ERYTHROMYCIN- erythromycin solution
E. FOUGERA & CO.

ERYTHROMYCIN PLEDGETS, USP

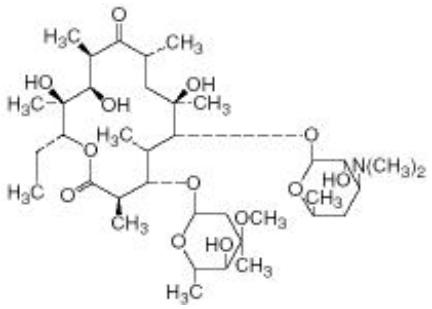
For Dermatologic Use Only
Not for Ophthalmic Use

Rx only

DESCRIPTION

Erythromycin Pledgets, USP contains erythromycin ((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-□-*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), for topical dermatologic use. Erythromycin is a macrolide antibiotic produced from a strain of *Saccharopolyspora erythraea* (formerly *Streptomyces erythreus*).

It is a base and readily forms salts with acids. Chemically, erythromycin is $C_{37}H_{67}NO_{13}$. It has the following structural formula:



Erythromycin has the molecular weight of 733.94

It is a white powder, is freely soluble in alcohols, acetone, chloroform, acetonitrile, ethyl acetate, and moderately soluble in ether, ethylene dichloride and amyl acetate. Erythromycin pledgets, USP are absorbent pads impregnated with Erythromycin Topical Solution 2%. Each pledget contains 1 mL of Erythromycin Topical Solution 2% and each 1 mL of Erythromycin Topical Solution 2% contains 20 mg of erythromycin base in a vehicle consisting of alcohol (71.5% v/v) and propylene glycol. May contain anhydrous citric acid and/or alcohol 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 pledgets, USP are indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS

Erythromycin pledgets, USP are 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 pledgets, USP 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 year) 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% 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 Ievels 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 pledgets, USP should be rubbed over the affected area twice a day 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. Additional pledgets may be used, if needed. Each pledget should be used once and discarded.

HOW SUPPLIED

Each pledget is filled to contain 1 mL of Erythromycin Topical Solution USP 2%. Each mL of Erythromycin Topical Solution USP 2% contains 20 mg of erythromycin.

Each pledget is supplied in an individual foil packet in boxes of 60.

NDC 0168-0215-01.

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

E. FOUGERA & CO.
a division of Altana Inc.
MELVILLE, NY 11747

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Remove this portion before dispensing

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MELVILLE, NEW YORK 11747

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)		20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
alcohol (UNII: 3K9958V90M)	71.5 mg in 1
propylene glycol (UNII: 6DC9Q167V3)	
anhydrous citric acid ()	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0168-0215-01	60 in 1 BOX		

Labeler - E. FOUGERA & CO.

Revised: 9/2007 E. FOUGERA & CO.