ERYTHROMYCIN- erythromycin ointment
Akorn, Inc.

Erythromycin Ophthalmic Ointment USP, 0.5%

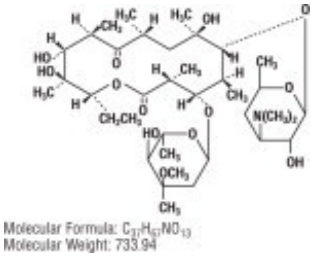
Sterile

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*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione)) is an antibiotic produced from a strain of *Streptomyces erythraeus.*

It has the following structural formula:



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 Opthalmic 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 17478-070-35)

Carton of fifty (50) Unit Dose 1 g tube (NDC 17478-070-31)

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

Avoid excessive heat.

Protect from freezing.

Akorn

Manufactured by: Akorn Inc
Lake Forest, IL 60045
ERT00N Rev. 06/16

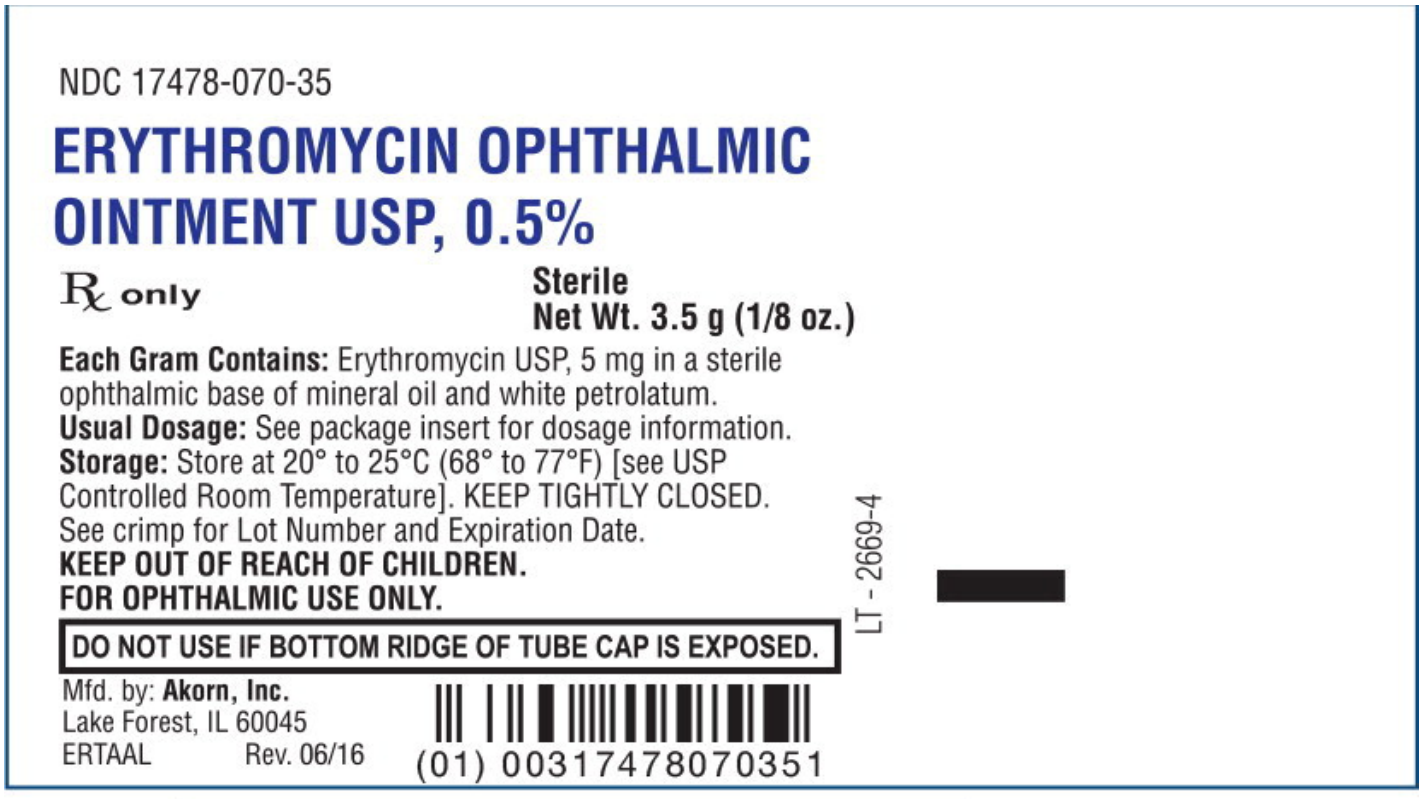
Principal Display Panel Text for Container Label

NDC 17478-070-35

ERYTHROMYCIN OPHTHALMIC

OINTMENT USP, 0.5%

Rx only Sterile Net Wt. 3.5 g (1/8 oz.)



Principal Display Panel Text for Carton Label

3.5 g NDC 17478-070-35

ERYTHROMYCIN OPHTHALMIC

OINTMENT USP, 0.5%

Rx only Sterile Net Wt 3.5 g (1/8 oz.) Akorn logo

ERYTHROMYCIN

erythromycin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17478-070
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
mineral oil (UNII: T5L8T28FGP)	
petrolatum (UNII: 4T6H12BN9U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-070-35	1 in 1 CARTON	07/18/1996	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:17478-070-31	50 in 1 CARTON	07/18/1996	
2		1 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	07/18/1996	

Labeler - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		603980319	MANUFACTURE(17478-070) , ANALYSIS(17478-070) , REPACK(17478-070)

Revised: 8/2018 Akorn, Inc.