

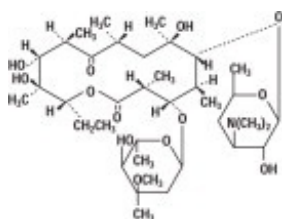
ERYTHROMYCIN- erythromycin ointment MWI

apexa™
Erythromycin
Ophthalmic Ointment USP, 0.5%
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- α -L-ribo-hexopyranosyl)-oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethyl-amino)- β -D-xylo-hexo-pyranosyl]oxy]oxacyclotetradecane-2,10-dione)) is an antibiotic produced from a strain of *Streptomyces erythraeus*.

It has the following structural formula:



Molecular Formula: C₃₇H₆₇NO₁₃

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 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 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.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS:

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

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, 0.5% is available as follows:

3.5 g (1/8 oz) sterile tamper-resistant tube

(NDC 13985-605-03)

STORAGE:

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Avoid excessive heat.

Protect from freezing.

apexa™

Manufactured by: Akorn Inc.

Lake Forest, IL 60045

Distributed by: MWI

Boise, ID 83705

MWER00N Rev. 07/14

Principal Display Panel Text for Container Label:

NDC 13985-605-03

Erythromycin STERILE

Ophthalmic Ointment Rx Only

USP, 0.5%

Apexa logo

AP 704007 Net Weight: 3.5g (1/8 oz)

NDC 13985-605-03

Erythromycin
Ophthalmic **Ointment**
USP, 0.5%

STERILE
Rx Only

apexa

AP 704007 Net Weight: 3.5g (1/8 oz)

FOR OPHTHALMIC USE ONLY
READ OUTER CARTON FOR INFORMATION BEFORE USING.
Each Gram Contains: Erythromycin USP, 5 mg in a sterile ophthalmic base of mineral oil and white petrolatum.
Usual Dosage: See package insert for dosage information.
Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. KEEP TIGHTLY CLOSED. See crimp of tube for Lot Number and Expiration Date.
Warning: KEEP OUT OF THE REACH OF CHILDREN.

DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.

LI-3526

Manufactured by: Akorn, Inc.
Lake Forest, IL 60045
www.akorn.com

Distributed by: MWI
Boise, ID 83705

MWERAAL Rev. 07/14

(01) 00313985605031

Principal Display Panel Text for Carton Label:

NDC 13985-605-03

Erythromycin

Ophthalmic

Ointment

USP, 0.5%

STERILE

Rx Only

Apexa logo

AP 704007

Net Weight: 3.5g (1/8 oz)



5601

NDC 13985-605-03

Each Gram Contains:
Erythromycin USP, 5 mg in a sterile ophthalmic base of mineral oil and white petrolatum.

Usual Dosage: Apply locally one or more times daily. See package insert for dosage information.

Rx Only

Storage: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. KEEP TIGHTLY CLOSED.

See crimp of tube for Lot No. and Exp. Date.

WARNING: KEEP OUT OF REACH OF CHILDREN.

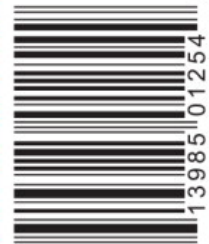
Erythromycin Ophthalmic Ointment
USP, 0.5%

Erythromycin Ophthalmic Ointment
USP, 0.5%

STERILE

FOR OPHTHALMIC USE ONLY.

STERILE
Rx Only



3 13985 01254 9

apexa

AP 704007

Net Weight: 3.5g (1/8 oz)

Manufactured by:
Akorn, Inc.
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Distributed by: MWI
Boise, ID 83705

MWERAAC Rev. 06/16

Erythromycin Ophthalmic Ointment 3.5g
USP, 0.5%

erythromycin ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13985-605
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:13985-605-03	1 in 1 CARTON	03/23/2015	
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	ANDA064030	03/23/2015	

Labeler - MWI (019926120)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(13985-605) , ANALYSIS(13985-605) , STERILIZE(13985-605) , PACK(13985-605) , LABEL(13985-605)

Revised: 1/2022

MW