AUSTRALIAN PRODUCT INFORMATION – MINIMS® CHLORAMPHENICOL 0.5% EYE DROPS

1 NAME OF THE MEDICINE

Chloramphenicol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Minims Chloramphenicol Eye Drops contain chloramphenicol 0.5% (5 mg/mL). No preservatives are included in the formulation.

Excipients with known effect
Minims Chloramphenicol contains borax and boric acid.

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

3 PHARMACEUTICAL FORM

A single-use eye drops, solution.

Minims Chloramphenicol Eye Drops are single-use, clear, colourless sterile eye drops. No preservatives are included in the formulation.

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

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of drops. This blocks the passage of the drops via the naso-lacrimal duct to wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.

Adults and children 2 years of age and over: one to two drops applied to each affected eye every two to six hours for two to three days. The interval between applications may then be increased. Severe infections may require one to two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled.

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.

Each Minims unit should be discarded after a single dose.

Minims Chloramphenicol should not be given to children less than 2 years old as it contains boron and may impair fertility in the future.

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

This product 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 wearer
- 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 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.

In severe infections topical use of chloramphenicol should be supplemented with appropriate systemic treatment.

The use of this antibiotic, as with other antibiotics, may result in the overgrowth of non-susceptible organisms, including fungi. If infections caused by non-susceptible organism appear during therapy, its use should be discontinued and appropriate measures taken.

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 this product. Contact lenses should not be worn during the course of treatment with this product. 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.

Local Effects:
Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis may occur.

Discontinue promptly if sensitisation or irritation occurs.

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

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 chloramphenicol may retard corneal wound healing.

Use in the elderly

No data available

Paediatric use

Minims Chloramphenicol should not be given to children less than 2 years old as it contains boron and may impair fertility in the future.

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Chymotrypsin (an eye drop used during cataract surgery) may not work properly if it is given at the same time as Minims Chloramphenicol.

4.6 FERTILITY, PREGNANCY AND LACTATION (CATEGORY A)

Effects on fertility

No data available

Use in pregnancy – Pregnancy 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 foetus having been observed.

Systematically 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.

There are no studies on use in lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery unless vision is clear.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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.

Blood dyscrasias have been reported in association with use of chloramphenicol (refer to 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 singular ocular exposure is unlikely.

Signs of local irritation with subjective symptoms of itching or burning. More serious side effects include 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 material in topical preparations may also occur.

4.9 OVERDOSE

Accidental ingestion of the drug is unlikely to cause any toxicity due to the low content of antibiotic. Minims Chloramphenicol contain borax and boric acid as a buffer and if ingestion by infants or young children occurs, the Poisons Information Centre should be contacted. It is advisable to keep medication out of the reach of children.

Treatment:

If irritation, pain, lacrimation or photophobia occurs 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 ophthalmic examination should be considered.

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, which is effective against both Gram-positive and Gram-negative organisms. Chloramphenicol is bacteriostatic and acts by inhibition of protein synthesis. Chloramphenicol is an antimicrobial substance produced by the growth of certain strains of *Streptomyces venezuelae*.

Clinical trials

This information is not available.

5.2 PHARMACOKINETIC PROPERTIES

Chloramphenicol is rapidly absorbed after oral administration. In the liver, chloramphenicol is inactivated by conjugation with glucuronic acid or by reduction to inactive aryl amines. Excretion is mainly renal, though some bile excretion occurs following oral administration.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Borax, boric acid and purified water.

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 at 2ºC to 8ºC. Refrigerate. Do not freeze. Do not expose to strong light.

6.5 NATURE AND CONTENTS OF CONTAINER

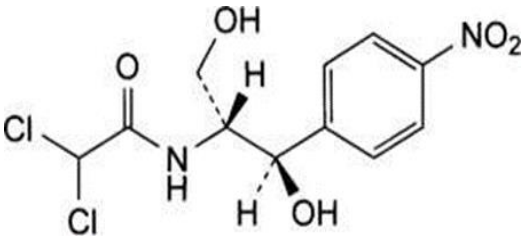
Minims Chloramphenicol Eye Drops are supplied as a clear colourless sterile eye drops in a single use polypropylene tube (unit) overwrapped in a polyester sachet. The sachets are packed in cartons of 20 units. Each unit containing approximately 0.5 mL solution.

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

Chemical structure



CAS number

56-75-7

Chemical name: 2,2-dichloro-N-[(α-R, β-R)-β-hydroxy-α-hydroxymethyl-4-nitrophenethylene]-acetamide

Molecular formula: $C_{11}H_{12}Cl_2N_2O_5$

Molecular weight: 323.1

Chloramphenicol is a white to greyish-white or yellowish-white, fine crystal powder or fine crystals, needles or elongated plates.

7 MEDICINE SCHEDULE (POISONS STANDARD)

Pharmacist Only Medicine: S3

8 SPONSOR

Bausch & Lomb (Australia) Pty Ltd
Level 2, 12 Help Street
Chatswood, NSW 2067

9 DATE OF FIRST APPROVAL

30th October 1991

10 DATE OF REVISION

31st August 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
2, 4.2 and 4.4	Update as per EMA guidance in relation to boron