

PRESCRIBING INFORMATION
Including Patient Medication
Information

CHLORAMPHENICOL
Chloramphenicol Ophthalmic Solution, USP 0.5%

Antibiotic

Eberth Pharmaceuticals Inc,
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PRESCRIBING INFORMATION

CHLORAMPHENICOL Chloramphenicol Ophthalmic Solution, USP 0.5%

Antibiotic

ACTION AND CLINICAL PHARMACOLOGY

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. Development of resistance to chloramphenicol can be regarded as minimal for staphylococci and many other species of bacteria.

NON-MEDICINAL INGREDIENTS

Chloramphenicol solution contains boric acid, sodium borate, sodium chloride, sodium hydroxide (to adjust pH) and purified water.

INDICATIONS

This product is indicated for the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by chloramphenicol-susceptible organisms. Bacteriological studies should be performed to determine the causative organisms and their sensitivity to chloramphenicol.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of CHLORAMPHENICOL and other antibacterial drugs, CHLORAMPHENICOL should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

CONTRAINDICATIONS

This product is contraindicated in those persons who have shown hypersensitivity to any of its components.

WARNINGS

Prolonged or frequent intermittent use of topical chloramphenicol should be avoided because of possibility of hypersensitivity reactions, including bone-marrow hypoplasia which may lead to aplastic anemia. Overuse of this product may produce increased redness of the eye.

PRECAUTIONS

Prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If new infections should appear during treatment, the therapy should be altered. In all except superficial infections the topical use of chloramphenicol should be supplemented by appropriate systemic medication.

Susceptibility/Resistance

Development of Drug Resistant bacteria

Prescribing CHLORAMPHENICOL in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant organisms.

Potential for Microbial Overgrowth

Prolonged use of CHLORAMPHENICOL may result in overgrowth of non-susceptible bacteria and fungi. If the infection is not improved following 2 days of treatment, cultures should be obtained to guide further treatment. If such infections occur, discontinue use and institute alternative therapy.

ADVERSE REACTIONS

Blood dyscrasias may be associated with the systemic use of chloramphenicol. One case of bone-marrow hypoplasia following the prolonged (23 month) topical use of chloramphenicol ophthalmic solution has been reported.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

Two drops applied to the affected eye(s) every three hours, or more frequently if deemed advisable by the prescribing physician. Administration should be continued day and night for the first 48 hours, after which the interval between applications may be increased. Treatment should be continued for at least 48 hours after the eye(s) appears normal.

AVAILABILITY

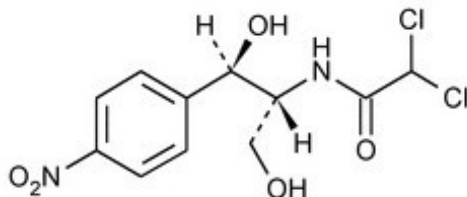
Each mL of sterile ophthalmic solution contains: Chloramphenicol USP 0.5 % (5 mg/mL); and the following non-medicinal ingredients: boric acid, sodium borate, sodium chloride, sodium hydroxide (to adjust pH) and purified water. Available in 15 mL plastic dropper bottles.

STORAGE CONDITIONS

Store between 2°C and 8°C until dispensed. After dispensing, keep the solution at room temperature (between 15°C and 30°C) for 21 days during treatment; after that period, discard unused portion. Protect from light.

PHARMACEUTICAL INFORMATION

Structural Formula:



Chemical Name: 2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-, [R-(R*,R*)]-acetamide

Molecular Formula: C₁₁H₁₂Cl₂N₂O₅

Molecular Weight: 323.13

Description: Fine, white to grayish-white or yellowish-white, needle-like crystals or elongated plates. Freely soluble in alcohol, in propylene glycol, in acetone, and in ethyl acetate; slightly soluble in water.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

CHLORAMPHENICOL
Chloramphenicol Ophthalmic Solution, USP

Read this carefully before you start taking **Chloramphenicol** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Chloramphenicol**.

What is Chloramphenicol used for?

- Chloramphenicol is used to treat eye infections caused by bacteria.
- Antibacterial drugs like **Chloramphenicol** treat only bacterial infections. They do not treat viral infections.

How does Chloramphenicol work?

Chloramphenicol is an antibiotic. It stops bacteria from growing and kills them.

What are the ingredients in Chloramphenicol?

Medicinal ingredient: Chloramphenicol

Non-medicinal ingredients: boric acid, purified water, sodium borate, sodium chloride, sodium hydroxide (to adjust pH)

Chloramphenicol comes in the following dosage forms:

Ophthalmic Solution 0.5% available in 15 mL plastic dropper bottles.

Do not use Chloramphenicol if you:

- Are allergic to chloramphenicol or any of the other ingredients in **Chloramphenicol**.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Chloramphenicol. Talk about any health conditions or problems you may have including if you:

- Experience eye pain, changes in vision, continued redness or irritation of the eye, or if your condition worsens or persists.

Other warnings you should know about:

- Your vision may be blurred for a few minutes after using Chloramphenicol. Wait until you can see clearly before driving or operating machines.
- You should use Chloramphenicol exactly as your doctor tells you to. If you use it for longer than you are supposed to, you can get serious reactions, including serious blood problems. Only use Chloramphenicol for as long as your doctor has told you to. If your eye does not get better after two days of using Chloramphenicol, contact your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals natural supplements or alternative medicines.

How to use Chloramphenicol:

- Always use **Chloramphenicol** exactly as your doctor has told you.

- Although you may feel better early treatment, **Chloramphenicol** should be used exactly as directed.
- Misuse or overuse of **Chloramphenicol** could lead to the growth of bacteria that will not be killed by **Chloramphenicol** (resistance). This means that **Chloramphenicol** may not work for you in the future.
- Do not share your medicine.
- Follow your doctor's instruction carefully about how much **Chloramphenicol** to apply and when to apply it.
- Do not use Chloramphenicol for longer than your doctor has told you to.
- If your eye does not get better after 2 days of using **Chloramphenicol**, contact your doctor.
- If you wear contact lenses, you should not wear them while you are using Chloramphenicol. When you have an eye infection, wearing contact lenses can make it worse.

Applying Chloramphenicol into the eye:

- Wash your hands with soap and water.
- Tilt your head back or lie down and look toward the ceiling.
- With your eyes open, gently pull your lower eyelid below the eyelashes away from the eye to form a pouch.
- Hold the bottle at least 2 cm away and squeeze one drop into this pouch.
- Do not touch your eye or eyelid with the dropper tip.
- Slowly release your lower eye lid.
- Gently close your eye for one or two minutes. Do not rub your eye and try not to blink.
- If you are applying multiple drops, wait three to five minutes between each drop.
- Repeat this procedure for the other eye if you have been advised to do so by your doctor or pharmacist.

Usual Dose:

The usual dose is two drops into your affected eye(s) every three hours for 48 hours. Your doctor might tell you to use it more or less often than this. Follow the dosing instructions that your doctor gives you. If your eye(s) does not get better after 2 days (48 hours), stop using it and contact your doctor.

Missed Dose:

If you missed a dose of this medicine, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose as directed by your doctor. Do not take two doses at the same time.

Overdose:

If you think you have taken too much **Chloramphenicol**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.

What are possible side effects from using Chloramphenicol?

These are not all the possible side effects you may feel when taking **Chloramphenicol**. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reaction: swelling of the face, mouth, throat, lips, eyes, difficulty breathing, burning and/or painful red eyes, tearing, skin reactions (rash, blisters, hives).			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Your pharmacist will store Chloramphenicol between 2°C and 8°C. Once it is dispensed to you, you can keep it at room temperature (between 15°C and 30°C) for up to 21 days while you are using it. After 21 days, discard the bottle. Protect from light. Keep out of reach and sight of children.

If you want more information about CHLORAMPHENICOL:

- Talk to your healthcare professional.
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>) or by calling 1-833-278-8556

This leaflet was prepared by Eberth Pharmaceuticals Inc.

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