

## AUSTRALIAN PRODUCT INFORMATION

# CHOLFEN<sup>®</sup> EYE DROPS AND CHOLFEN<sup>®</sup> EYE OINTMENT



*chloramphenicol eye drops and chloramphenicol eye ointment*

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## 1 NAME OF THE MEDICINE

Chloramphenicol

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

CHOLFEN EYE DROPS contains 0.5% w/v chloramphenicol in aqueous base thickened with hypromellose.

CHOLFEN EYE OINTMENT contains 1% w/w chloramphenicol in a sterile oculentum base.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

## 3 PHARMACEUTICAL FORM

CHOLFEN EYE DROPS is a clear to slightly hazy colourless, slightly viscous liquid and odourless.

CHOLFEN EYE OINTMENT is a pale yellow opaque ointment.

## 4 CLINICAL PARTICULARS

### 4.1 THERAPEUTIC 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.

### 4.2 DOSE AND METHOD OF ADMINISTRATION

#### CHOLFEN EYE DROPS

Adults and children 2 years and over: Instil 1 or 2 drops in the affected eye(s) every two to six hours for two to three days. The interval between applications may then be increased. Treatment should be continued for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice.

To minimise contamination do not allow the dropper to contact the surface of the eye. Discard solution within one month of opening container.

The systemic absorption of CHOLFEN EYE DROPS can be minimised by applying gentle pressure on the tear-duct for approximately one minute immediately after application.

#### CHOLFEN EYE OINTMENT

Adults and children 2 years and over: Apply 1.5 cm of ointment into the affected eye(s) every 3 hours. If ointment is used together with drops for day and night coverage, 1.5 cm should be applied before bedtime, while using the drops during the day. Continue treatment for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice.

To minimise contamination do not allow the tip to contact the surface of the eye.

CHOLFEN EYE DROPS AND CHOLFEN EYE OINTMENT are not recommended for children under 2 years except on medical advice.

### 4.3 CONTRAINDICATIONS

Chloramphenicol is contraindicated in individuals with a history of hypersensitivity to any excipients and/or toxic reaction to the drug.

### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

#### Identified precautions

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. Ophthalmic agents may retard corneal wound healing.

The use of this antibiotic, as with other antibiotics, may result in the 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.

The mechanism for the irreversible aplastic anaemia following ophthalmic use of chloramphenicol has not been established.

Chloramphenicol eye drops and ointment 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
- Contact lens wear
- 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
- Patient is a contact lens user
- Patient is using other eye drops or eye ointments 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

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

#### Instructions to Patients

- If symptoms worsen at any time or if the eye infection does not improve within 48 hours, seek prompt medical advice.
- Patients who wear contact lenses should be advised to seek advice from their doctor or optometrist before using CHOLFEN EYE DROPS and CHOLFEN EYE OINTMENT. Contact lenses should not be worn during the course of CHOLFEN EYE DROPS and CHOLFEN EYE OINTMENT treatment. If wearing **hard** or **disposable** contact lenses, patients can start using their lenses again after successfully completing the course of treatment. If wearing **soft** contact lenses, patients should wait 24 hours after successfully completing a course of treatment before starting to use their lenses again.

**Use in Hepatic Impairment**

No data available.

**Use in Renal Impairment**

No data available.

**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**

No data available.

**4.6 FERTILITY, PREGNANCY AND LACTATION****Effects on Fertility****CHOLFEN EYE DROPS**

Excipients containing boron such as boric acid or borate compounds have been shown to cause reduced fertility and effects on embryofetal development in animal studies and this appears to be dose related. The relevance of this to humans is uncertain.

**CHOLFEN EYE OINTMENT**

No data available.

**Use in Pregnancy****Category A**

Systemically absorbed/ administered forms of chloramphenicol enter the foetal circulation. If given systemically to the mother shortly before parturition, chloramphenicol may cause bone marrow suppression or “grey 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 recommended dosage is generally not expected to pose a risk to the foetus or neonate.

**Use in Lactation**

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 the “grey 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 neonate.

**4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

CHOLFEN EYE DROPS AND EYE OINTMENT may distort vision temporarily. It is recommended that patients using CHOLFEN EYE DROPS AND EYE OINTMENT understand how it may affect them before driving a motor vehicle, or operating machinery.

## 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Blood dyscrasias have been reported in association with the use of chloramphenicol (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE). 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. Local irritation with the ophthalmic form may include subjective symptoms of itching or burning. More serious side effects such as angioneurotic oedema; anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported in patients sensitive to chloramphenicol and are causes for discontinuing the medication. Similar sensitivity reactions to other materials in topical preparations also may occur.

### 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](http://www.tga.gov.au/reporting-problems).

## 4.9 OVERDOSE

Accidental ingestion of the drug is unlikely to cause any toxicity due to low content of antibiotic.

CHOLFEN EYE DROPS contains 19 mg/mL of borax/boric acid as buffer.

If the eye drops or eye ointment is accidentally ingested by infants or young children, Poisons Information Centre (Telephone 13 11 26 in Australia) should be contacted. The medication should be kept out of reach of children.

### Treatment:

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 ophthalmological examination should be considered.

## 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

No data available.

### 5.3 PRECLINICAL SAFETY DATA

#### Genotoxicity

No data available.

#### Carcinogenicity

No data available.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 LIST OF EXCIPIENTS**

#### CHOLFEN EYE DROPS

Phenylmercuric nitrate, Boric acid, Borax, Hypromellose, Water for Injection.

Phenylmercuric nitrate (0.002% w/v) is used as a preservative.

#### CHOLFEN EYE OINTMENT

Liquid paraffin, White soft paraffin, Wool fat.

Contains no preservatives.

### **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**

#### CHOLFEN EYE DROPS

Store between 2 - 8°C until opened. Refrigerate. Do not freeze. On opening the drops may be stored at room temperature (below 25°C). Discard 4 weeks after opening. Protect from light.

#### CHOLFEN EYE OINTMENT

Store below 25°C. Discard 4 weeks after opening. Protect from light.

### **6.5 NATURE AND CONTENTS OF CONTAINER**

#### CHOLFEN EYE DROPS

Plastic dropper bottle contains 10 mL sterile eye drops.

#### CHOLFEN EYE OINTMENT

5 g tube with an ophthalmic cap.

### **Australian Register of Therapeutic Goods (ARTG)**

AUST R 349371 – CHOLFEN EYE DROPS chloramphenicol 5 mg/mL bottle

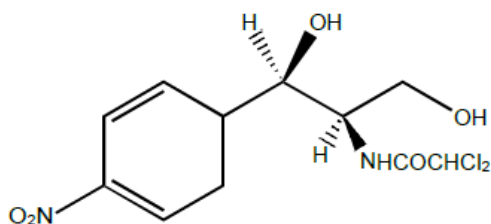
AUST R 380304 – CHOLFEN EYE OINTMENT chloramphenicol 10 mg/g eye ointment tube

### **6.6 SPECIAL PRECAUTIONS FOR DISPOSAL**

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

## 6.7 PHYSICOCHEMICAL PROPERTIES

### Chemical Structure



Molecular formula is  $C_{11}H_{12}Cl_2N_2O_5$  and a molecular weight of 323.1.

### Physical and Chemical Properties

Chloramphenicol exists as a white to greyish-white or yellowish white, fine crystalline powder or fine crystals, needles or elongated plates.

Chloramphenicol is slightly soluble in water (1 in 400), chloroform and ether. Freely soluble in ethanol (1 in 2.5), propylene glycol (1 in 7), acetone and ethyl acetate.

### CAS Number

56-75-7

## 7 MEDICINE SCHEDULE (POISONS STANDARD)

S3 (Pharmacist Only Medicine)

## 8 SPONSOR

Alphapharm Pty Ltd trading as Viatris

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## 9 DATE OF FIRST APPROVAL

CHOLFEN EYE DROPS: 23/11/2020

CHOLFEN EYE OINTMENT: 06/12/2021

## 10 DATE OF REVISION

03/03/2025

### Summary Table of Changes

Section Changed	Summary of New Information
ALL	Minor editorial changes include combining the Product Information of CHOLFEN EYE DROPS and CHOLFEN EYE OINTMENT
4.6	Included boron-containing excipients and fertility concerns.

CHOLFEN® is a Viartis company trade mark

**CHOLFEN EYE DROPS and CHOLFEN EYE OINTMENT\_pi\Mar25/00**