Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Chlorsig?

Chlorsig contains the active ingredient chloramphenicol. Chlorsig is used to treat an eye infection called bacterial conjunctivitis, which is a bacterial infection involving the mucous membrane of the surface of the eye.

For more information, see Section <u>1. Why am I using Chlorsig?</u> in the full CMI.

2. What should I know before I use Chlorsig?

Do not use if you have ever had an allergic reaction to Chlorsig or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Chlorsig? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Chlorsig and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Chlorsig?

- The dose of Chlorsig may be different for each person and their medical condition. Your doctor, optometrist or pharmacist will recommend the right dose for you.
- Usual recommended doses for adults and children (2 years and over): <u>Chlorsig eye drops</u>: Instil 1 or 2 eye drops in the affected eye(s) every two to six hours for up to 5 days or as directed by your doctor, optometrist or pharmacist.

<u>Chlorsig eye ointment</u>: Apply 1.5 cm of eye ointment every three hours for up to 5 days or as directed by your doctor, optometrist or pharmacist.

More instructions can be found in Section <u>4. How do I use Chlorsig?</u> in the full CMI.

5. What should I know while using Chlorsig?

Things you should do	 Use Chlorsig exactly as directed. Remind any doctor, dentist, optometrist or pharmacist you visit that you are using Chlorsig. Tell your doctor immediately if you become pregnant while you are using Chlorsig.
Things you should not do	 Do not use Chlorsig for a longer time than your doctor, optometrist or pharmacist has prescribed. Do not increase the dose or treat any other complaints without first checking with your doctor, optometrist or pharmacist. Do not use Chlorsig to without checking with your doctor, optometrist or pharmacist.
Driving or using machines	Do not drive or operate machinery until you know how Chlorsig affects you.
Looking after your medicine	 Chlorsig eye drops: Store unopened bottles at between 2-8°C in a refrigerator. Do not freeze. Protected from light. After opening, store at room temperature (below 25°C). Discard 4 weeks after opening. Protect from light. Chlorsig eye ointment: Store in a cool, dry place below 25°C, protected from light. Discard 4 weeks after opening.

For more information, see Section <u>5. What should I know while using Chlorsig?</u> in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Chlorsig[®] eye drops and eye ointment

Active ingredient: chloramphenicol

Consumer Medicine Information (CMI)

This leaflet provides important information about using Chlorsig. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Chlorsig.

Where to find information in this leaflet:

- 1. Why am I using Chlorsig?
- 2. What should I know before I use Chlorsig?
- 3. What if I am taking other medicines?
- 4. How do I use Chlorsig?
- 5. What should I know while using Chlorsig?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Chlorsig?

Chlorsig contains the active ingredient chloramphenicol, a synthetic antibiotic. Chlorsig is available as eye drops and eye ointment, for external use only.

Chlorsig is used to treat an eye infection called bacterial conjunctivitis, which is a bacterial infection involving the mucous membrane of the surface of the eye.

The most common symptom is the presence of a sticky yellow-white discharge with mucus and pus (or glued eyes, especially in the morning on waking). Other symptoms include a gritty sensation in the eye, redness, irritation and watering of the eyes. The infection usually starts in one eye and then spreads to the other.

2. What should I know before I use Chlorsig?

Warnings

Do not use Chlorsig if:

- you are allergic to chloramphenicol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- the packaging is torn, broken or shows signs of tampering.
- after the expiry date (EXP.) printed on the pack.

Do not give Chlorsig to children under 2 years of age unless your doctor or optometrist tells you.

Some of the symptoms of an allergic reaction to Chlorsig may include:

• irritation, pain and swelling in the eye

- Skin rashes, blisters
- fever.

Check with your doctor if:

- you or your family have blood disorders (e.g. anaemia) or problems with bone marrow
- you have an injury to the cornea. Eye preparations may inhibit the healing of the wound
- you wear contact lenses.
 - Contact lenses should not be worn during the course of Chlorsig treatment. If you wear hard or disposable contact lenses, you can start using them again after completing the course of treatment. If wearing soft contact lenses, you should wait 24 hours after completing a course of treatment before starting to use them again.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor, optometrist or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor, optometrist or pharmacist if you are breastfeeding or intend to breastfeed.

If you have bought this medicine without a prescription and without prior consultation from a doctor or optometrist, it is important to check the following list. Speak to your doctor or optometrist if any apply before you start to use Chlorsig:

- you are allergic to any other antibiotic eye drops or ointments
- you are using other eye drops or eye ointments
- you have pain within your eye (rather than just feeling sore or gritty)
- swelling around the eye
- blurred vision or sensitivity to light
- limited eye movement
- abnormal pupil (the black circle in the centre of the eye) your eye looks cloudy
- there is copious yellow-green purulent discharge that accumulates after being wiped away
- you have injured your eye or there is a foreign body in the eye
- you have been welding without eye protection immediately before your eye symptoms appeared
- you have glaucoma
- you have dry eye syndrome
- you have had similar symptoms in the past

- you have had eye surgery or laser treatment in the past six months
- you have recently travelled overseas
- you are allergic to any other medicines or any foods, dyes or preservatives
- you have surgery (including dental surgery) using a general anaesthetic
- you feel unwell
- you have any other medical conditions.

If you have not told your doctor or optometrist about any of the above, tell them before you use Chlorsig.

3. What if I am taking other medicines?

Tell your doctor, optometrist or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Chlorsig and affect how it works. These include other eye drops and eye ointments.

These medicines may reduce or increase the effectiveness of Chlorsig, reduce its own effectiveness and/or react with Chlorsig resulting in untoward or sometimes dangerous side effects.

Your doctor, optometrist or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

4. How do I use Chlorsig?

Follow all directions given to you by your doctor, optometrist or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to use

- The dose of Chlorsig may be different for each person and their medical condition. Your doctor, optometrist or pharmacist will recommend the right dose for you.
 Do not use in children under 2 years of age except on doctor's advice.
- The usual recommended doses are:

Chlorsig eye drops:

For adults and children (2 years and over): Instil 1 or 2 eye drops in the affected eye(s) every two to six hours for up to 5 days or as directed by your doctor, optometrist or pharmacist.

Chlorsig eye ointment:

For adults and children (2 years and over): Apply 1.5 cm of eye ointment every three hours for up to 5 days or as directed by your doctor, optometrist or pharmacist. If ointment is used together with drops for day and night coverage, eye ointment should be applied before bedtime while using the drops during the day.

 If the condition does not get better after 2 days, seek medical advice.

How to apply Chlorsig eye drops

wash hands thoroughly before and after use

- open the eye, tilt head back and look upwards
- gently pull down the lower lid to form a pouch
- approach the eye from the side and hold the bottle dropper near the lid, but do not let the tip of the dropper touch the eye, eyelids or lashes
- apply one drop into the pouch
- close the eyes (do not rub them) and try not to blink for a short time
- apply gentle pressure for a few minutes with a finger to the bridge of the nose to prevent the medicine being drained from the eye
- blot excess solution around the eye with a tissue
- if instilling more than one drop in an eye, separate each installation by several minutes to avoid washing drops out of the eye
- to minimise contamination, do not allow the dropper to contact the surface of the eye.

How to apply Chlorsig eye ointment

- wash hands thoroughly before and after use
- tilt head back gently
- gently pull lower eyelid down
- squeeze 1.5 cm of eye ointment inside the lower eyelid, but do not let the tip of the tube touch the eye, eyelids or lashes
- release the eyelid slowly and close eyes gently for 1-2 minutes or blink a few times to help spread the ointment over the eye
- blot excessive ointment from around the eye with a tissue
- to minimise contamination, do not allow the tip to contact the surface of the eye.

Vision may be temporarily blurred. Avoid activities that require good visual ability until vision clears.

How long to use Chlorsig

Chlorsig should be used for up to 5 days or as directed by your doctor, optometrist or pharmacist.

If you forget to use Chlorsig

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

If you are unsure about whether to use your next dose, speak to your doctor, optometrist or pharmacist.

Do not use a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you use too much Chlorsig

Accidental ingestion of the drug in adults is unlikely to cause any toxicity due to the low content of antibiotic, but consult your doctor or Poison Information Centre (see below).

If the eye drops are accidentally ingested by infants or young children, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

• go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Chlorsig?

Things you should do

- Use Chlorsig exactly as directed.
- Tell all doctors, dentists, optometrists or pharmacists who are treating you that you are using Chlorsig.
- Tell your doctor immediately if you become pregnant while you are using Chlorsig.
- Always discuss with your doctor, optometrist or pharmacist any problems or difficulties during or after using this medicine.
- Tell your doctor, optometrist or pharmacist if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise they may think that it was not effective and change your treatment unnecessarily.

Things you should not do

- Do not use Chlorsig for a longer time than your doctor, optometrist or pharmacist has prescribed.
- Do not increase the dose, without first checking with your doctor, optometrist or pharmacist.
- Do not use this medicine to treat any other complaints without checking with your doctor, optometrist or pharmacist
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Do not drive or use any machines or tools until you know how Chlorsig affects you.

Chlorsig may distort your vision temporarily. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous.

Looking after your medicine

Chlorsig eye drops

Store unopened bottles at between 2-8°C in a refrigerator. Do not freeze. Protected from light. After opening, store at room temperature (below 25°C). Discard 4 weeks after opening. Protect from light.

• Chlorsig eye ointment Store in a cool, dry place below 25°C, protected from light. Discard 4 weeks after opening.

Store Chlorsig in a cool dry place away from moisture, heat or sunlight; do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 eye irritation or swelling that may include itching or burning skin rashes or blisters fever. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergy reactions: • fever • rash • swelling of the face, lips, mouth • sore throat that may cause difficulty in swallowing or breathing • shortness of breath • swelling of the hands, feet or ankles.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Chlorsig contains

Chlorsig eye drops

Active ingredient (main ingredient)	chloramphenicol 5 mg/mL (0.5%)
Other ingredients	boric acid
(inactive ingredients)	• borax
	hypromellose
	• sodium hydroxide
	phenylmercuric acetate
	 water-purified

Chlorsig eye drops contain the preservative phenylmercuric acetate (0.002% w/v).

Chlorsig eye ointment

Active ingredient (main ingredient)	chloramphenicol 10 mg/g (1%)
Other ingredients	 paraffin – liquid
(inactive ingredients)	• paraffin - soft white
	• wool fat

Chlorsig eye ointment is free from preservatives.

Do not take this medicine if you are allergic to any of these ingredients.

What Chlorsig looks like

Chlorsig eye drops is in a plastic dropper bottle with tamper seals. It is a clear to slightly hazy, slightly viscous, colourless, odourless liquid (Aust R 19661).

Chlorsig eye ointment is a white opaque ointment in a 4 g tube with an ophthalmic cap (Aust R 19662).

Who distributes Chlorsig

Aspen Pharma Pty Ltd 34-36 Chandos Street St Leonards NSW 2065 Australia

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