

# PRODUCT INFORMATION

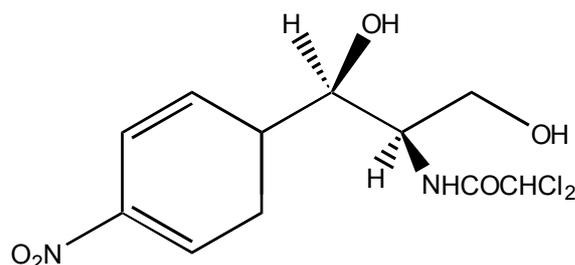
## CHLORSIG

### NAME OF DRUG

**CHLORSIG EYE DROPS** contains 0.5% w/v chloramphenicol.

**CHLORSIG EYE OINTMENT** contains 1.0% w/w chloramphenicol.

The structural formula of chloramphenicol (CAS - 56-75-7) is:



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.

### DESCRIPTION

**CHLORSIG 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 acetate (0.002% w/v) is used as a preservative.

**CHLORSIG EYE OINTMENT** is a yellowish-white, slightly translucent suspension ointment, free of visible contamination, with an odour faintly of paraffin and wool fat. It contains chloramphenicol 1.0% w/w in a sterile oculentum base. Contains no preservatives.

#### **Excipients**

**CHLORSIG Eye Drops and CHLORSIG Eye Ointment** contain the following excipients:

<b>CHLORSIG EYE DROPS</b>	<b>CHLORSIG EYE OINTMENT</b>
Phenylmercuric acetate	Paraffin - liquid
Boric acid	Paraffin - soft white
Borax	Wool fat
Hypromellose	
Sodium hydroxide	
Purified water	

### PHARMACOLOGY

**Actions**

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.

**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.

**CONTRAINDICATIONS**

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

**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 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.

### **Use in Pregnancy (Category A) and lactation:**

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.

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.

## **ADVERSE REACTIONS**

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.

## **DOSAGE and 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 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.

*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 1.5 cm 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, 1.5 cm 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.

### OVERDOSAGE

Accidental ingestion of the drug is unlikely to cause any toxicity due to low content of antibiotic. CHLORSIG EYE DROPS contains 18.80 mg/mL of borax/boric acid as buffer with less than 0.13 mg/mL of sodium hydroxide. If the eye drops are accidentally ingested by infants or young children, Poisons Information Centre (Telephone 131126) 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.

### PRESENTATION

**Chlorsig Eye Drops:** 10 mL plastic dropper bottle with tamper seals.

**Chlorsig Eye Ointment:** 4 g tube with an ophthalmic cap.

### STORAGE

#### CHLORSIG 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.

#### CHLORSIG EYE OINTMENT:

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

### POISONS SCHEDULE:

PHARMACIST ONLY MEDICINE: S3.

## **SPONSOR**

Aspen Pharma Pty Ltd  
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St. Leonards NSW 2065  
Australia

Amendments approved by the Therapeutic Goods Administration on 18 June 1996, 20 November 1998, 8 August 2007 12 Oct 2007 (The product information was initially prepared in the 1980's).

Date of safety-related change notifications to TGA: 19 January 2001 and 27 September 2004.  
Date of most recent amendment: October 2010