

**ERYTHROMYCIN- erythromycin solution**  
**VersaPharm Incorporated**

-----  
**ERYTHROMYCIN PLEDGETS USP, 2%**

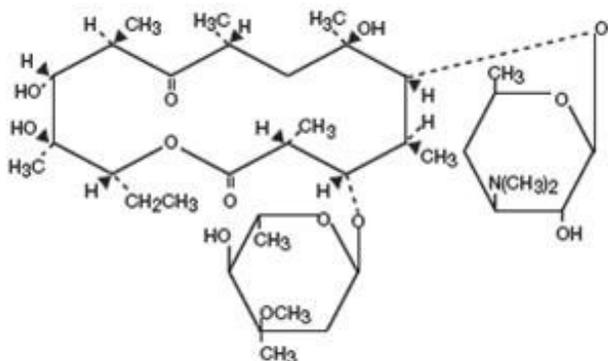
**Rx only**

**For Dermatologic Use Only**

**Not for Ophthalmic Use**

**DESCRIPTION**

Erythromycin Pledgets USP, 2% contain 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 C<sub>37</sub>H<sub>67</sub>NO<sub>13</sub>. It has the following structural formula:



Molecular weight of 733.94

The chemical name for erythromycin is (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-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy] oxacyclotetradecane-2,10-dione.

Erythromycin is a white or slightly yellow, crystalline powder, slightly soluble in water, soluble in alcohol, in chloroform, and in ether. It is odorless or practically odorless. It has a pH range between 8.0 and 10.5 in a methanol and water solution prepared by diluting 1 volume of a methanol solution, containing 40 mg per mL, with 19 volumes of water.

Each mL of expressible liquid contains 20 mg erythromycin in a base of alcohol (68.5%) (denatured with *tert*-butyl alcohol and denatonium benzoate), propylene glycol and citric acid to adjust pH. Each pledget is filled to contain 0.8 mL of erythromycin topical solution.

**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, and lincomycin, chloramphenicol, and clindamycin.

## INDICATIONS AND USAGE

Erythromycin Pledgets USP, 2% are indicated for the topical treatment of acne vulgaris.

## CONTRAINDICATIONS

Erythromycin Pledgets USP, 2% 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, 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, and 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 levels are generally low.

### **Nursing women**

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 women.

### **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**

The Erythromycin Pledgets USP, 2% should be rubbed over the affected area twice a day (morning and evening) after 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. Wash hands after application. Close jar tightly after each use. Drying and peeling may be controlled by reducing the frequency of applications.

## **HOW SUPPLIED**

Erythromycin Pledgets USP, 2% are available in a plastic jar containing 60 pledgets - NDC 61748-202-60.

Each pledget is filled to contain 0.8 mL of erythromycin topical solution, 2%.

Keep jar tightly closed.

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

Manufactured by:

**Ei Inc.**

Kannapolis, NC 28083

Marketed by:

**VersaPharm Incorporated**

Marietta, GA 30062

IS1VP20260-00

Issued: 01-23-2012

P001

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL-Container Label**

**NDC 61748-202-60**

**ERYTHROMYCIN**

**PLEDGETS USP, 2%**

**For External Use.**

**Avoid contact with eyes.**

**Rx Only**

**60 Pledgets**

**NDC 61748-202-60**

**ERYTHROMYCIN**  
**PLEDGETS USP, 2%**  
**For External Use.**  
**Avoid contact with eyes.**  
**Rx Only**  
**60 Pledgets**

LS1VP20260N0112

Usual Dosage: See package insert for complete product information. Keep jar tightly closed. Keep out of the reach of children. Store at 20° - 25°C (68° - 77° F) [See USP Controlled Room Temperature].

Instructions for use:

1. Wash affected area with warm water and soap and then pat dry.
2. Use pledget to apply to affected areas twice a day. Keep pledget away from eyes, nose, mouth and other mucous membranes. If medication accidentally enters eyes, rinse thoroughly with tap water. Additional pledgets may be used, if needed. Each pledget should be used once and discarded.
3. Close jar tightly after each use.

Lot No. and Exp. Date: See label or bottom of container.

Each mL of expressible liquid contains 20 mg erythromycin in a base of alcohol (68.5%) (denatured with *tert*-butyl alcohol and denatonium benzoate), propylene glycol and citric acid to adjust pH. Each pledget is filled to contain 0.8 mL Erythromycin Topical Solution, 2%. If protective seal is missing or broken, return to place of purchase.

Marketed by: **VersaPharm Incorporated**  
Marietta, GA 30062

Manufactured by: **Ei Inc.**  
Kannapolis, NC 28083



N  
3 6 1 7 4 8 - 2 0 2 - 6 0 7

Unvarnished Area

**ERYTHROMYCIN**

erythromycin solution

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG LABEL	<b>Item Code (Source)</b>	NDC:61748-202
<b>Route of Administration</b>	TOPICAL	<b>DEA Schedule</b>	

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ERYTHROMYCIN (ERYTHROMYCIN)	ERYTHROMYCIN	20 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALCOHOL	

<b>PROPYLENE GLYCOL</b>	
<b>ANHYDROUS CITRIC ACID</b>	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61748-202-60	60 in 1 JAR		
1		0.8 mL in 1 PACKET		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090215	08/01/2010	

**Labeler** - VersaPharm Incorporated (956741896)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	MANUFACTURE(61748-202), PACK(61748-202)

Revised: 2/2013

VersaPharm Incorporated