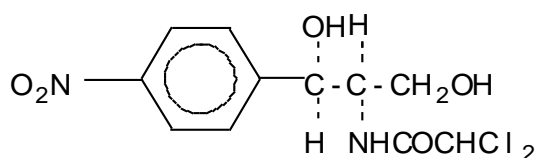


PRODUCT INFORMATION

CHLOROMYCETIN[®] EYE DROPS

NAME OF THE MEDICINE

The active component of CHLOROMYCETIN eye drops is chloramphenicol.



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

Molecular Formula: C₁₁H₁₂Cl₂N₂O₅

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 eye 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 found in measurable amounts in the aqueous humor following local application to the eye.

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

For the treatment of bacterial conjunctivitis. For use under medical supervision only in the treatment of other superficial ocular infections caused by chloramphenicol-sensitive organisms.

CONTRAINDICATIONS

CHLOROMYCETIN eye drops are contraindicated in individuals with a history of hypersensitivity and/or toxic reaction to chloramphenicol or any other component of the medication.

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.

Ophthalmic agents may retard corneal wound healing.

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. If infections 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.

Chloramphenicol eye preparations should not be recommended for OTC use under the following circumstances:

- Photophobia
- Severe pain in the eye or pain and swelling around the eye
- Loss of, reduced or blurred vision
- Restriction of eye movement
- Cloudy cornea
- Copious yellow-green purulent discharge that accumulates after being wiped away
- Abnormal pupils
- Injury to the eye or suspicion of a foreign body in the eye
- History of welding without eye protection immediately prior to onset of symptoms
- Glaucoma
- Dry eye syndrome
- Individuals who wear contact lenses except on medical advice
- Patient is using other eye preparations at the time of presentation
- Patient has had eye surgery or laser treatment in the past six months

- Individual or family history of bone marrow problems
- Recent overseas travel
- Patient has had similar symptoms in the past
- Patient feels unwell
- Children under the age of 2 years except on medical advice
- Use for longer than 5 days unless on medical advice.

In these cases, referral to a doctor or optometrist is required.

Use in Pregnancy (Category A) and Lactation

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

Systemically absorbed/administered 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 neonate's liver. However, limited absorption following ophthalmic 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

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. 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. The adverse reactions are listed by system organ class and frequency (Common: $\geq 1\%$ and $< 10\%$, Uncommon: $\geq 0.1\%$ and $< 1\%$, Not known: Cannot be estimated from available data).

Blood and Lymphatic System Disorders

Not known: Blood disorder (see PRECAUTIONS).

Immune System Disorders

Uncommon: Hypersensitivity.

Not known: Anaphylactic reaction*, reaction to drug excipients.

Nervous System Disorders

Uncommon: Burning sensation.

Eye Disorders

Common: Eye swelling, ocular hyperaemia.

Skin and Subcutaneous Tissue Disorders

Not known: Angioedema*, rash vesicular*, urticaria*, rash maculopapular*, pruritus.

General Disorders and Administration Site Conditions

Not known: Pyrexia*.

DOSAGE AND ADMINISTRATION

Instil one or two drops in the affected eye(s) two to six-hourly for two to three days. The interval between applications may then be increased. Discard the solution within one month of opening the container.

Blinking following eye drop instillation discourages the intraocular penetration of a drug which minimises therapeutic effect and maximises systemic toxicity. Nasolacrimal occlusion (NLO) and eyelids closure (ELC) improves intraocular penetration and decreases systemic absorption.

Instructions to Patients

- If symptoms worsen at any time or if the eye infection does not improve within 48 hours, seek prompt medical advice.
- Do not use in children under 2 years of age except on medical advice.
- Patients who wear contact lenses should be advised to seek medical advice from their doctor or optometrist before using Chloromycetin. Contact lenses should not be worn during the course of Chloromycetin treatment. If wearing hard or disposable contact lenses, patients can start using their contact lenses again after successfully completing the course of treatment. If wearing soft contact lenses, patients should wait 24 hours after successfully completing the course of treatment before starting to use their lenses again.
- Treatment should be continued for at least 2 days after the eye appears normal but do not use for longer than 5 days except on medical advice.

OVERDOSAGE

Accidental ingestion of chloramphenicol eye drops is unlikely to cause any toxicity due to the low content of antibiotic. Each mL of CHLOROMYCETIN eye 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 microgram/mL are frequently considered toxic.

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.

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

PRESENTATION AND STORAGE CONDITIONS

Eye Drops, plastic dropper bottle (with tamper seals): 10 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 3 (Pharmacist Only Medicine).

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

9 September 1996

DATE OF MOST RECENT AMENDMENT

3 February 2014