

New Zealand Consumer Medicine Information

CHLORSIG (*Klor - sig*)

EYE DROPS and EYE OINTMENT

Chloramphenicol

What is in this leaflet

This leaflet answers some common questions about CHLORSIG.

It does not contain all of the available information.

It does not take the place of talking to your doctor, pharmacist or optometrist.

All medicines have risks and benefits. Your doctor, pharmacist or optometrist has weighed the risks of you taking CHLORSIG against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor, pharmacist or optometrist.

Keep this leaflet with the medicine.

You may need to read it again.

What is CHLORSIG

The name of your medicine is CHLORSIG.

The active ingredient is called *Chloramphenicol*.

Chloramphenicol is a synthetic antibiotic.

CHLORSIG is available as eye drops and eye ointment.

What CHLORSIG is used for

CHLORSIG is used to treat an eye infection called bacterial conjunctivitis

Bacterial conjunctivitis 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. Your doctor may have prescribed CHLORSIG for another purpose.

Ask your doctor, pharmacist or optometrist if you have any questions about why CHLORSIG has been prescribed for you.

Do not use Chlorsig and talk to your pharmacist or doctor straight away if any of the following applies to you.

- You have pain within your eye (rather than just feeling sore or gritty) and swelling around the eye, blurred vision or sensitivity to light
- Your pupil (the black circle in the centre of the eye) may be torn, not round, very big or does not change size in the light
- Your eye looks cloudy
- There is copious yellow-green purulent discharge that accumulates after being wiped away
- You have injured your eye
- You have been welding without eye protection immediately before your eye symptoms appeared
- You have glaucoma
- You have dry eye syndrome
- You are using other eye drops or eye ointments
- You have had similar symptoms in the past few weeks
- You feel unwell

- You have had eye surgery or laser treatment in the past six months
- Recent overseas travel
- You wear contact lenses

If you wear contact lenses and your doctor has advised you to use Chlorsig, do not wear contact lenses during the course of Chlorsig treatment. If you wear hard or disposable contact lenses, you can start using contact lenses again after successfully completing the course of treatment. If wearing soft contact lenses, you should wait 24 hours after successfully completing a course of treatment before starting to use contact lenses again.

Before you use CHLORSIG

When you must not use it

Do not use CHLORSIG if you are allergic to:

- CHLORSIG or any of the ingredients listed at the end of this leaflet
- other antibiotic eye drops or eye ointments

Some of the symptoms of an allergic reaction to CHLORSIG may include irritation, pain and swelling in the eye. Skin rashes, blisters and fever may also occur.

Do not use CHLORSIG after the expiry date (EXP.) printed on the pack.

If you use it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

Do not purchase or use CHLORSIG if the packaging is

torn or shows signs of tampering.

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

Before you start to use it

You must tell your doctor, or pharmacist if:

- 1. you are allergic to any other medicines or any foods, dyes or preservatives**
- 2. you have surgery (including dental surgery) using a general anaesthetic**
- 3. you have any other medical conditions/health problems**
- 4. you are pregnant or plan to become pregnant**

Your pharmacist or doctor will advise you of the risks and benefits of taking Chlorsig in pregnancy.

- 5. you are breastfeeding or plan to breastfeed**

Your pharmacist or doctor will advise you of the risks and benefits of taking Chlorsig while breastfeeding

If you have not told your doctor, pharmacist or optometrist about any of the above, tell them before you take any CHLORSIG.

Taking other medicines

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

Some medicines may interfere with CHLORSIG. These include other eye drops and eye ointments.

These medicines may either 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, pharmacist or optometrist has more information on medicines to be careful with or avoid while using CHLORSIG.

How to use CHLORSIG

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

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to use

The dose of CHLORSIG may be different for each person and their medical condition. Your doctor and pharmacist will recommend the right dose for you.

Do not use Chlorsig in children under 2 years of age except on doctor's advice.

The 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 pharmacist or doctor.
- **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 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, consult your doctor or pharmacist

How to apply the 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 the 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.

- To minimise contamination, do not allow the tip to contact the surface of the eye.

How long to use it

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

If you forget to use it

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

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

Do not use a double dose to make up for the dose that you missed.

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

Do not try to make up for missed doses by using more than one dose at a time.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose):

Accidental ingestion of the drug in adults is unlikely to cause any toxicity due to 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:

Immediately telephone your doctor or Poisons Information Centre (telephone: 0800 764 766) for advice, or go to

Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Urgent medical attention may be needed.

While you are using CHLORSIG

Things you must do:

Use CHLORSIG exactly as your doctor or pharmacist has prescribed.

Tell all doctors, dentists, optometrists and 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 or pharmacist any problems or difficulties during or after taking CHLORSIG.

Tell your doctor, optometrist or pharmacist if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor, optometrist or pharmacist may think that it was not effective and change your treatment unnecessarily.

Things you must not do:

Do not drive or operate machinery until you know how CHLORSIG affects you.

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

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 or pharmacist..

Unless your doctor says to do not use this medicine to treat any other complaints..

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of:

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as distorted or blurred vision, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using CHLORSIG.

CHLORSIG helps most people with eye infections, but it may have unwanted side effects in a few people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist if you have any questions.

Tell your doctor or pharmacist immediately if you notice any of the following:

- local eye irritation with itching or burning
- skin rashes and urticaria
- skin blisters or fever

Check with your doctor or pharmacist as soon as possible if you have any problems while using CHLORSIG even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using CHLORSIG

Storage

Keep *CHLORSIG eye drops*

- In a refrigerator where the temperature stays between 2 - 8°C until opened
- Do not freeze
- On opening the drops may be stored at room temperature (below 25°C)
- Discard 4 weeks after opening
- Protect from light

Keep *CHLORSIG eye ointment*

- in a cool dry place where the temperature stays below 25°C
- Discard 4 weeks after opening

Do not store Chlorsig or any other medicine in a bathroom or near a sink. Do not leave *CHLORSIG* in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep *CHLORSIG* out of the reach of children .

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using *CHLORSIG* or the expiry date has passed, ask your pharmacist what to do with any *CHLORSIG* that is left over.

Product description

What it looks like

CHLORSIG eye drops is in a plastic dropper bottle with tamper seals. It is a clear to slightly hazy colourless, slightly viscous liquid and odourless.

CHLORSIG eye ointment is in a 4g tube with an ophthalmic cap.

Ingredients

CHLORSIG eye drops contain:

Active Ingredient

- Chloramphenicol (5 mg/mL)

Excipients

- phenylmercuric acetate
- boric acid
- borax
- hypromellose
- sodium hydroxide
- purified water

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

CHLORSIG eye ointment contains:

Active Ingredient

- Chloramphenicol (10 mg/g)

Excipients

- Paraffin – liquid
- Paraffin – soft white
- Wool fat

***CHLORSIG eye ointment* is free from preservatives.**

Manufacturer

Aspen Pharma Pty Ltd
(A.C.N. 004 118 594)
96 Merrindale Drive
Croydon Victoria 3136
AUSTRALIA

Telephone: 03 - 9839 2800

The Australian Registration numbers are:
CHLORSIG eye drops AUST R 19661 and *CHLORSIG eye ointment* AUST R 19662.

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