

Chlormet® Eye Drops
Dexamethasone Phosphate 0.1%
Chloramphenicol 0.5%

Description: Dexamethasone is a 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. 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.

Chloramphenicol is a broad spectrum bacteriostatic antibiotic active against a wide variety of gram-negative and gram-positive organisms. Chloramphenicol exerts its antibacterial effect by binding to bacterial ribosomes and inhibiting bacterial protein synthesis at an early stage.

Indications

For steroid-responsive inflammatory ocular condition for which a corticosteroid 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 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 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.

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.

Adverse 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. Fungal infections of the cornea are particularly prone to develop with the long term applications of steroids. Secondary bacterial ocular infection following suppression of host responses also occur.

Precautions: 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. In all serious infections topical use of chloramphenicol should be supplemented by appropriate systemic medication. Chloramphenicol should be reserved for use only in infections for which it is specifically indicated. Bone marrow hypoplasia, including aplastic anaemia has been reported following topical use of chloramphenicol. The product should not be used during pregnancy and lactation.

High Risk Group: Pregnancy & Lactation:

Dexamethasone: There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human pregnancy.

Chloramphenicol: The safety of chloramphenicol eye drops during pregnancy and lactation has not been established. As this product is for sale without prescription it is not recommended for use during pregnancy. In view of the fact that chloramphenicol may appear in breast milk, use of the product during lactation should be avoided.

Drug Interactions:

Dexamethasone: None relevant to topical use.

Chloramphenicol: Chloramphenicol should not be administered simultaneously with bactericidal substances (penicillins, cephalosporins, gentamicin, tetracyclines, polymyxin B, or vancomycin) since bacteriostatic antibiotics may inhibit bactericidal antibiotics. Furthermore Chloramphenicol should not be administered at the same time as systemic treatment with drugs which have an adverse effect on hematopoiesis, nor simultaneously with sulphonylureas, coumarin derivatives, hydantoins and methotrexate (precautionary measure).

Pharmaceutical Precautions: Store below 25°C preferably in a refrigerator; do not freeze, away from light. Keep out of reach of children.

Commercial Pack: Chlormet® Eye Drops: Plastic dropper bottle contains 5 ml sterile eye drops. Each ml contains Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 1 mg and Chloramphenicol BP 5 mg.

Manufactured by
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