

Description

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. Bacterial species like *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, Other beta-haemolytic streptococci, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae* are recognised conjunctival pathogens and may be susceptible to chloramphenicol.

Indications

Eye: Chloramphenicol eye drops is indicated in surface bacterial infection involving conjunctiva or cornea. Sepsis caused by some species of *Bacteroides* may respond to chloramphenicol eye drops.

Ear: Chloramphenicol can inhibit or destroy the bacteria present in ear canal.

Dosage and Administration

Eye: *Adults, children aged 2 years and over and elderly:* One drop instilled into the infected eye every 2 hours for the first 48 hours and 4 hourly thereafter. To be used during waking hours only. The course of treatment is 5 days. Treatment should continue for 5 days even if symptoms improve.

Ear: 2-3 drops into ear canal three to four times daily.

Contraindications

Chloramphenicol eye drops must not be administered to:

- Patients who have a history of hypersensitivity to chloramphenicol or to

any other ingredient of the drops.

- Patients who have experienced myelosuppression during previous exposure to chloramphenicol.
- Patients with a family history of blood dyscrasias.

Adverse Effects

Transient burning or stinging sensations may occur with the use of chloramphenicol eye drops. Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis. Treatment must be discontinued immediately in such cases.

Bone marrow depression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

Precautions

Chloramphenicol therapy is associated with a potential risk of aplastic anaemia or other hematodyscrasias. A careful risk/benefit evaluation should therefore be made in each individual case. The product should only be used where alternative therapies are ineffective and/or contraindicated.

High risk group

Pregnancy: 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.

Nursing Mothers: In view of the fact that chloramphenicol may appear in breast milk, use of the product during lactation should be

avoided.

Drug Interactions

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 measured).

Overdosage

In view of the relatively small amount of chloramphenicol in chloramphenicol eye drops, overdosage with this product is unlikely to constitute a hazard. No specific treatment would be required.

Pharmaceutical Precautions

Store below 25° C, preferably in a refrigerator; do not freeze. Keep out of reach of children.

Commercial Pack

Ocutex[®] Eye/Ear Drops: Plastic dropper bottle contains 10 ml sterile eye drops. Each ml contains Chloramphenicol BP 5 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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IL 1960

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