

**PRESCRIBING INFORMATION**  
**Including Patient Medication Information**

**CHLORAMPHENICOL**  
**Chloramphenicol Ophthalmic Ointment, USP 1.0%**

**Antibiotic**

Eberth Pharmaceuticals Inc,  
56 Eastview Ave.,  
Pointe-Claire, Québec H9R 5N6

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## PRESCRIBING INFORMATION

### CHLORAMPHENICOL Chloramphenicol Ophthalmic Ointment, USP 1.0%

Antibiotic

#### ACTION AND CLINICAL PHARMACOLOGY

Chloramphenicol is a broad-spectrum antibiotic originally isolated from *Streptomyces venezuelae*. It is primarily bacteriostatic and acts by blocking protein synthesis via inhibition of peptidyl transferase within the 50S ribosomal subunit. This inhibition blocks peptide bond formation, thereby preventing the transfer of amino acids to the growing polypeptide chains.

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

#### 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

### ***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

Apply a small amount (1 cm strip) to the lower conjunctiva sac(s) at bedtime as a supplement to the drops.

### **AVAILABILITY**

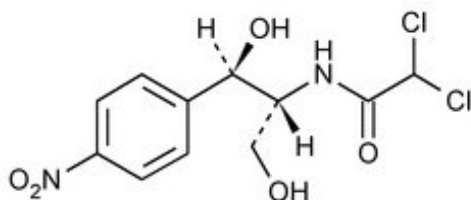
Each gram of sterile ophthalmic ointment contains: Chloramphenicol USP 1% (10 mg/g); and the following non-medicinal ingredients: mineral oil, polysorbate 60 and white petrolatum. Available in 3.5 grams tubes.

### **STORAGE CONDITIONS**

Store between 15°C and 30°C. Keep container tightly closed.

## PHARMACEUTICAL INFORMATION

Structural Formula:



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

Molecular Formula: C<sub>11</sub>H<sub>12</sub>Cl<sub>2</sub>N<sub>2</sub>O<sub>5</sub>

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 Ointment, 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 that:

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

**What are the ingredients in Chloramphenicol?**

Medicinal ingredient: Chloramphenicol

Non-medicinal ingredients: Mineral Oil, Polysorbate 60, White Petrolatum,

**Chloramphenicol comes in the following dosage forms:**

Ointment Solution 1.0% available in 3.5 grams tubes

**Do not use Chloramphenicol if you:**

- Are allergic to chloramphenicol or any other ingredients of **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 the condition worsens or persists.

**Other warnings you should know about:**

- Do not use **Chloramphenicol** longer than directed by your doctor.
- If there is no improvement within two days of starting treatment, stop use and consult a physician.
- **Your vision may be blurred for a few minutes after using the product. Do not drive or operate machinery until you can see clearly.**

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

**How to use Chloramphenicol:**

- 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 wear contact lenses while you are using **Chloramphenicol**. When you have an eye infection, wearing contact lenses can make it worse.

**Chloramphenicol Ophthalmic Ointment, 1.0%:**

Apply a small amount to the lower conjunctiva sac(s) at bedtime as a supplement to the drops.

**Applying Chloramphenicol Ophthalmic Solution into the eye:**

- Wash hands with soap and water.
- Sit in front of a mirror so you can see what you are doing.
- Take the lid off the ointment.
- Tilt your head back.
- Gently pull down your lower eyelid and look up.
- Hold the tube above the eye and gently squeeze a 1cm line of ointment along the inside of the lower eyelid, taking care not to touch the eye or eyelashes with the tip of the tube.
- Blink your eyes to spread the ointment over the surface of the eyeball.
- Your vision may be blurred when you open your eyes - DON'T rub your eyes. The blurring will clear after a few moments if you keep blinking.
- Repeat this procedure for the other eye if you have been advised to do so by your doctor or pharmacist.
- Replace the cap on the tube.
- Take care not to touch the tip of the tube with your fingers.

**Usual Dose:**

Apply a small amount (1 cm strip) to the lower conjunctiva sac(s) at bedtime as a supplement to the drops.

**Missed Dose:**

If you missed a dose of this medication, take it as soon as you remember. But, 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 effect you may feel when taking **Chloramphenicol**. If you experience any side effects not listed here, contact your healthcare professional.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reaction with symptoms such as: 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:**

Store between 15°C and 30°C. Keep container tightly

### **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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