

Chloramphenicol 0.5%
Dexamethasone Phosphate 0.1%
Eye Drops

Composition:

Sonexa-C Eye Drops: Each ml contains Chloramphenicol BP 5 mg & Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 1 mg.

Preservative: Phenylmercuric Acetate USP-NF 0.002%.

Vehicle: HPMC USP 0.5%.

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

Indications:

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 steriod use in certain infective conjunctivitis is accepted to obtain a diminution in oedema and inflammation. For chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

Dosage and Administration:

1 drop 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 eve appears normal.

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 steriod is always contraindicated after uncomplicated removal of a corneal foreign body.

Precautions :

Prolonged use of steroids containing product may result in posterior subcapsular cataract formation and glaucoma with optic nerve damage. Intraocular pressure monitoring is 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 steriods.

Secondary infection has occured after use of combinations containing steriods and antimicrobials. Fungal infections of the cornea are particularly prone to develop with the long term application of steriods. Secondary bacterial ocular infection following suppression of host responses also occur.

Use in pregnancy and Lactation:

It should only be administered during pregnancy if the potential benefit exceeds the foreseeable risk to the fetus. It should be given in lactating mother if clearly indicated by the physician.

Storage:

- Keep unopened bottle at 2-8°C. After opening keep the bottle in a dry place below 25°C.
- Should be dispensed only on the prescription of a registered physician.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

Sonexa-C Eye Drops: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.





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