

New Zealand Data Sheet

1. CHLORSIG (Eye drops 0.5% and Eye ointment 1%)

2. QUANTITATIVE AND QUALITATIVE COMPOSITION

Chlorsig eye drops contain chloramphenicol 0.5% w/v in aqueous base thickened with hypromellose. Phenylmercuric acetate (0.002% w/v) is used as a preservative.

Chlorsig eye ointment contains chloramphenicol 1.0% w/w in a sterile ointment base. Contains no preservatives.

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

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chlorsig eye drops is a clear to slightly hazy colourless, slightly viscous liquid and odourless.

Chlorsig eye ointment is a yellowish-white unctuous ointment, free of visible contamination. Odour faintly of paraffin and wool fat.

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

CHLORSIG EYE DROPS:

For adults and children (2 years and over): Instil 1 or 2 drops in the affected eye(s) every two to six hours for up to 5 to three days. The interval between applications may then be increased. To minimise contamination do not allow the dropper to contact the surface of the eye. Discard solution within one month of opening container.

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

The systemic absorption of CHLORSIG eye drops can be minimised by applying gentle pressure on the tear-duct for a few minutes immediately after application.

CHLORSIG EYE OINTMENT:

For adults and children (2 years and over): Apply 1.5cm into lower eye lid of the affected eye every three hours for up to 5 days. If ointment is used together with drops for day and night coverage, 1.5cm should be applied before bedtime, while using the drops during the day. To minimise contamination do not allow the tip to contact the surface of the eye.

Chlorsig is not recommended for children under 2 years except on medical advice.

Treatment should be continued for at least 48 hours after the eye appears normal.

The systemic absorption of CHLORSIG 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 medicine.

4.4 Special warnings and precautions for use

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 non-susceptible organisms, including fungi. If infections caused by non-susceptible 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 Chlorsig. Contact lenses should not be worn during the course of Chlorsig 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.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Fertility

No data available. Excipients containing boron such as boric acid or borate compounds 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.

Pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Blood dyscrasias have been reported in association with the use of chloramphenicol (see Warnings and 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 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

Accidental ingestion of the medicine is unlikely to cause any toxicity due to low content of antibiotic. CHLORSIG EYE DROPS contains 18.80mg/ml of borax/boric acid as buffer with less than 0.13mg/ml of sodium hydroxide. If the eye drops are accidentally ingested by infants or young children, Poisons Information Centre (Telephone: 0800 764 766) 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.

{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 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.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CHLORSIG EYE DROPS and CHLORSIG EYE OINTMENT contain the following excipients:

Chlorsig Eye Drops	Chlorsig Eye Ointment
Phenylmercuric acetate	liquid paraffin
Boric acid	white soft paraffin
Borax	Wool fat
Hypromellose	
Sodium hydroxide	
Purified Water	

6.2 Incompatibilities

No data available.

6.3 Shelf-life

Chlorsig Eye Ointment: 36 months from date of manufacture.

Chlorsig Eye Drops: 24 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze)

6.4 Special precautions for storage

CHLORSIG EYE DROPS: Store between 2-8°C. Refrigerate. Do not freeze. After dispensing, store below 25°C. Discard one month after opening. Protect from light.

CHLORSIG EYE OINTMENT: Store below 25°C.

6.5 Nature and contents of container

Packaged Quantities

CHLORSIG EYE DROPS: 10mL plastic dropper bottle with tamper seals.

CHLORSIG EYE OINTMENT: 4g tube with an ophthalmic cap.

6.6 Special precautions for disposal (and other handling)

No data available.

7. MEDICINE SCHEDULE

Restricted Medicine.

8. SPONSOR

Pharmacy Retailing (NZ) Limited Trading as Healthcare Logistics
58 Richard Pearce Drive
Airport Oaks
Auckland
New Zealand

9. DATE OF FIRST APPROVAL

1st March 2011

10. DATE OF REVISION OF THE TEXT

5th October 2021

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All sections revised	Update to the SPC-style format
4.2, 4.6	Included dosage of Eye Drops for children below 2 years of age, and boron-containing excipients and fertility concerns.

Please note: Chlorsig eye drops are not available in New Zealand.