NEW ZEALAND DATA SHEET

1 MINIMS Chloramphenicol, eye drops solution 0.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5mL contains 5 mg of Chloramphenicol.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear, colourless, single use, sterile eye drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol is indicated for the topical treatment of infections due to micro- organisms sensitive to the anti-infective.

4.2 Dose and method of administration

Adults (including the elderly) and children:

One to two drops applied topically to each affected eye up to six times daily or more frequently if required. (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).

The product is not recommended for children under 2 years of age except on medical advice. If used in children under 2 years of age the following is recommended dosage: One drop in the affected eye(s) four times daily for five days.

4.3 Contraindications

Use in patients with a history of hypersensitivity or toxicity to chloramphenicol or any other component of the preparation.

4.4 Special warnings and precautions for use

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

Aplastic anaemia has, very rarely, followed topical use of chloramphenicol eye drops and, whilst this hazard is an uncommon one, it should be borne in mind when the benefits of the use of chloramphenicol are assessed.

Prolonged use should be avoided as it may increase the likelihood of sensitisation and the emergence of resistant organisms.

Chloramphenicol should be reserved for use only in infections for which it is specifically indicated.

Contact lenses should be removed during the period of treatment.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the

passage of the drops via the naso lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

4.5 Interaction with other medicaments and other forms of interaction

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established, therefore, use only when considered essential by the physician.

Excipients containing boron have been shown to cause reduced fertility and effects on embryofoetal development in animal studies and this appears to be dose related. The relevance of this to humans is uncertain.

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 Undesirable effects

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

Systemic:
Rarely, cases of major adverse haematological events (bone marrow depression, aplastic anaemia and death) have been reported following ocular use of chloramphenicol.

Possible Side Effects:
Angioedema (with not known frequency).

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Not applicable.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chloramphenicol is an antibiotic which is mainly bacteriostatic in action, but exerts a bactericidal effect against some strains of gram-positive cocci and against Haemophilus Influenzae and Neisseria. It has a broad spectrum of action against both gram-positive and gram-negative bacteria, rickettsiae and chlamydia.

Chloramphenicol binds specifically to the 50s subunit of 70s ribosomes, preventing its

movement along messenger RNA, which occurs in the early stages of protein synthesis.

Chloramphenicol also inhibits NADH oxidase, affecting the mitochondrial respiratory chain.

5.2 Pharmacokinetic properties

In a study in patients, instillation of chloramphenicol eye drops to the eye (2 drops of a 0.5% solution instilled every 5 minutes for a total of 6 doses, into the eyes of 14 patients) gave concentrations of chloramphenicol of 3.5 - 6.7μg/ml in the aqueous humour.

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

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the data sheet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax
Boric acid
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store between 2° and 8°C. Do not freeze. Protect from light.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch.

6.6 Special precautions for disposal

Each Minims unit should be discarded after a single use.

7 MEDICINE SCHEDULE

Prescription medicine.

8 SPONSOR

Bausch & Lomb (NZ) Ltd
c/- Bell Gully
Auckland Vero Centre
48 Shortland Street
Auckland 1140 New Zealand

9 DATE OF FIRST APPROVAL

01 April 1977

10 DATE OF REVISION OF THE TEXT

11 August 2021

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.2 and 4.6	Update in accordance with the recommendations of the Medicines Adverse Reactions Committee for medicines with boron-containing excipients.