ERYTHROMYCIN- erythromycin solution
MICRO LABS LIMITED

Erythromycin Topical Solution, USP 2%

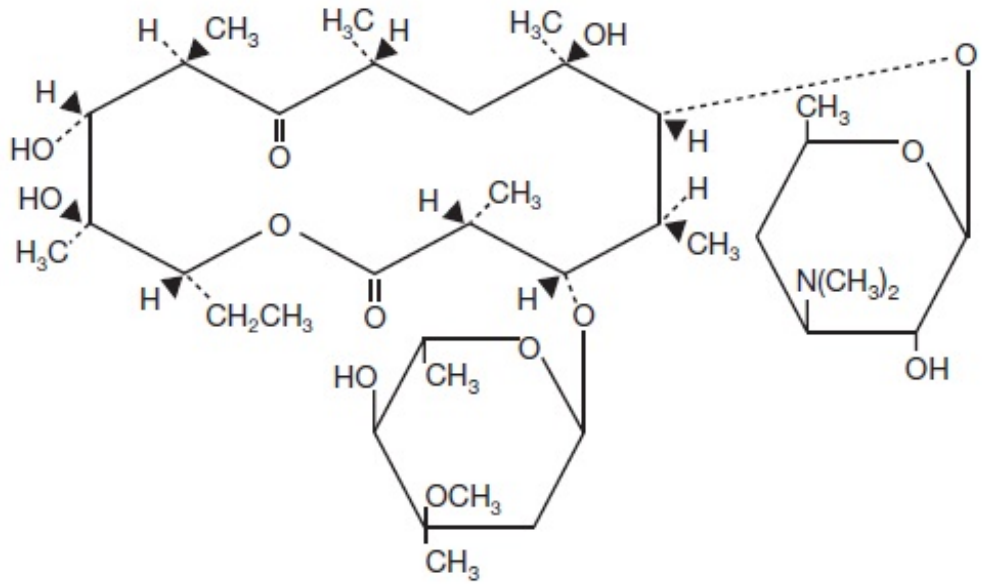
For Topical Use Only

Not for Ophthalmic Use

Rx Only

DESCRIPTION

Erythromycin topical solution, USP 2% contains erythromycin, USP 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-*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)-ß-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, USP is a white or slightly yellow, crystalline powder that is soluble in water, alcohol, chloroform and in ether.

Each mL of erythromycin topical solution, USP 2% contains 20 mg of erythromycin base in a vehicle consisting of alcohol (66%), citric acid, and propylene glycol.

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 50S 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, 2% is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS

Erythromycin topical solution, 2% 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, 2% 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

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.

To report SUSPECTED ADVERSE REACTIONS, contact Saptalis Pharmaceuticals, LLC at 1-833-727-8254 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Erythromycin topical solution, 2% 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, shoulders, 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 available as follows:

60 mL bottle with applicator (NDC 42571-384-25)

Store at 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Keep container tightly closed.

Manufactured by:
Saptalis Pharmaceuticals, LLC
Hauppauge, NY 11788

Distributed by:
Micro Labs USA, Inc.
Somerset, NJ 08873

Rev. 01/22-R2

Principal dispaly panel-Label

NDC 42571-384-25

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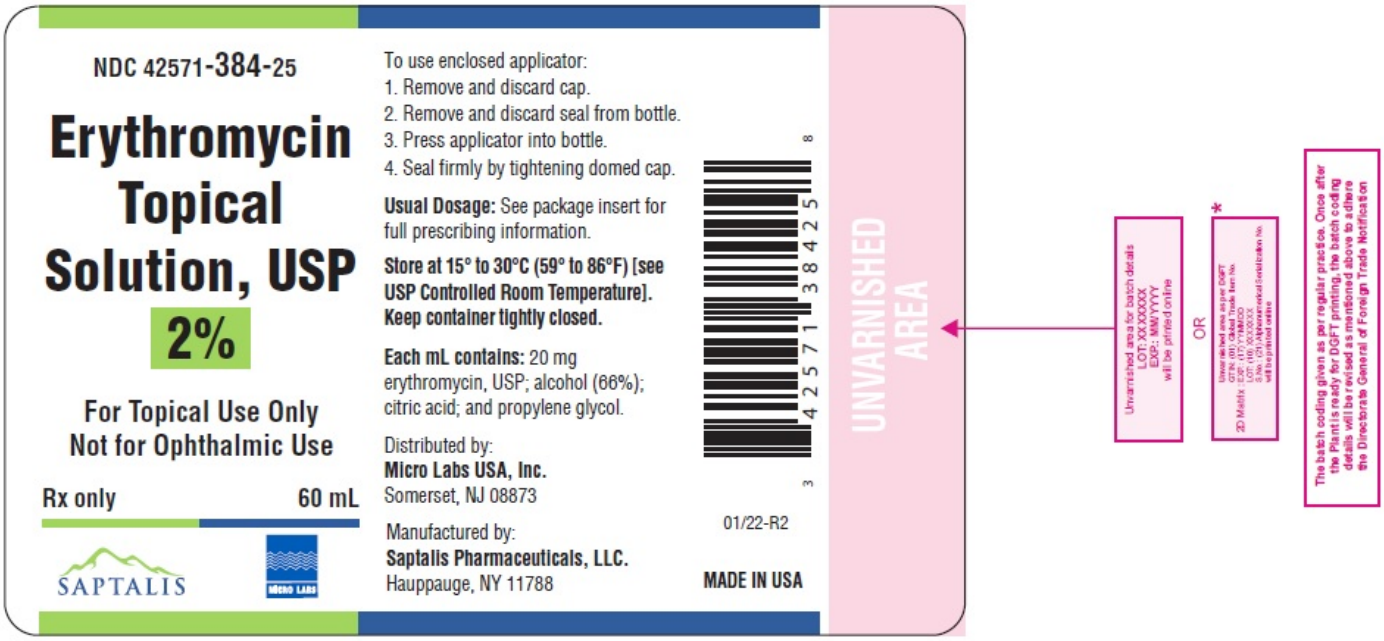
60 mL



Principal dispaly panel-Carton

NDC 42571-384-25

Erythromycin Topical Solution, USP 2%

For Topical Use Only

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Rx only

60 mL

ERYTHROMYCIN

erythromycin solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42571-384
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42571-384-25	1 in 1 CARTON	06/04/2021	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062687	06/04/2021	

Labeler - MICRO LABS LIMITED (862174955)

Registrant - Saptalis Pharmaceuticals, LLC. (080145868)

Establishment

Name	Address	ID/FEI	Business Operations
Saptalis Pharmaceuticals, LLC.		080145868	manufacture(42571-384)

Revised: 6/2022 MICRO LABS LIMITED