

CHLOROMYCETIN- chloramphenicol ointment
PARKE-DAVIS

Chloromycetin® Ophthalmic Ointment, 1%
(Chloramphenicol Ophthalmic Ointment, USP)

WARNING

Bone marrow hypoplasia including aplastic anemia and death has been reported following topical application of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment.

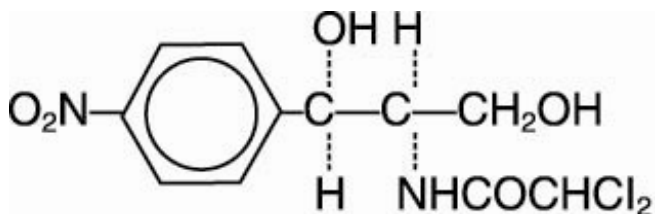
Description

Each gram of Chloromycetin Ophthalmic Ointment, 1% contains 10 mg of chloramphenicol in a special base of liquid petrolatum and polyethylene. It contains no preservatives. Sterile ointment.

The chemical names for chloramphenicol are:

- (1) Acetamide, 2,2-dichloro-*N*-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl) ethyl]-, and
- (2) *D-threo*-(—)-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-nitrophenethyl] acetamide.

Chloramphenicol has the following empirical and structural formulas:



$C_{11}H_{12}Cl_2N_2O_5$

Mol Wt 323.13

Clinical Pharmacology

Chloramphenicol is a broad-spectrum antibiotic originally isolated from *Streptomyces venezuelae*. It is primarily bacteriostatic and acts by inhibition of 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 used only in those serious infections for which less potentially dangerous drugs are ineffective or contraindicated. Bacteriological studies should be performed to determine the causative organisms and their sensitivity to chloramphenicol (see Boxed Warning).

Chloromycetin Ophthalmic Ointment, 1% (Chloramphenicol Ophthalmic Ointment, USP) is indicated for the treatment of surface ocular infections involving the conjunctiva and/or cornea caused by chloramphenicol-susceptible organisms.

The particular antiinfective drug in this product is active against the following common bacterial eye pathogens:

Staphylococcus aureus

Streptococcus, including *Streptococcus pneumoniae*

Escherichia coli

Haemophilus influenzae

Klebsiella/Enterobacter species

Moraxella lucunata

(Morax-Axenfeld bacillus)

Neisseria species

This product does not provide adequate coverage against:

Pseudomonas aeruginosa

Serratia marcescens

Contraindications

This product is contraindicated in persons sensitive to any of its components.

Warnings

SEE BOXED WARNING

Ophthalmic ointments may retard corneal wound healing.

Precautions

The prolonged use of antibiotics may occasionally result in overgrowth of nonsusceptible organisms including fungi. If new infections appear during medication, the drug 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).

Allergic or inflammatory reactions due to individual hypersensitivity and occasional burning or stinging may occur with the use of Chloromycetin Ophthalmic Ointment.

Dosage and Administration

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

How Supplied

N 0071-3070-07

Chloromycetin Ophthalmic Ointment, 1% (Chloramphenicol Ophthalmic Ointment, USP) is supplied,

sterile, in ophthalmic ointment tubes of 3.5 grams.

Chloromycetin, brand of chloramphenicol. Reg US Pat Off
Caution—Federal law prohibits dispensing without prescription.

March 1997

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CHLOROMYCETIN

chloramphenicol ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0071-3070
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
chloramphenicol (UNII: 66974FR9Q1) (chloramphenicol - UNII:66974FR9Q1)		10 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0071-3070-07	3.5 g in 1 TUBE		

Labeler - PARKE-DAVIS

Revised: 10/2006

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