PRODUCT INFORMATION
CHLOROMYCETIN EAR DROPS
chloramphenicol 5 mg per mL

NAME OF THE MEDICINE

The active component of CHLOROMYCETIN ear drops is chloramphenicol.

\[\text{Chemical Name: } 2,2\text{-Dichloro-N-}\{(\alpha R,\beta R)-\beta\text{-hydroxy-}\alpha\text{-hydroxymethyl-4-nitrophenoxyethyl}\}\text{ acetamide.}\]

\[\text{Molecular Formula: } C_{11}H_{12}Cl_{2}N_{2}O_{5}\]

\[\text{Molecular Weight: } 323.1.\]

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.

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

PHARMACOLOGY

Pharmacodynamics

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

Treatment of otitis externa due to chloramphenicol sensitive organisms. May be used with caution in patients with chronic suppurative otitis media.

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 be used with caution in patients who have been identified as having an individual or family history of blood disorders. 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 foetal 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 ‘gray 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 foetus or the neonate.

INTERACTIONS WITH OTHER MEDICINES

Systemically absorbed/administered forms of chloramphenicol have been known to interact with certain drugs.
ADVERSE EFFECTS

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:** Bone marrow hypoplasia, including aplastic anaemia and death*, blood disorder (see PRECAUTIONS).

**Immune System Disorders:** Anaphylactic reaction*, reaction to drug excipients.

**Nervous System Disorders:** Burning sensation.

**Skin and Subcutaneous Tissue Disorders:** Angioedema*, urticaria*, rash vesicular*, rash maculopapular*, pruritus.

**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, pyrexia*

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.

CHLOROMYCETIN ear drops are recommended for short-term use only.

OVERDOSAGE

Accidental ingestion of CHLOROMYCETIN ear drops is unlikely to cause systemic toxicity due to the low content of antibiotic. Each mL of CHLOROMYCETIN ear drops contains 19 mg of borax/boric acid as buffer. It is advisable to keep medication out of reach of children. If accidentally ingested by infants or young children, a local Poisons Information Centre should be contacted. As there is individual variability in the pharmacokinetics of chloramphenicol in infants and children monitor plasma levels. Levels exceeding 25 micrograms/mL are frequently considered toxic.

Contact the Poisons Information Centre on 13 11 26 for advice on the management of an overdose.

PRESENTATION AND STORAGE CONDITIONS

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

**Storage Conditions**

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.

NAME AND ADDRESS OF THE SPONSOR

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Rd
WEST RYDE NSW 2114

POISON SCHEDULE

Schedule 4 (Prescription Only Medicine).

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

9 September 1996

DATE OF MOST RECENT AMENDMENT

7 March 2014