AUSTRALIAN PRODUCT INFORMATION – CHOLFEN (CHLORAMPHENICOL) EYE DROPS

1 NAME OF THE MEDICINE

Chloramphenicol

2 and 3 QUALITATIVE AND QUANTITATIVE COMPOSITION and PHARMACEUTICAL FORM

CHOLFEN EYE DROPS is a clear to slightly hazy colourless, slightly viscous liquid and odourless. It contains chloramphenicol 0.5% w/v in aqueous base thickened with hypromellose. Phenylmercuric nitrate (0.002% w/v) is used as a preservative.

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.

For the full list of excipients, see Section 6.1 List of excipients.

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

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.

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 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.

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. Contact lenses should not be worn during the course of CHOLFEN EYE DROPS. 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 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

No data available

Use in pregnancy

The Australian categorisation definition of:

Category A: Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.
Systemically absorbed/administered forms of chloramphenicol enter the foetal circulation and are distributed into breast milk. If given systematically 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 foetus or neonate.

Use in lactation.

No data available

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

CHOLFEN EYE DROPS may distort vision temporarily. It is recommended that patients using CHOLFEN EYE DROPS 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 Precautions).** 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.

4.9 OVERDOSE

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

Accidental ingestion of the drug is unlikely to cause any toxicity due to low content of antibiotic. CHOLFEN EYE DROPS contains 18.80 mg/mL of borax/boric acid as buffer. If the eye drops are accidentally ingested by infants or young children, Poisons Information Centre (Telephone 13 11 26) should be contacted. The medication should be kept out of reach of children.

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

Absorption

No data available

Distribution

No data available

Metabolism

No data available

Excretion

No data available

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

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

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 - 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.

6.5 NATURE AND CONTENTS OF CONTAINER

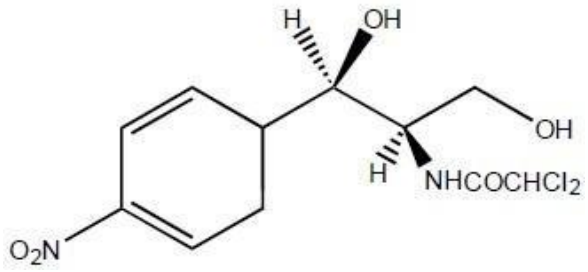
Plastic dropper bottle contains 10 ml sterile eye drops.

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.

CAS number

The CAS number of chloramphenicol is *CAS - 56-75-7*

7 MEDICINE SCHEDULE (POISONS STANDARD)

PHARMACIST ONLY MEDICINE: S3

8 SPONSOR

BEXIMCO PHARMACEUTICALS AUSTRALIA PTY LTD.

4 Miami Key, Broadbeach Waters, QLD 4218

9 DATE OF FIRST APPROVAL

23/11/2020

10 DATE OF REVISION

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information