

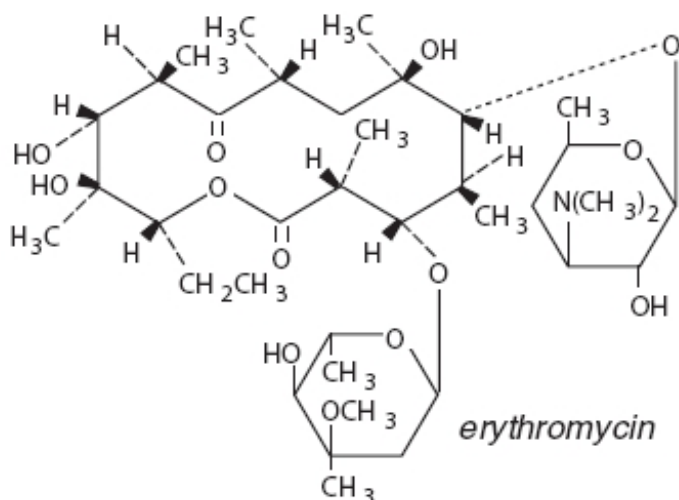
## **ERYTHROMYCIN- erythromycin ointment** **NuCare Pharmaceuticals, Inc.**

### **Erythromycin Ophthalmic Ointment, USP 0.5% (Sterile)**

**Rx only**

#### **DESCRIPTION**

Erythromycin Ophthalmic Ointment, USP belongs to the macrolide group of antibiotics. The sterile ophthalmic ointment flows freely over the conjunctiva. Erythromycin base, as crystals or powder, is slightly soluble in water, moderately soluble in ether, and readily soluble in alcohol or chloroform. Erythromycin is an antibiotic produced from a strain of *Streptomyces erythraeus*. It is basic and readily forms a salt when combined with an acid. It has the following structural formula:



C<sub>37</sub>H<sub>67</sub>NO<sub>13</sub>

Mol. Wt. 733.94

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

Each Gram Contains: ACTIVE: Erythromycin, USP 5 mg (0.5%); INACTIVES: Mineral Oil, 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 non-susceptible organisms including fungi; in such a case, antibiotic administration should be stopped and appropriate measures taken.

### **Information for Patients:**

Avoid contaminating the tip of container 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 or harm to the fetus that appeared related to erythromycin was reported in these studies.

### **Pregnancy:**

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. 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 Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC at 1-800-321-4576 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, erythromycin ophthalmic ointment approximately 1 cm in length should be applied directly to the infected eye(s) up to six times daily, depending on the severity of the infection.

For prophylaxis of neonatal gonococcal or chlamydial ophthalmia, 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**

Erythromycin Ophthalmic Ointment, USP 0.5% is available in the following sizes:

1/8 oz. (3.5 g) tamper-resistant tube - NDC 68071-4228-3

**DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.**

### **Storage:**

Store between 15°-25°C (59°-77°F).

KEEP OUT OF REACH OF CHILDREN.

Revised: July 2016

Bausch + Lomb, a division of  
Valeant Pharmaceuticals North America LLC  
Bridgewater, NJ 08807 USA

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9043404 (Folded)

9043504 (Flat)

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**

**NuCare Pharmaceuticals, Inc.**

NDC: 68071-4228-3

**Erythromycin 0.5%**  
**3.5g Ophth. Oint.**

Each gram contains:  
Active: Erythromycin USP,  
5mg (0.5%)  
See manufacturer's label  
for full list of ingredients.

Product #: R0261305  
**Rx Only**

Manufactured by: 3  
Bausch & Lomb Incorporated  
Tampa, FL 33637

Packaged By:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92867

Patent Instructions

Apply every \_\_\_\_\_ hours  
\_\_\_\_\_ times a day.

680714228033500000-00000

Rev. 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-77°F.

Erythromycin 0.5%  
Lot: 00000 NDC: 68071-4228-03  
MFR NDC: 24208-910-55 Exp.: 00-00  
Serial# 0000000002

Erythromycin 0.5%  
Lot: 00000 NDC: 68071-4228-03  
MFR NDC: 24208-910-55 Exp.: 00-00  
Serial# 0000000002

GTIN 00368071422832  
Serial# 0000000002  
Exp. Date 00-00  
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**ERYTHROMYCIN**

erythromycin ointment

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68071-4228(NDC:24208-910)
<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:68071-	3.5 g in 1 BOX; Type 0: Not a Combination	01/13/2018	

4228-3	Product	01/12/2018	
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064067	07/29/1994	

**Labeler - NuCare Pharmaceuticals, Inc. (010632300)**

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-4228)

Revised: 6/2024

NuCare Pharmaceuticals, Inc.