

Ocubac

Chloramphenicol BP 0.5%

Sterile Eye/Ear Drops

Composition:

Each ml eye/ear drops contains Chloramphenicol BP 5 mg.

Description:

Chloramphenicol is a broad spectrum antibiotic which was first isolated from cultures of *Streptomyces venezuelae* but it is now produced synthetically.

Chloramphenicol is an antibiotic which is mainly bacteriostatic in action, but exerts a bactericidal effect against some strains of Gram-positive cocci and against *Haemophilus Influenzae* and *Neisseria*. It has a broad spectrum of action against both Gram-positive and Gram-negative bacteria, *Rickettsiae* and *Chlamydia*.

Chloramphenicol binds specifically to the 50s subunit of 70s ribosomes, preventing its movement along messenger RNA, which occurs in the early stages of protein synthesis. Chloramphenicol also inhibits NADH oxidase, affecting the mitochondrial respiratory chain. Chloramphenicol penetrates the cornea thoroughly, and therapeutically effective concentrations are detectable in the aqueous humour only 15-30 minutes after local administration. The half life is 3-5 hours. In the inflamed eye, the retention time is expected to be shorter.

Indications and usage:

Chloramphenicol ophthalmic solution is used --

- For the treatment of bacterial conjunctivitis and other superficial ocular infections caused by Chloramphenicol sensitive organisms.
- Infection prophylaxis pre and post-operatively.
- After chemical or other burn.
- Trachoma.
- For prophylactic and therapeutic irrigation of the tear ducts.

Contraindications:

Known hypersensitivity to any ingredient of the product--

- Acute intermittent porphyria
- Severe blood disorders and hepatic dysfunctions due to bone marrow depression.
- New-born babies
- Family history of bone marrow depression

Precautions:

If no improvement is seen after 7-8 days' treatment, other therapeutic measures should be adopted. The treatment should also be discontinued in the presence of an allergic reaction. Caution is advisable when Chloramphenicol is administered to children. In very rare instances, cases of aplastic anemia were observed after topical long-term treatment (over 3 months duration) with Chloramphenicol.

Side-effects:

Local: Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis, may occasionally occur.

Systemic: Rarely, cases of major adverse haematological events (bone marrow depression, aplastic anaemia etc.) have been reported following ocular use of Chloramphenicol.

Drug Interactions:

Chloramphenicol should not be administered simultaneously with bactericidal substances (penicillins, cephalosporins, gentamicin, tetracyclines, polymyxin B, vancomycin or sulphadiazine) since bacteriostatic antibiotics may inhibit bactericidal antibiotics.

Dosage and administration:

Insert 1 drop into the conjunctival sac 2-4 times per day. In acute cases up to 1 drop every hour. Children: No specific data are available and thus no specific dosage recommendation can be given.

Storage :

Store in a cool & dry place, protected from light, use within one month after the first opening & Keep out of the reach of children.

Packing :

Each plastic dropper bottle contains 10 ml sterile Eye/Ear Drops.



Manufactured by
Apex Pharma Ltd.
(Eye Care Division)
Shafipur, Gazipur