

PRESCRIBING INFORMATION

PrODAN-ERYTHROMYCIN

Erythromycin Ophthalmic Ointment, USP

5 mg / g

ANTIBIOTIC

ODAN LABORATORIES LTD.
325 Stillview Ave., Pointe Claire,
Québec H9R 2Y6

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www.odanlab.com

PRESCRIBING INFORMATION

PrODAN-ERYTHROMYCIN
Erythromycin Ophthalmic Ointment, USP
5 mg / g

THERAPEUTIC CLASSIFICATION

Antibiotic

ACTION AND CLINICAL PHARMACOLOGY

Erythromycin inhibits protein synthesis by binding to the 50S ribosomal subunit within the microorganism. It is usually bacteriostatic but may be bactericidal depending on the sensitivity and number of organisms and the concentrations of the drug. Its spectrum of activity is similar to that of penicillin G. Resistance to erythromycin of some strains of H. influenza and Staphylococci has been demonstrated.

INDICATIONS

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to erythromycin.

For prophylaxis of ophthalmic neonatorum due to N. gonorrhoeae or C. trachomatis. The Canadian Pediatric Society, the Centers for Diseases Control and the Committee on Drugs (US), the Committee of Fetus and Newborn and the Committee on Infectious Diseases of the American Academy of Pediatrics recommend 1% silver nitrate solution in single dose ampoules or single use tubes of an ophthalmic ointment containing 0.5% erythromycin or 1% tetracycline as effective and acceptable regimens for prophylaxis of gonococcal ophthalmia neonatorum.

Erythromycin ophthalmic ointment has also been effective for prevention of neonatal conjunctivitis due to C. trachomatis, a condition that may develop one to several weeks after delivery in infants of mothers whose birth canal harbor the organism.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ODAN-ERYTHROMYCIN and other antibacterial drugs, ODAN-ERYTHROMYCIN should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

WARNINGS

Susceptibility/Resistance

Prescribing ODAN-ERYTHROMYCIN 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 bacteria.

CONTRAINDICATIONS

Erythromycin and its derivatives should not be used in patients with known hypersensitivity to these drugs or any ingredient in the formulations or with infections that are resistant to the drug (primarily certain Staphylococci organisms).

PRECAUTIONS

The rare possibility of superinfection caused by overgrowth of non-susceptible bacteria or fungi should be kept in mind during prolonged or repeated therapy, especially when other antibacterial agents are simultaneously employed. In such instances the drug should be withdrawn and appropriate treatment instituted if necessary.

OVERDOSE

In case of drug overdose, including ingestion, contact a healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms.

ADVERSE REACTIONS

Serious allergic reactions to erythromycin have been extremely infrequent. Mild allergic reactions, such as urticaria and morbilliform skin rashes have occurred. Should a patient demonstrate signs of hypersensitivity, administer appropriate countermeasures such as epinephrine, corticosteroid and antihistamines, and withdraw the antibiotic.

DOSAGE AND ADMINISTRATION

In the treatment of external ocular infections, apply the ointment directly to the infected structure one or more times daily, depending on the severity of the infection.

For prophylaxis of neonatal gonococcal or chlamydial conjunctivitis, a ribbon of ointment approximately 0.5 to 1 cm in length should be instilled into each conjunctival sac. The ointment should not be flushed from the eye following installation. A new tube should be used for each infant. Infants born by cesarean section as well as those delivered by the vaginal route should receive prophylaxis.

AVAILABILITY

Each 1 g of sterile ophthalmic ointment contains: Erythromycin (base) 5 mg and the following non-medicinal ingredients: Mineral Oil and White Petrolatum. Single tubes of 3.5 g and unit dose tubes of 1 g in boxes of 50.

STORAGE CONDITIONS

Store at room temperature (15°C to 30°C). Protect from freezing.

SCIENTIFIC INFORMATION

Drug Substance

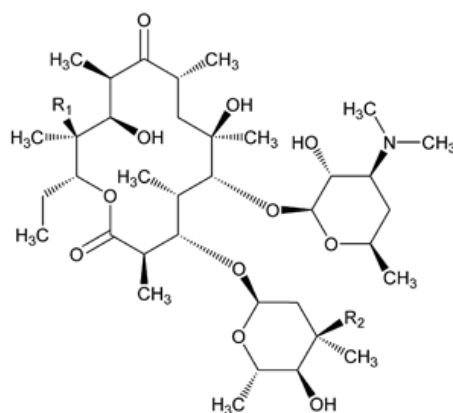
Proper Name: Erythromycin

Chemical Name: (3R*,4S*,5S*,6R*,7R*,9R*,11R*,12R*,13S*,14R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione

Molecular Formula: C₃₇H₆₇NO₁₃

Molecular Weight: 733.94

Structural Formula:



Erythromycin	R ₁	R ₂
A	OH	OCH ₃
B	H	OCH ₃
C	OH	OH

Erythromycin contains primarily erythromycin A but also contains erythromycin B and C, with each having antibacterial activity.

Melting Point: 133-140°C

Physicochemical properties:

Physical description: White or slightly yellow, odorless or almost odorless, slightly hygroscopic crystals or powder with a bitter taste.

Solubility: It is freely soluble in methanol, ethanol, acetone and chloroform. It is soluble in water at 2 mg/mL.

SUPPORTING PRODUCT MONOGRAPHS

pdp-ERYTHROMYCIN (Erythromycin Ophthalmic Ointment, USP; 5 mg / g), submission control. No. 200704, Prescribing Information, Pendopharm, Division of Pharmascience Inc., January 16, 2017.

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

^{Pr}
ODAN-ERYTHROMYCIN
Erythromycin Ophthalmic Ointment, USP

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

What is ODAN-ERYTHROMYCIN used for?

ODAN-ERYTHROMYCIN is used to treat bacterial eye infections.

Antibacterial drugs like **ODAN-ERYTHROMYCIN** treat only bacterial infections. They do not treat viral infections. Although you may feel better early in the treatment, **ODAN-ERYTHROMYCIN** should be used exactly as directed. Misuse or overuse of **ODAN-ERYTHROMYCIN** could lead to the growth of bacteria that will not be killed by **ODAN-ERYTHROMYCIN** (resistance). This means that **ODAN-ERYTHROMYCIN** may not work for you in the future. Do not share your medicine.

How does ODAN-ERYTHROMYCIN work?

ODAN-ERYTHROMYCIN is an antibiotic. It works by killing or stopping the growth of the bacteria that cause your infection.

What are the ingredients in ODAN-ERYTHROMYCIN?

Active ingredient: Erythromycin

Inactive ingredients: Mineral Oil, Petrolatum.

ODAN-ERYTHROMYCIN comes in the following dosage forms:

Ointment: 5 mg / g

Do not use ODAN-ERYTHROMYCIN if you:

- are allergic to erythromycin or any other ingredients of **ODAN-ERYTHROMYCIN**
- have infections that are resistant to this medication (bacteria will not be killed).

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

- If you wear contact lenses, remove them before applying **ODAN-ERYTHROMYCIN**. These can be re-inserted 15 minutes after application of the ointment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. How to take ODAN-ERYTHROMYCIN:

Follow your doctor's instruction carefully about how much **ODAN-ERYTHROMYCIN** to apply and when to apply it.

Usual dose:

Apply the ointment directly into the affected eye(s) one or more times daily as directed by your doctor.

Administration:

1. Wash hands before use.
2. Remove tube cap.
3. Tilt head up when looking in a mirror.
4. Gently pull down the lower eyelid until there is a “pocket” (see picture below).
5. Apply a ribbon of ointment 0.5- 1 cm along in this pocket (see picture below).
6. Let go of the lower eyelid and close the eye for 30 seconds.
7. If you use ointment in both eyes, repeat the steps for the other eye.
8. To avoid contamination and injury, do not let the tip of the tube touch your eye.
9. If you are using another eye medicine, wait at least 15 minutes before applying the other medicine.
10. For the multiple-use 3.5 g tube, close and tighten the cap. If you are using a 1 g single-use tube, discard tube after use.

**Missed Dose:**

If you forget to apply the ointment, simply apply it as soon as you remember. Then go back to the original schedule as directed by your doctor. Do not apply 2 doses to make up for the missed dose.

Overdose:

In case of drug overdose, including ingestion, contact a healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptom

What are possible side effects from using ODAN-ERYTHROMYCIN?

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

Side effects may include:

- Hives
- Skin rashes

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	
<u>RARE</u> Severe 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/drugproducts/drug-product-database.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.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 at room temperature (15°C to 30°C). Protect from freezing.

Keep out of reach and sight of children.

If you want more information about ODAN-ERYTHROMYCIN:

- 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 (<http://hc-sc.gc.ca/index-eng.php>); or by calling 1-800-387-9342.

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

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