ERYTHROMYCIN- erythromycin solution
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

ERYTHROMYCIN TOPICAL SOLUTION USP 2%

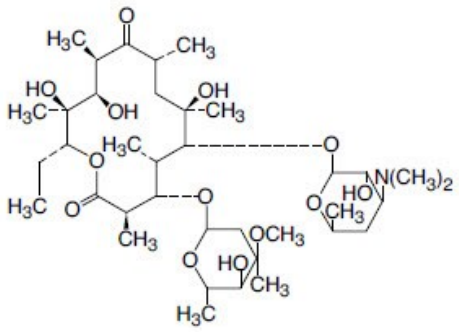
FOR TOPICAL USE ONLY.

NOT FOR USE IN EYES.

Rx Only

DESCRIPTION:

Erythromycin Topical Solution contains erythromycin for topical dermatologic use. Erythromycin is a macrolide antibiotic produced from a strain of *Saccaropolyspora erythraea* (formerly *Streptomyces erythreus*). It is a base and readily forms salts with acids. Chemically, erythromycin is: (3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**, 12*R**,13*S**,14*R**)-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. It has the following structural formula:



Molecular Formula: $C_{37}H_{67}NO_{13}$ Molecular Weight: 733.94

Erythromycin is a white or slightly yellow crystalline powder that is very soluble in water, freely soluble in alcohols, acetone, chloroform, acetonitrile, ethyl acetate, and moderately soluble in ether, ethylene dichloride and amyl acetate.

Each mL of Erythromycin Topical Solution USP 2% contains 20 mg of erythromycin base in a vehicle consisting of alcohol (71.5%), and propylene glycol. It may contain citric acid to adjust pH.

CLINICAL PHARMACOLOGY:

The exact mechanism by which erythromycin reduces lesions of acne vulgaris is not fully known; however, the effect appears to be due in part to the antibacterial activity of the drug.

Microbiology: Erythromycin acts by inhibition of protein synthesis in susceptible organisms by reversibly binding to 50 S ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis. Antagonism has been demonstrated *in vitro* between erythromycin, lincomycin, chloramphenicol, and clindamycin.

INDICATIONS AND USAGE:

Erythromycin Topical Solution is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS:

Erythromycin Topical Solution is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNINGS:

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including erythromycin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-associated colitis".

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

PRECAUTIONS:

General: For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents.

The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, discontinue use and take appropriate measures.

Avoid contact with eyes and all mucous membranes.

Information for Patients: Patients using Erythromycin Topical Solution should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes, nose, mouth, and all mucous membranes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. Patients should not use any other topical acne medication unless otherwise directed by their physician.
4. Patients should report to their physician any signs of local adverse reactions.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2 years) oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet.

Pregnancy: Teratogenic effects–*Pregnancy Category B*. There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of diet) prior to and during mating, during gestation and through weaning of two successive litters.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed. Erythromycin has been reported to cross the placental barrier in

humans, but fetal plasma levels are generally low.

Nursing Mothers: It is not known whether erythromycin is excreted in human milk after topical application. However, erythromycin is excreted in human milk following oral and parenteral erythromycin administration. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of this product in pediatric patients have not been established.

ADVERSE REACTIONS:

The following local adverse reactions have been reported occasionally: peeling, dryness, itching, erythema, and oiliness. Irritation of the eyes and tenderness of the skin have also been reported with topical use of erythromycin. Generalized urticarial reactions possibly related to the use of erythromycin, which required systemic steroid therapy have been reported.

DOSAGE AND ADMINISTRATION:

Erythromycin Topical Solution should be applied over the affected areas twice a day (morning and evening) after the skin is thoroughly washed with warm water and soap and patted dry. Acne lesions on the face, neck, shoulder, chest, and back may be treated in this manner.

This medication should be applied with applicator top. If fingertips are used, wash hands after application. Drying and peeling may be controlled by reducing the frequency of applications.

HOW SUPPLIED:

Erythromycin Topical Solution USP, 2% is supplied as follows:
60 mL bottle with applicator NDC 0168-0215-60

Store in a dry place at temperatures between 15° - 25°C (59° - 77°F)[See USP Controlled Room Temperature].

E. FOUGERA & CO.
A division of
Fougera
PHARMACEUTICALS INC.
Melville, New York 11747

I2215F/IF2215H
R12/11
#85

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CONTAINER

NDC 0168-0215-60

Fougera®

ERYTHROMYCIN
TOPICAL SOLUTION
USP 2%

60 mL

FOR TOPICAL USE ONLY.
NOT FOR USE IN EYES.

Rx only

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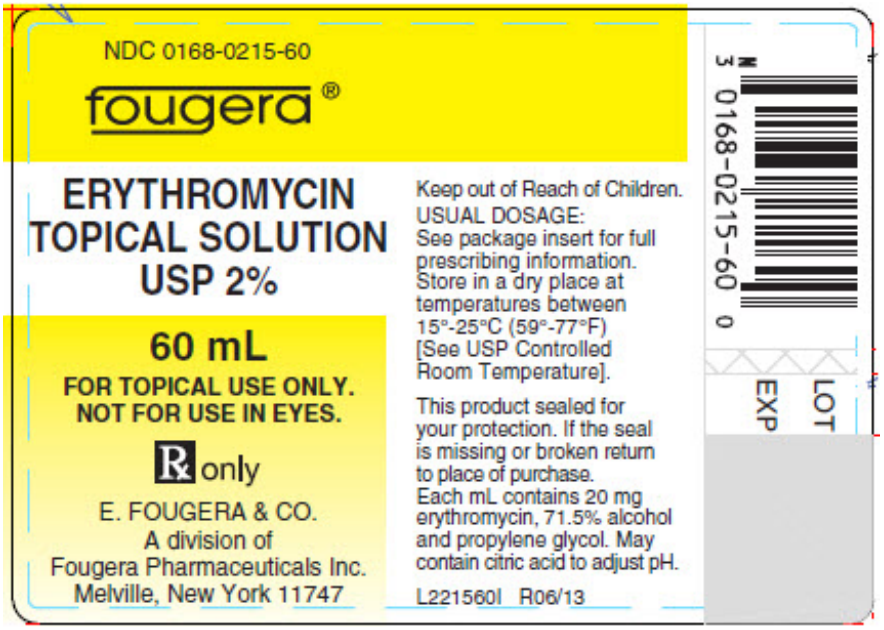

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CARTON

NDC 0168-0215-60

Fougera®

ERYTHROMYCIN
TOPICAL
SOLUTION
USP 2%

FOR TOPICAL
USE ONLY.
NOT FOR
USE IN EYES.

60 mL

Rx only

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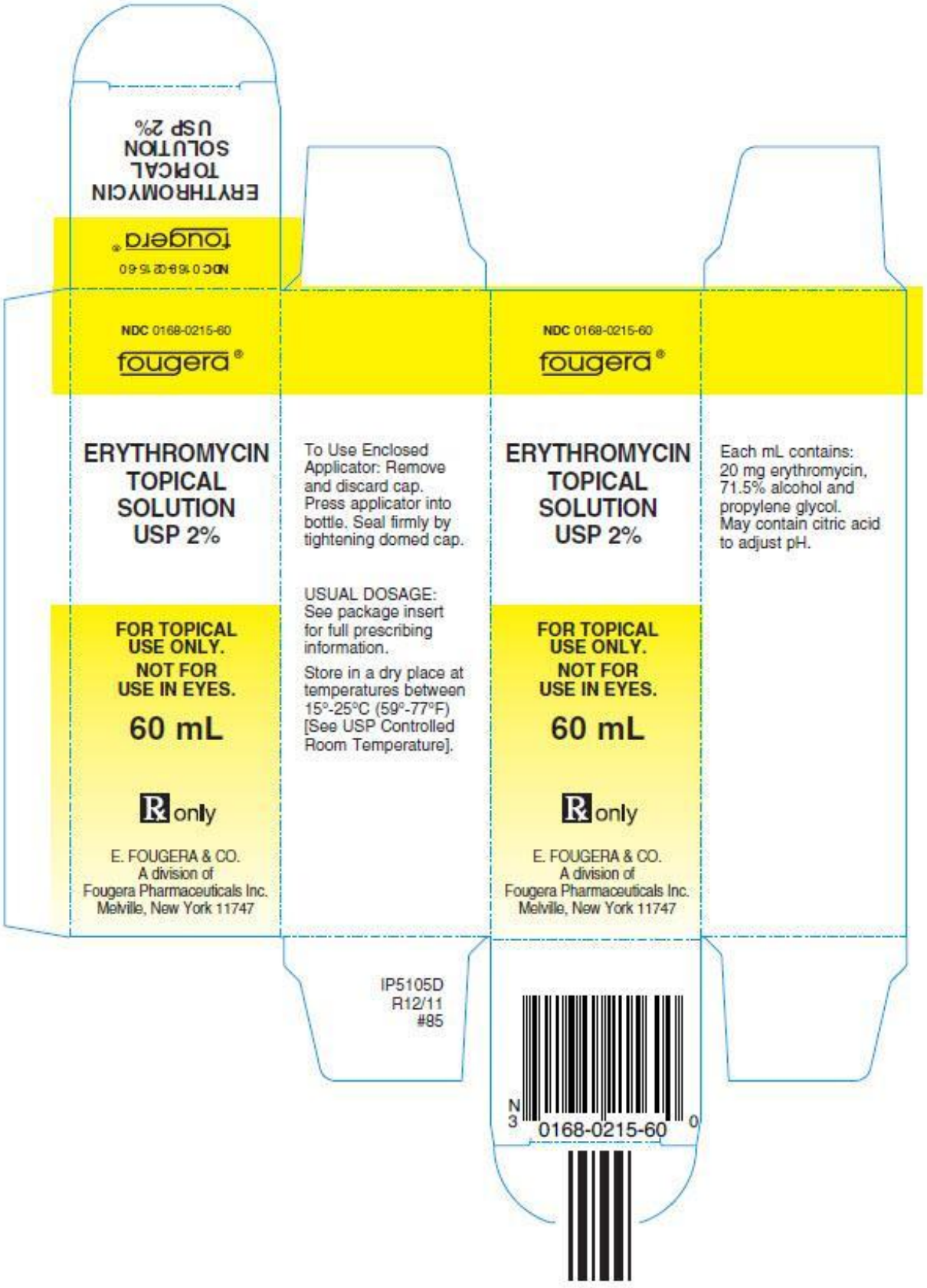

ERYTHROMYCIN

erythromycin solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0215-60	60 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064187	09/30/1997	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 7/2014 E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.