

## **PRESCRIBING INFORMATION**

INCLUDING PATIENT MEDICATION INFORMATION

Pr **ERYTHROMYCIN Ophthalmic ointment USP**

Erythromycin ophthalmic ointment USP

5mg / g

ANTIBIOTIC

Steri-Med Pharma Inc.  
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## PRESCRIBING INFORMATION

### Pr **ERYTHROMYCIN Ophthalmic ointment USP**

Erythromycin ophthalmic ointment USP 5mg / 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 Disease 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 ERYTHROMYCIN ophthalmic ointment and other antibacterial drugs, ERYTHROMYCIN ophthalmic ointment 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 AND PRECAUTIONS**

##### **Susceptibility/Resistance**

Prescribing ERYTHROMYCIN ophthalmic ointment 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.

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.

## **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).

## **ADVERSE EFFECTS**

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 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 vaginal route should receive prophylaxis.

## **AVAILABILITY**

Each 1 g of sterile ophthalmic ointment contains: Erythromycin (base) 5 mg in a Mineral Oil and Petrolatum. Tubes of 3.5 g and unit dose tubes of 1 g in boxes of 50.

## **STORAGE CONDITIONS**

Store at room temperature (15-30°C). Protect from freezing. Keep tightly closed.

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

Pr **ERYTHROMYCIN Ophthalmic ointment USP**  
Erythromycin ophthalmic ointment USP 5mg / g

Read this carefully before you start taking **ERYTHROMYCIN Ophthalmic ointment USP** 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 **ERYTHROMYCIN Ophthalmic ointment USP**.

**What is ERYTHROMYCIN Ophthalmic ointment USP used for?**

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

**How does ERYTHROMYCIN Ophthalmic ointment USP work?**

**ERYTHROMYCIN Ophthalmic ointment USP** is an antibiotic. It works by killing or stopping the growth of the bacteria that cause your infection.

**What are the ingredients in ERYTHROMYCIN Ophthalmic ointment USP?**

Medicinal ingredients: Erythromycin

Non-medicinal ingredients: Mineral oil, Petrolatum

**ERYTHROMYCIN Ophthalmic ointment USP comes in the following dosage forms:**

Ointment: 5mg / g

**Do not use ERYTHROMYCIN Ophthalmic ointment USP if you:**

- Are allergic to erythromycin or any other ingredients of **ERYTHROMYCIN Ophthalmic ointment USP**
- 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 ERYTHROMYCIN Ophthalmic ointment USP. Talk about any health conditions or problems you may have.**

- If you wear contact lenses, remove them before applying **ERYTHROMYCIN Ophthalmic ointment USP**. 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 ERYTHROMYCIN Ophthalmic ointment USP:**

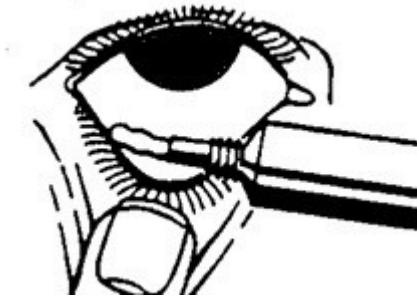
Follow your doctor's instruction carefully about how much **ERYTHROMYCIN Ophthalmic ointment USP** to apply and when to apply it.

**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.

**Overdose:**

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

**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.

**What are possible side effects from using ERYTHROMYCIN Ophthalmic ointment USP?**

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

Side effects may include:

- Hives
- Skin rashes

<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	
<b>RARE</b> <b>Severe allergic reaction</b> 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, and hives).			X

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.

<p><b>Reporting Side Effects</b></p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"><li>• Visiting the Web page on Adverse Reaction Reporting (<a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php</a>) for information on how to report online, by mail or by fax; or</li><li>• Calling toll-free at 1-866-234-2345.</li></ul> <p><i>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.</i></p>
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**Storage:**

Store at room temperature (15-30°C). Protect from freezing. Keep tightly closed.

Keep out of reach and sight of children.

**If you want more information about ERYTHROMYCIN Ophthalmic ointment USP:**

- 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>).

This leaflet was prepared by Steri-Med Pharma Inc.

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