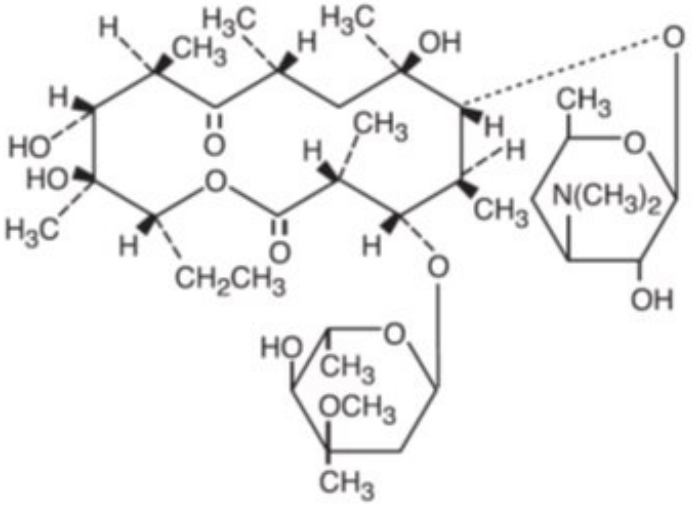
ERYTHROMYCIN- erythromycin ointment
RPK Pharmaceuticals, Inc.

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:



Molecular Formula: $C_{37}H_{67}NO_{13}$ Mol. Wt. 733.94

Chemical Name: ((3R●,4S●,5S●,6R●,7R●,9R●,11R●,12R●,13S●,14R●)-4-[(2,6-dideoxy-3-*C*-methyl-3-*0*-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 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 β-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 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: 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 Bausch & Lomb Incorporated at 1-800-553-5340 or FDA at 1-800-FDA-1088 or 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

Product: 53002-9050

NDC: 53002-9050-1 3.5 g in a TUBE

Erythromycin Ophthalmic Ointment

ERYTHROMYCIN

erythromycin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53002-9050(NDC:24208-910)
Route of Administration	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:53002-9050-1	3.5 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064067	07/29/1994	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-9050) , REPACK(53002-9050)

Revised: 6/2023 RPK Pharmaceuticals, Inc.