

PRESCRIBING INFORMATION

PrODAN-CHLORAMPHENICOL

**Chloramphenicol Ophthalmic Solution, USP
0.5%**

and

**Chloramphenicol Ophthalmic Ointment, USP
1%**

Antibiotic

ODAN LABORATORIES LTD.
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www.odanlab.com

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ODAN-CHLORAMPHENICOL

**Chloramphenicol Ophthalmic Solution USP, 0.5%
and
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THERAPEUTIC CLASSIFICATION

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.

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 ODAN-CHLORAMPHENICOL and other antibacterial drugs, ODAN-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. Ophthalmic ointment may retard corneal wound healing.

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 ODAN-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 ODAN-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

Solution:

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.

Ointment:

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

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.

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

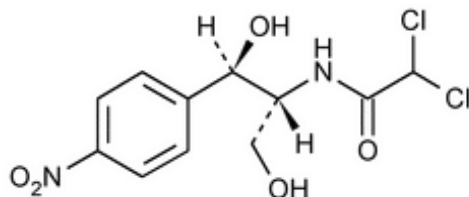
STORAGE CONDITIONS

Solution: 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.

Ointment: 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: 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

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ODAN-CHLORAMPHENICOL
Chloramphenicol Ophthalmic Solution, USP 0.5%
Chloramphenicol Ophthalmic Ointment, USP 1%

Read this carefully before you start taking **ODAN-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 **ODAN-CHLORAMPHENICOL**.

What is ODAN-CHLORAMPHENICOL used for?

- ODAN-CHLORAMPHENICOL is used to treat eye infections.
- Antibacterial drugs like ODAN-CHLORAMPHENICOL treat only bacterial infections. They do not treat viral infections.

How does ODAN-CHLORAMPHENICOL work?

ODAN-CHLORAMPHENICOL is an antibiotic that:

- Stops the bacterial growth
- Kills bacteria

What are the ingredients in ODAN-CHLORAMPHENICOL?

ODAN-CHLORAMPHENICOL, Chloramphenicol Ophthalmic Solution, 0.5%:

Medicinal ingredient: Chloramphenicol 0.5%

Non-medicinal ingredients: Boric Acid, Sodium Borate, Sodium Chloride, Sodium Hydroxide (to adjust pH), purified water

ODAN-CHLORAMPHENICOL, Chloramphenicol Ophthalmic Ointment, 1%:

Medicinal ingredient: Chloramphenicol 1%

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

ODAN-CHLORAMPHENICOL comes in the following dosage forms:

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

Ointment 1% available in 3.5 grams tubes

Do not use ODAN-CHLORAMPHENICOL if you:

- are allergic to chloramphenicol or any other ingredients of ODAN-CHLORAMPHENICOL

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ODAN-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 ODAN-CHLORAMPHENICOL longer than directed by your doctor.
- Overuse of this product may produce increased redness of the eye
- 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 take ODAN-CHLORAMPHENICOL:

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

ODAN-CHLORAMPHENICOL, Chloramphenicol Ophthalmic Solution, 0.5%:

Apply 2 drops to the affected eye(s), every 3 hours or more often if recommended by your doctor. Continue this treatment for 48 hours, after which the interval between applications may be increased. Continue treatment for at least 48 hours after the eye(s) appears normal.

Applying ODAN-CHLORAMPHENICOL Ophthalmic Solution into the eye:

- Wash hands with soap and water.
- Tilt the head back or lie down and look toward the ceiling.
- With the eyes open, gently pull the 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 the pouch.
- Do not touch your eye or eyelid with the dropper tip.
- Slowly release the lower lid.
- Gently close the eye for one or two minutes. Do not rub the eye and try not to blink.
- If multiple drops are used, 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.

ODAN-CHLORAMPHENICOL, Chloramphenicol Ointment, 1%:

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

Applying ODAN-CHLORAMPHENICOL Ointment 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.

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 ODAN-CHLORAMPHENICOL, contact your healthcare
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professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using ODAN-CHLORAMPHENICOL?

These are not all the possible side effects you may feel when taking ODAN-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 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:

ODAN-CHLORAMPHENICOL, Chloramphenicol Ophthalmic Solution 0.5%:

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.

ODAN-CHLORAMPHENICOL, Chloramphenicol Ophthalmic Ointment, 1%:

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

Keep out of reach and sight of children.

If you want more information about ODAN-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 1-800-387-9342.

This leaflet was prepared by Odan Laboratories Ltd., Montreal, Canada, H9R 2Y6

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