by the physician.

Contraindications

It is contraindicated in fungal, viral, tuberculous and other infections of the eye and in glaucoma. It is also contraindicated in patients hypersensitive to any component of this product. The use of anti-infective and steroid is always contraindicated after uncomplicated removal of a corneal foreign body.

Warning & Precaution

Prolonged use of steroids containing product may result in posterior subcapsular cataract formation and glaucoma with optic nerve damage. Intraocular pressure monitoring needed. It delays wound healing. The prolonged use of antibiotics may occasionally result in over growth of non-susceptible organisms, including fungi. If new infections appear during treatment, the drug should be discontinued and appropriate measures should be taken.

Side Effects

Blood dyscrasias have been reported in association with the local use of chloramphenicol. Allergic sensitization may occur with the local use of chloramphenicol. Elevation of intraocular pressure with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing may occur with the use of steroids. Secondary infection has occurred after use of combinations containing steroids and antimicrobials

Use in Pregnancy & Lactation:

The safety during pregnancy and laction has not been established.

Use in Children & Adolescents

No data found.

Drug Interactions

No data found

Overdosage

Storage

Store below 30°C, away from light and in a dry place. Keep all medicine out of the reach of children.

Packing
Stedex[™]-C Sterile Eye/Ear Drops: Each plastic dropper bottle contains 5 ml Sterile Eye/Ear Drops.

Manufactured by: Navana Pharmaceuticals Ltd. Rupshi, Rupganj, Narayanganj, Bangladesh NCLT0521_01-22_03

