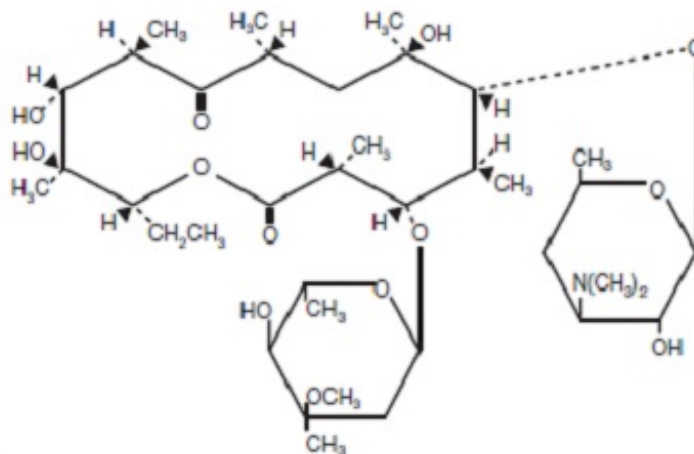


**ERYTHROMYCIN- erythromycin ointment**  
**Asclemed USA, Inc.**

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**ERYTHROMYCIN OPHTHALMIC OINTMENT USP**  
**STERILE**  
**RX ONLY**

**DESCRIPTION:**

Erythromycin Ophthalmic Ointment belongs to the macrolide group of antibiotics. It is basic and readily forms a salt when combined with an acid. The base, as crystals or powder, is slightly soluble in water, moderately soluble in ether, and readily soluble in alcohol or chloroform. Erythromycin ((3R\*,4S\*,5S\*,6R\*,7R\*,9R\*,11R\*,12R\*,13S\*,14R\*)-4-[(2,6-dideoxy-3- C-methyl-3- O-methyl- $\alpha$ -L- ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)- $\beta$ -D- xylo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione) is antibiotic produced from a strain of *Streptomyces erythraeus*. It has the following structural formula:



Molecular Formula:  $C_{37}H_{67}NO_{13}$   
Molecular Weight: 733.94

Each gram contains Erythromycin USP 5 mg in a sterile ophthalmic base of mineral oil and white petrolatum.

**CLINICAL PHARMACOLOGY:**

**Microbiology:**

Erythromycin inhibits protein synthesis without affecting nucleic acid synthesis. Erythromycin is usually active against the following organisms *in vitro* and in clinical infections:

*Streptococcus pyogenes* (group A  $\beta$ -hemolytic)

Alpha-hemolytic streptococci (viridans group)

*Staphylococcus aureus*, including penicillinase-producing strains (methicillin-resistant staphylococci are uniformly resistant to erythromycin)

*Streptococcus pneumoniae*

*Mycoplasma pneumoniae*(Eaton Agent, PPLO)

*Haemophilus influenzae*(not all strains of this organism are susceptible at the erythromycin concentrations ordinarily achieved)

*Treponema pallidum*

*Corynebacterium diphtheriae*

*Neisseria gonorrhoeae*

*Chlamydia trachomatis*

### **INDICATIONS AND USAGE:**

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

For prophylaxis of ophthalmia neonatorum due to *N. gonorrhoeae* or *C. trachomatis*. The effectiveness of erythromycin in the prevention of ophthalmia caused by penicillinase-producing *N. gonorrhoeae* is not established.

For infants born to mothers with clinically apparent gonorrhea, intravenous or intramuscular injections of aqueous crystalline penicillin G should be given; a single dose of 50,000 units for term infants or 20,000 units for infants of low birth weight. Topical prophylaxis alone is inadequate for these infants.

### **CONTRAINDICATIONS:**

This drug is contraindicated in patients with a history of hypersensitivity to erythromycin.

### **PRECAUTIONS:**

#### **General:**

The use of antimicrobial agents may be associated with the overgrowth of nonsusceptible organisms including fungi; in such a case, antibiotic administration should be stopped and appropriate measures taken.

#### **Information for Patients:**

Avoid contaminating the applicator tip with material from the eye, fingers, or other source.

#### **Carcinogenesis, Mutagenesis, Impairment of Fertility:**

Two year oral studies conducted in rats with erythromycin did not provide evidence of

tumorigenicity. Mutagenicity studies have not been conducted.

No evidence of impaired fertility that appeared related to erythromycin was reported in animal studies.

### **Pregnancy:**

#### Teratogenic effects -

#### *Pregnancy Category B.*

Reproduction studies have been performed in rats, mice, and rabbits using erythromycin and its various salts and esters, at doses that were several multiples of the usual human dose. No evidence of harm to the fetus that appeared related to erythromycin was reported in these studies. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, the erythromycins should be used during pregnancy only if clearly needed.

### **Nursing Mothers:**

Caution should be exercised when erythromycin is administered to a nursing woman.

### **Pediatric Use:**

See **INDICATIONS AND USAGE** and **DOSAGE AND ADMINISTRATION**.

### **ADVERSE REACTIONS:**

The most frequently reported adverse reactions are minor ocular irritations, redness, and hypersensitivity reactions.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **DOSAGE AND ADMINISTRATION:**

In the treatment of superficial ocular infections, a ribbon approximately 1 cm in length of Erythromycin Ophthalmic Ointment should be applied directly to the infected structure up to 6 times daily, depending on the severity of the infection. For prophylaxis of neonatal gonococcal or chlamydial conjunctivitis, a ribbon of ointment approximately 1 cm in length should be instilled into each lower conjunctival sac. The ointment should not be flushed from the eye following instillation. A new tube should be used for each infant.

### **HOW SUPPLIED**

Sterile Erythromycin Ophthalmic Ointment USP, 5 mg/g as follows:

3.5 g (1/8 oz) tamper-evident tubes NDC 76420-612-03 (relabelled from NDC 0574-4024-35)

Store at controlled room temperature 15°-30°C (59°-86°F). Avoid excessive heat.

Protect from freezing.

**Relabeled by:**

Enovachem PHARMACEUTICALS

Torrance, CA 90501

**Package/Label Display Panel**

Relabeled By:



Erythromycin Ophthalmic Ointment USP

NDC: 76420-612-03

Qty: 3.5



Manufactured For: Perrigo

Source NDC: 0574-4024-35

Description: 3.5g sterile ointment in tamper-evident tube

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: RX



(01) 0 0376420 61203 2

(17)

(10) 00000000

(21)

Erythromycin Ophthalmic Ointment USP

NDC: 76420-612-03

S/N:

Qty: 3.5

Erythromycin Ophthalmic Ointment USP

NDC: 76420-612-03

S/N:

Qty: 3.5

Erythromycin Ophthalmic Ointment USP

NDC: 76420-612-03

S/N:

Qty: 3.5

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

**ERYTHROMYCIN**

erythromycin ointment

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:76420-612(NDC:0574-4024)
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	5 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-612-03	1 in 1 CARTON	09/12/2023	

<b>1</b>	3.5 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA062447	05/08/2014	

**Labeler** - Asclemed USA, Inc. (059888437)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-612)

Revised: 9/2023

Asclemed USA, Inc.