

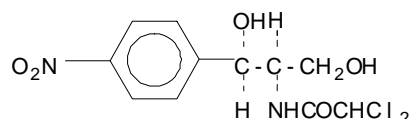
DATA SHEET

CHLOROMYCETIN[®] EAR DROPS

(chloramphenicol 5 mg per mL)

The active component of CHLOROMYCETIN ear drops is chloramphenicol.

Structure of chloramphenicol:



DESCRIPTION

Chloramphenicol is a white to greyish-white or yellowish-white, fine crystalline powder or fine crystals, needles or elongated plates. Soluble 1 in 400 of water, 1 in 2.5 of alcohol, and 1 in 7 of propylene glycol; freely soluble in acetone and ethyl acetate; slightly soluble in ether. A 2.5% suspension in water has a pH of 4.5 to 7.5.

Chemical Name: 2,2-Dichloro-N-[(α R, β R)- β -hydroxy- α -hydroxymethyl-4-nitrophenethyl] acetamide.

Molecular Formula: C₁₁H₁₂Cl₂N₂O₅

Molecular Weight: 323.1

CHLOROMYCETIN ear drops contain chloramphenicol 5 mg per 1 mL of purified water with boric acid, borax and phenylmercuric nitrate as the preservative.

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.

Pharmacokinetics

Chloramphenicol is rapidly absorbed from the gastrointestinal tract when given by mouth and widely distributed throughout most body tissues and fluids. It is inactivated primarily in the liver by glucuronyl transferase and excreted mainly in the urine.

INDICATIONS

CHLOROMYCETIN ear drops are indicated for the short term treatment of infections in otitis externa due to chloramphenicol-sensitive organisms in patients with intact tympanic membranes.

CONTRAINDICATIONS

Perforated tympanic membrane is considered a contraindication to the use of this medication in the external ear canal.

CHLOROMYCETIN ear drops are contraindicated in individuals with a history of hypersensitivity and/or toxic reaction to chloramphenicol or any of its components.

PRECAUTIONS

Discontinue promptly if sensitisation or irritation occurs.

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

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of non-susceptible organisms, including fungi. If infections caused by non-susceptible 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.

Use in pregnancy (Category A) and lactation

There are no studies to establish the safety of this drug in pregnancy.

Systemically absorbed forms of chloramphenicol enter the fetal circulation and are distributed into breast milk. If given systemically to the mother shortly before parturition or whilst breastfeeding, chloramphenicol may cause bone marrow suppression of the neonate or the “grey baby syndrome”, characterised by cyanosis and hypothermia, owing to the limited glucuronidating capacity of the newborn infant's liver. However, limited absorption following otic use at the recommended dosage is generally not expected to pose a risk to the fetus or the neonate.

ADVERSE REACTIONS

The following clinical adverse experiences have been observed with the use of chloramphenicol. More serious side effects (indicated by *) have been reported in patients sensitive to chloramphenicol and are causes for discontinuing the medication.

Blood and lymphatic system disorders: Blood dyscrasias have been reported in association with the use of chloramphenicol (see PRECAUTIONS).

Immune system disorders: anaphylaxis*

Skin and subcutaneous tissue disorders: angioneurotic oedema,* urticaria,* vesicular and maculopapular dermatitis,* superinfection, such as with *Candida* may occur.

General disorders and administration site conditions: local irritation may include subjective symptoms of itching and burning, fever,* similar sensitivity reactions to other materials in topical preparations also may occur.

Interactions with other drugs: systemically absorbed/administered forms of chloramphenicol have been known to interact with certain drugs.

DOSAGE AND ADMINISTRATION

Instil four drops in the affected ear(s) four times daily, or as directed by a physician. Discard the solution within one month of opening the container.

OVERDOSAGE

Accidental ingestion of the drug is unlikely to cause any toxicity due to the low content of antibiotic. Each mL of CHLOROMYCETIN ear drops contains 19 mg of borax/boric acid as buffer and if accidentally ingested by infants or young children, a local Poisons Information Centre should be contacted. It is advisable to keep medication out of reach of children.

PRESENTATION

Ear Drops, plastic dropper bottle (with tamper seals): 5 mg per mL. 5 mL.

Store between 2°C and 8°C. After dispensing, the drops may be stored below 25°C for up to 1 month and should then be discarded. Protect from light.

MEDICINE CLASSIFICATION

Prescription Medicine.

SPONSOR

Pfizer New Zealand Ltd
PO Box 3998
Auckland
New Zealand

Toll free number: 0800 736 363

DATE OF PREPARATION

1 March 2005