CHLOROMYCETIN APLICAP

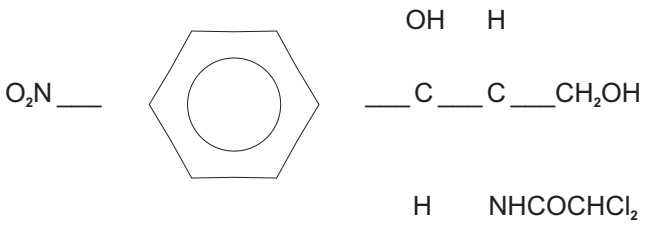
(Chloramphenicol eye ointment 1%)

In line with
CPL Sept.99

PRESCRIBING INFORMATION

Description

Chloramphenicol is an antibiotic originally isolated from Streptomyces venezuelae. Its chemical name is 2,2-Dichloro-N- [(2R,3R)-3-hydroxy-2-hydroxymethyl-4-nitrophenethyl]acetamide, $C_{11}H_{12}Cl_2N_2O_5$. Its molecular weight = 323.1. The structure for Chloramphenicol is:



Chloramphenicol occurs as fine, white to grayish or yellowish white, needle-like crystals, has a solubility of approximately 2.5 mg/ml in water at 25 ° C, and is freely soluble in alcohol. The pK_a of the drug is 5.5.

Chloromycetin Aplicap is a pliable gelatin capsule containing chloramphenicol ointment for single application. Each Aplicap contains 250 mg of chloramphenicol eye ointment I.P. (1%) in an oleaginous ointment base.

CLINICAL PHARMACOLOGY

Chloramphenicol is a broad-spectrum antibiotic with primarily bacteriostatic activity. It inhibits protein synthesis by interfering with the transfer of activated amino acids from soluble RNA to ribosomes.

It has been noted that chloramphenicol is found in measurable amounts in the aqueous humor following local application to the eye. Development of resistance to chloramphenicol can be regarded as minimal for staphylococci and many other species of bacteria.

INDICATIONS AND USAGE

Chloramphenicol should be reserved for serious infections caused by organisms susceptible to its antimicrobial effects when less potentially hazardous therapeutic agents are ineffective or contraindicated. Bacteriological studies should be performed to determine the causative organisms and their sensitivity to chloramphenicol.

Chloromycetin Aplicap is indicated for the treatment of surface ocular infections involving the conjunctiva and/or cornea caused by chloramphenicol susceptible organisms.

Chloromycetin Aplicap is effective against the following common bacterial eye pathogens :
Staphylococcus aureus,
Streptococci, including Streptococcus pneumoniae,
Escherichia coli,
Hemophilus influenzae,
Klebsiella/Enterobactor species,
Moraxella lacunata (Morax-Axenfeld bacillus),
Neisseria species.

This product does not provide adequate coverage against Pseudomonas aeruginosa, Serratia marcescens.

CONTRAINDICATIONS

Chloramphenicol is contraindicated in individuals with a history of hypersensitivity and/or toxic reaction to the product or its components.

WARNINGS

Bone marrow hypoplasia, including aplastic anemia and death, has been reported following local application of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment. Eye ointments may retard corneal wound healing.

PRECAUTIONS

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. If infection caused by nonsusceptible organisms appear during therapy, its use should be discontinued and appropriate measures should be taken. In all serious infections, the topical use of chloramphenicol should be supplemented by appropriate systemic medication.

ADVERSE REACTIONS

Blood dyscrasias have been reported in association with the use of chloramphenicol (See Warnings). Chloramphenicol is absorbed systemically from the eye, and toxicity has been reported following chronic exposure. Dose-related toxicity following a single ocular exposure is unlikely. Local irritation with the ophthalmic form may include subjective symptoms of itching or burning. More serious side effects such as angioneurotic edema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported in patients sensitive to chloramphenicol and are causes for discontinuing the medication. Similar sensitivity reactions to other materials in topical preparations also may occur.

OVERDOSAGE

Accidental ingestion of Chloromycetin Aplicap is unlikely to cause systemic toxicity due to the low content of antibiotic. However, it should be kept out of reach of infants and small children. If irritation, pain, swelling, lacrimation, or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated with copious amounts of room temperature water for at least 15 minutes. If symptoms persist after 15 minutes of irrigation, an ophthalmologic examination should be considered.

DOSAGE AND ADMINISTRATION

Each Aplicap contains sufficient medication for a single application to both eyes.

A small amount of ointment should be placed in the lower conjunctival sac every three hours, or more frequently if deemed advisable by the prescribing physician. The 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.

The aplicap minimizes cross contamination of patients and the possibility of introducing a new infection.

To use the aplicap, wipe the tip with alcohol, cut the end with a clean instrument and compress the body to squeeze out the contents.

STORAGE

Keep bottles securely closed in a cool, dry place. Protect from light.