Minims® Chloramphenicol

Consumer Medicine Information (CMI) summary

The full CMI 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 Minims Chloramphenicol?

Minims Chloramphenicol contains the active ingredient chloramphenicol. Minims Chloramphenicol 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 1. Why am I using Minims Chloramphenicol? in the full CMI.

2. What should I know before I use Minims Chloramphenicol?

Do not use if you have ever had an allergic reaction to chloramphenicol 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 Minims Chloramphenicol? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Minims Chloramphenicol 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 Minims Chloramphenicol?

The usual dose in adults and children 2 years and over is one or two drops instilled into each affected eye every two to six hours for two to three days. The interval between applications may then be increased. Continue treatment for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice.

More instructions can be found in Section 4. How do I use Minims Chloramphenicol? in the full CMI.

5. What should I know while using Minims Chloramphenicol?

Things you should do	 Tell your doctor if you are to have or have had eye surgery. If you have any irritation, pain, swelling, excessive tear production or light-sensitivity while using the eye drops, flush the treated eye(s) with lots of water (room temperature) for at least 15 minutes. Stop using the eye drops and contact your doctor. If you wear contact lenses, stop wearing them while you are using Minims Chloramphenicol.
Things you should not do	 Do not stop treatment without first checking with your pharmacist, doctor or optometrist unless you are experiencing painful sensitivity reactions such as irritation, burning, stinging or itching. Do not use this medicine to treat any other complaints unless your doctor tells you to. Do not give this medicine to anyone else, even if you think they have the same condition as you. Do not increase the dose without first checking with your doctor, optometrist or pharmacist.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Minims Chloramphenicol affects you. It may cause blurred vision for a short time when it is instilled into the eye. Allow enough time to regain clear vision before driving or using machines.
Looking after your medicine	Keep the unopened eye drops in a refrigerator (2-8°C) where children cannot reach them. Do not freeze the eye drops or expose them to strong light.

For more information, see Section 5. What should I know while using Minims Chloramphenicol? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them. Less serious side effects include blurred vision and/or problems seeing clearly, local eye irritation, itching or burning. Serious side effects that require urgent medical attention include allergic reaction, symptoms of a blood disorder and effects to the body as a whole. 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.

Minims® Chloramphenicol

Active ingredient: Chloramphenicol

Consumer Medicine Information (CMI)

This leaflet provides important information about using Minims Chloramphenicol. 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 Minims Chloramphenicol.

Where to find information in this leaflet:

- 1. Why am I using Minims Chloramphenicol?
- 2. What should I know before I use Minims Chloramphenicol?
- 3. What if I am taking other medicines?
- 4. How do I use Minims Chloramphenicol?
- 5. What should I know while using Minims

Chloramphenicol?

- 6. Are there any side effects?
- Product details

1. Why am I using Minims Chloramphenicol?

Minims Chloramphenicol contains the active ingredient chloramphenicol. Minims Chloramphenicol is a broad-spectrum antibiotic solution.

Minims Chloramphenicol 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 Minims Chloramphenicol?

Warnings

Do not use Minims Chloramphenicol 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.

Check with your doctor, pharmacist or optometrist if:

- You have had an allergy to any other medicines, foods, preservatives or dyes.
- You have the following symptoms or any other medical conditions, especially:
 - o Photophobia (light sensitivity)
 - o Severe pain in the eye or pain and swelling around the eye

- Loss of, reduced or blurred vision
- o Restriction of eye movement
- o Cloudy-looking eyes
- Large amount of yellow-green, thick, milky discharge that accumulates after being wiped away
- o Abnormal pupil
- o Injury to the eye or suspect there is a foreign body in the eye
- o Glaucoma (high pressure in the eye)
- o Dry eye syndrome
- Any blood disorder such as reduced blood cells, or lack of white blood cells or low blood platelet count.
- You wear contact lenses.
- You have been welding without eye protection immediately prior to onset of symptoms.
- You are currently using other eye drops or eye ointments.
- You had eye surgery or laser treatment in the past six months.
- You have individual or family history of bone marrow problems.
- You recently travelled overseas.
- You have had similar symptoms in the past.
- You feel unwell.
- You take any medicines for any other condition.

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</u>. Are there any side effects?

This medicine has been developed for use in the eye only. It should not be swallowed or injected.

Pregnancy and breastfeeding

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

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

Children

Minims Chloramphenicol should not be given to children less than 2 years old.

3. What if I am taking other medicines?

Tell your doctor 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 and Minims Chloramphenicol may interfere with each other. These medicines may be affected by Minims Chloramphenicol or may affect how well it works. These include:

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 Chymotrypsin (an eye drop used during cataract surgery).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Minims Chloramphenicol.

4. How do I use Minims Chloramphenicol?

How much to use

- Use Minims Chloramphenicol only when prescribed by your pharmacist, doctor or optometrist. The dose of the eye drops may be different for each person and their medical condition. Your pharmacist, doctor or optometrist will tell you how often to use the eye drops and how many drops to use each time.
- The usual dose of Minims Chloramphenicol in adults and children 2 years and over is one or two drops instilled into each affected eye every two to six hours for two to three days. The interval between applications may then be increased.
- Severe infections may require one or two drops every fifteen to twenty minutes to begin with, then gradually reducing the frequency of application as the infection is controlled.
- Continue treatment for at least 48 hours after the eye appears normal.
- Do not use for more than 5 days in total except on medical advice. If the condition becomes worse or does not get better after 2 days, seek medical advice.

How to use Minims Chloramphenicol

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are instilling your own drops, then follow these steps to use the eye drops:

- 1. Wash your hands well with soap and water.
- 2. Shake the container.
- 3. Break the seal.
- 4. Hold the container upside down in one hand between your thumb and forefinger.
- 5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
- 6. Tilt your head back and look up.
- 7. Put the tip of the container close to your lower eyelid. Do not let it touch your eye.
- 8. Release one or two drops into the pouch or pocket formed between your eye and eyelid by gently squeezing the container.
- 9. Close your eye. Do not blink or rub your eye.
- 10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This is very important when administering to children. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body.
- 11. Repeat steps 4-10 for the other eye if needed.
- 12. Throw away any eye drops left in the container.

If you forget to use Minims Chloramphenicol

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

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

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble using your medicine, ask your pharmacist for some hints.

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

If you use too much Minims Chloramphenicol

If you think that you have used too much Minims Chloramphenicol, you may need urgent medical attention.

Accidental swallowing of the solution is unlikely to cause any bad side effects due to the low content of Chloramphenicol.

If you think that you or anyone else may have swallowed Minims Chloramphenicol or used too much Minims Chloramphenicol, you should immediately:

- phone the Poisons Information Centre (in Australia phone 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 Minims Chloramphenicol?

Things you should do

- Tell your doctor if you are to have or have had eye surgery. Your doctor may advise you to stop using Minims Chloramphenicol as it may slow corneal wound healing.
- If you have any irritation, pain, swelling, excessive tear production or light-sensitivity while using the eye drops, flush the treated eye(s) with lots of water (room temperature) for at least 15 minutes. Stop using the eye drops and contact your doctor if symptoms persist.
- If you wear contact lenses, stop wearing them while you are using Minims Chloramphenicol.

Things you should not do

 Do not stop using Minims Chloramphenicol without first checking with your pharmacist, doctor or optometrist unless you are experiencing painful sensitivity reactions such as irritation, burning, stinging or itching. If you do not complete the full course as prescribed by your pharmacist, doctor or optometrist, the infection may not be completely cured. The bacteria may grow again and your symptoms may return.

If you need to stop because of sensitisation, irritation or lack of effect, contact your pharmacist, doctor or optometrist immediately.

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if you think they have the same condition as you.
- Do not increase the dose without first checking with your doctor, optometrist or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Minims Chloramphenicol affects you.

Minims Chloramphenicol generally does not cause any problems with your ability to drive a car or use machines. However, it may cause blurred vision for a short time when it is instilled into the eye. Allow enough time to regain clear vision before driving or using machines.

Looking after your medicine

Keep the unopened eye drops in a refrigerator (2-8°C) where children cannot reach them. Do not freeze the eye drops or expose them to strong light.

When to discard your medicine

Discard each single dose unit and any remaining solution in it immediately after use. Do not save unused contents.

Getting rid of any unwanted medicine

If your doctor tells you to stop using the eye drops 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
blurred vision and/or problems seeing clearly local eye irritation, itching or burning	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
Symptoms of an allergic reaction, such as: shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin. Symptoms of a blood disorder, such as: bruising or bleeding more easily than usual fatigue	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.
Effects to the body as a whole, such as: swelling under the skin red, itchy bumps or hives on the skin fever skin skin rash or blistering skin	

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 online (in Australia, go to www.tga.gov.au/reporting-problems). 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 available from a pharmacist without a doctor's prescription.

What Minims Chloramphenicol contains

Active ingredient (main ingredient)	chloramphenicol (0.5% w/v)	
Other ingredients (inactive ingredients)	purified waterboraxboric acid	

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

The eye drops do not contain any preservatives.

What Minims Chloramphenicol looks like

Minims Chloramphenicol comes in single dose units (tubes) containing 0.5mL of a clear, colourless solution.

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Each tube is wrapped in a polyester sachet. The sachets are packed in cartons of 20 units (AUST R 32263).

Who distributes Minims Chloramphenicol

In Australia, Minims Chloramphenicol is supplied by: Bausch & Lomb (Australia) Pty Ltd Level 2, 12 Help Street

Chatswood, NSW 2067 Phone: 1800 251 150

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