

ERYTHROMYCIN- erythromycin ointment
Asclemed USA, Inc.

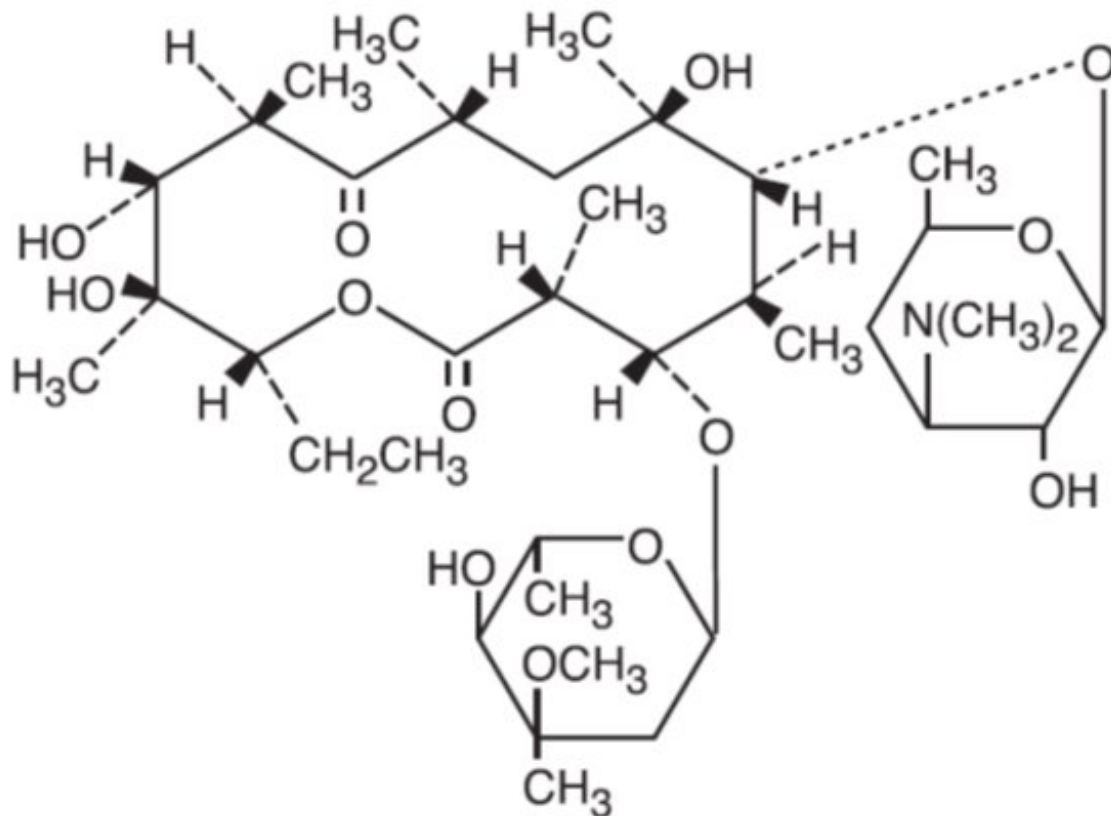
Erythromycin Ophthalmic Ointment, USP

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: C₃₇H₆₇NO₁₃

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 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: 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 Bausch & Lomb Incorporated at 1-800-321-4576 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

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

1/8 oz. (3.5 g) tamper-resistant tube -NDC 76420-196-03 (relabelled from NDC 24208-910-55)

DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.

Storage: Store between 15° to 25°C (59° to 77°F).

Keep out of reach of children.

Relabeled by:

Enovachem PHARMACEUTICALS
Torrance, CA 90501

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Relabeled By:



Erythromycin Ophthalmic Ointment, USP 0.5%

NDC: 76420-196-03

Qty: 3.5

Bausch + Lomb, a division of Bausch Health US, LLC

Source NDC: 24208-910-55

Description: 3.5g tamper resistant tube

Lot #: 00000000

Exp:

Batch #: 00000000

Drug Status: RX



(01) 0 0376420 19603 7

(17)

(10) 00000000

(21)

Erythromycin Ophthalmic Ointment, USP 0.5%

NDC: 76420-196-03

S/N:

Qty: 3.5

Erythromycin Ophthalmic Ointment, USP 0.5%

NDC: 76420-196-03

S/N:

Qty: 3.5

Erythromycin Ophthalmic Ointment, USP 0.5%

NDC: 76420-196-03

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

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76420-196(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:76420-196-03	1 in 1 CARTON	11/30/2021	
1		3.5 g in 1 TUBE; Type 0: Not a Combination		

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

Labeler - Asclemed USA, Inc. (059888437)

Establishment			
Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-196)

Revised: 11/2021

Asclemed USA, Inc.