AUSTRALIAN PRODUCT INFORMATION – CHLOROMYCETIN (CHLORAMPHENICOL) EAR DROPS

1. NAME OF THE MEDICINE

Chloramphenicol

2. QUALITATIVE AND QUANTITATIVE

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

3. PHARMACEUTICAL FORM

Ear drops.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Dose and method of administration

Dosage

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.

4.3 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.

4.4 Special warnings and precautions for use

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 the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 Interactions with other medicines and other forms of interactions

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

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category A

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

Use in lactation

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.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (undesirable 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 section **4.4 Special warnings and precautions for use**).

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*

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 Overdose

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.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

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.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

Boric acid

Borax

Phenylmercuric nitrate

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

Plastic dropper bottle with tamper seals: 5 mL.

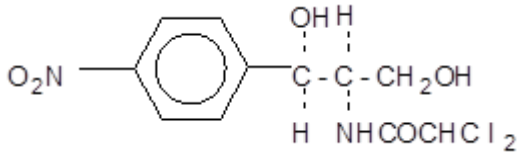
6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

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 structure



Chemical Name

2,2-Dichloro-N-[(αR,βR)-β-hydroxy-α-hydroxymethyl-4-nitrophenethyl] acetamide.

Molecular formula

$C_{11}H_{12}Cl_2N_2O_5$

Molecular weight

323.1

CAS Number

56-75-7

7. MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 (Prescription Only Medicine).

8. SPONSOR

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Toll Free Number: 1800 675 229
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9. DATE OF FIRST APPROVAL

9 September 1996

10. DATE OF REVISION

06 November 2019

Summary Table of Changes

Section changed	Summary of new information
All	All sections reformatted in line with the new form.
6.7	Addition of CAS number
8	Update sponsor address.