

**CLINDAMYCIN PHOSPHATE- clindamycin phosphate lotion**  
**CLINDAMYCIN PHOSPHATE- clindamycin phosphate solution**  
**CLINDAMYCIN PHOSPHATE- clindamycin phosphate gel**  
**E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.**

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**Clindamycin Phosphate Topical Solution USP, 1%,**  
**Clindamycin Phosphate Gel USP, 1%,**  
**Clindamycin Phosphate Lotion**  
**(Clindamycin Phosphate Topical Suspension USP, 1%)**

**Rx only**

**For External Use.**

## **DESCRIPTION**

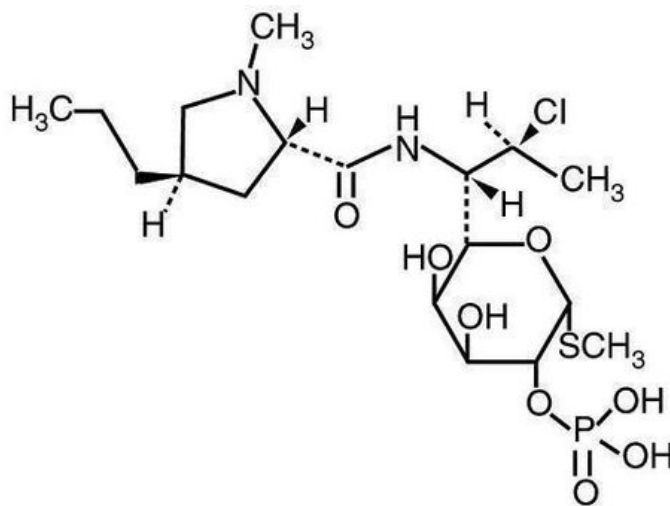
Clindamycin Phosphate Topical Solution and Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension USP, 1%) contain clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Clindamycin Phosphate Gel contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

The solution contains isopropyl alcohol 50% v/v, propylene glycol, and purified water.

The gel contains allantoin, carbomer 974P, methylparaben, polyethylene glycol 400, propylene glycol, sodium hydroxide, and purified water.

The lotion contains cetostearyl alcohol (2.5%); glycerin; glyceryl stearate SE (with potassium monostearate); isostearyl alcohol (2.5%); methylparaben (0.3%); sodium lauroyl sarcosinate; stearic acid; and purified water.

The structural formula is represented below:



Molecular Formula:  $C_{18}H_{34}ClN_2O_8PS$

Molecular Weight: 504.97

The chemical name for clindamycin phosphate is Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*- $\alpha$ -D-galacto-octopyranoside 2-(dihydrogen phosphate).

## CLINICAL PHARMACOLOGY

Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin.

Cross resistance has been demonstrated between clindamycin and lincomycin.

Antagonism has been demonstrated between clindamycin and erythromycin.

Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per mL in an isopropyl alcohol and water solution, very low levels of clindamycin are present in the serum (0 to 3 ng/mL) and less than 0.2% of the dose is recovered in urine as clindamycin.

Clindamycin activity has been demonstrated in comedones from acne patients. The mean concentration of antibiotic activity in extracted comedones after application of Clindamycin Phosphate Topical Solution for 4 weeks was 597 mcg/g of comedonal material (range 0 to 1,490). Clindamycin *in vitro* inhibits all *Propionibacterium acnes* cultures tested (MICs 0.4 mcg/mL). Free fatty acids on the skin surface have been decreased from approximately 14% to 2% following application of clindamycin.

## INDICATIONS AND USAGE

Clindamycin Phosphate Topical Solution, Clindamycin Phosphate Gel, and Clindamycin Phosphate Lotion are indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate. (See **CONTRAINDICATIONS**, **WARNINGS** and **ADVERSE REACTIONS**.)

## CONTRAINDICATIONS

Clindamycin Phosphate Topical Solution, Clindamycin Phosphate Gel, and Clindamycin Phosphate Lotion are contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

## WARNINGS

**Orally and parenterally administered clindamycin has been associated with severe colitis which may result in patient death. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.**

**Studies indicate a toxin(s) produced by clostridia is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis. Stool culture for *Clostridium difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.**

**When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea.**

**Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dosage is 500 mg to 2 grams of vancomycin orally per day in three to four divided doses administered for 7 to 10 days.**

**Cholestyramine or colestipol resins bind vancomycin *in vitro*. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of**

each drug.

**Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.**

## PRECAUTIONS

**General:** Clindamycin Phosphate Topical Solution contains an alcohol base which will cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), bathe with copious amounts of cool tap water. The solution has an unpleasant taste and caution should be exercised when applying medication around the mouth.

Clindamycin phosphate should be prescribed with caution in atopic individuals.

**Drug Interactions:** Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore it should be used with caution in patients receiving such agents.

**Pregnancy:Teratogenic Effects—Pregnancy Category B.** In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities. There are no adequate studies in pregnant women during the first trimester of pregnancy. Clindamycin should be used during the first trimester of pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether clindamycin is excreted in human milk following use of clindamycin phosphate. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric Use:** Safety and effectiveness in pediatric patients under the age of 12 have not been established.

**Geriatric Use:** Clinical studies for topical Clindamycin products did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

## ADVERSE REACTIONS

In 18 clinical studies of various formulations of clindamycin phosphate using placebo vehicle and/or active comparator drugs as controls, patients experienced a number of treatment emergent adverse dermatologic events [see table below].

**Number of Patients Reporting Events**

Treatment Emergent Adverse Event	Solution	Gel	Lotion
	n=553 (%)	n=148 (%)	n=160 (%)
Burning	62 (11)	15 (10)	17 (11)
Itching	36 (7)	15 (10)	17 (11)
Burning/Itching	60 (11)	# (–)	# (–)
Dryness	105 (19)	34 (23)	29 (18)
Erythema	86 (16)	10 (7)	22 (14)
Oiliness/Oily Skin	8 (1)	26 (18)	12* (10)

Peeling	61 (11)	# (-)	11 (7)
# not recorded			
* of 126 subjects			

Orally and parenterally administered clindamycin has been associated with severe colitis which may end fatally.

Cases of diarrhea, bloody diarrhea and colitis (including pseudomembranous colitis) have been reported as adverse reactions in patients treated with oral and parenteral formulations of clindamycin and rarely with topical clindamycin. (see **WARNINGS**.)

Abdominal pain and gastrointestinal disturbances as well as gram-negative folliculitis have also been reported in association with the use of topical formulations of clindamycin.

## **OVERDOSAGE**

Topically applied clindamycin phosphate can be absorbed in sufficient amounts to produce systemic effects. (see **WARNINGS**.)

## **DOSAGE AND ADMINISTRATION**

Apply a thin film of Clindamycin Phosphate Topical Solution, Clindamycin Phosphate Lotion, or Clindamycin Phosphate Gel twice daily to affected area.

Lotion: Shake well immediately before using.

Keep all liquid dosage forms in containers tightly closed.

## **HOW SUPPLIED**

Clindamycin Phosphate Topical Solution, USP 1% containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following sizes:

30 mL applicator bottle NDC 0168-0201-30

60 mL applicator bottle NDC 0168-0201-60

Clindamycin Phosphate Gel, USP 1% containing clindamycin phosphate equivalent to 10 mg clindamycin per gram is available in the following sizes:

30 gram tube NDC 0168-0202-30

60 gram tube NDC 0168-0202-60

Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension, USP 1%) containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following size:

60 mL bottle NDC 0168-0203-60

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing.

**Fougera  
PHARMACEUTICALS INC.**

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.  
MELVILLE, NEW YORK 11747

I201C/IF201C

R07/14

#90

**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CONTAINER**

NDC 0168-0203-60

**Fougera®**

**CLINDAMYCIN  
PHOSPHATE LOTION  
(Clindamycin Phosphate  
Topical Suspension  
USP, 1%)**

**Equivalent to 1% (10 mg/mL)  
clindamycin**

**FOR TOPICAL USE ONLY.  
60 mL**

Rx only

E. FOUGERA & CO.

A division of

Fougera Pharmaceuticals Inc.

Melville, New York 11747

**NDC 0168-0203-60**

**fougera®**

**CLINDAMYCIN  
PHOSPHATE LOTION  
(Clindamycin Phosphate  
Topical Suspension  
USP, 1%)**

**Equivalent to 1% (10 mg/mL)  
clindamycin**

**FOR TOPICAL USE ONLY.  
60 mL**

**Rx only**

E. FOUGERA & CO.  
A division of  
Fougera Pharmaceuticals Inc.  
Melville, New York 11747

**USUAL DOSAGE:** Apply a thin film twice daily to affected area. See package insert for complete product information.

**FOR EXTERNAL USE ONLY.  
AVOID CONTACT WITH EYES.**

Keep container tightly closed. SHAKE WELL IMMEDIATELY BEFORE USING.

This product sealed for your protection. If the seal is missing or broken return to place of purchase. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing.

**WARNING: Keep out of reach of children.**

Each mL contains clindamycin phosphate, equivalent to clindamycin 10 mg/mL, cetostearyl alcohol (2.5%), glycerin, glyceryl stearate SE (with potassium monostearate), isostearyl alcohol (2.5%), methylparaben (0.3%), sodium lauryl sarcosinate, stearic acid and purified water.

L220360F R07/14

0168-0203-607

EXP: LOT:

**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CARTON**

NDC 0168-0203-60

**Fougera®**

**CLINDAMYCIN  
PHOSPHATE  
LOTION  
(Clindamycin  
Phosphate Topical  
Suspension**

**USP, 1%)**

**Equivalent to 1%  
(10 mg/mL) clindamycin**

**FOR TOPICAL USE ONLY.**

**60 mL**

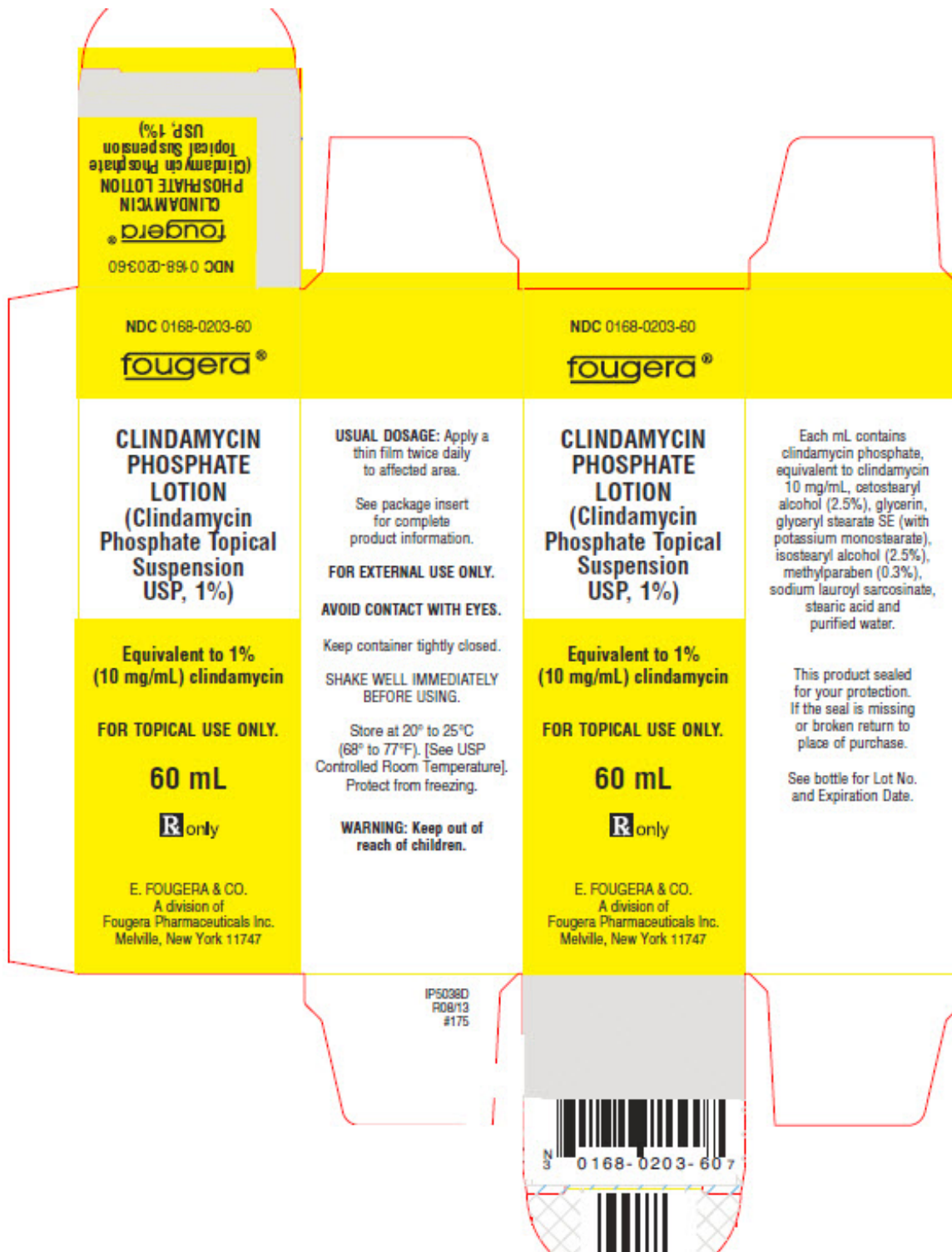
Rx only

E. FOUGERA & CO.

A division of

Fougera Pharmaceuticals Inc.

Melville, New York 11747



**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CONTAINER**

NDC 0168-0201-60

**Fougera®**

**CLINDAMYCIN  
PHOSPHATE  
Topical Solution USP, 1%**  
Equivalent to 1%  
(10 mg/mL) clindamycin  
**WARNING: Keep out**

**of reach of children.  
For Topical Use Only.**

Rx only  
**60 mL**

E. FOUGERA & CO.  
A division of  
Fougera Pharmaceuticals Inc.  
Melville, New York 11747

NDC 0168-0201-60

**fougera**<sup>®</sup>

**CLINDAMYCIN  
PHOSPHATE**

**Topical Solution USP, 1%**  
Equivalent to 1%  
(10 mg/mL) clindamycin  
**WARNING: Keep out  
of reach of children.**  
**For Topical Use Only.**

**R** only  
**60 mL**  
E. FOUGERA & CO.  
A division of  
Fougera Pharmaceuticals Inc.  
Melville, New York 11747

This product sealed for your protection.  
If the seal is missing or broken return to  
place of purchase.

Each mL contains: Clindamycin phosphate  
equivalent to clindamycin 1%. Also,  
propylene glycol; isopropyl alcohol,  
50% (v/v); and purified water.

Usual Dosage: See Package Insert for  
complete product information.

**For external use only.**  
**Avoid contact with eyes.**  
Store at 20° to 25°C (68° to 77°F).  
[See USP Controlled Room Temperature].  
Flash Point 75°F. Protect from freezing.

**Keep Container Tightly Closed.**  
Store in an upright fashion.

**Instructions for Use:**

1. Clean and dry skin area to be treated.
2. Apply a thin film of medication to the  
affected area. Use sparingly avoiding  
eyes and mouth. If medication  
accidentally enters eyes, rinse  
thoroughly with tap water.
3. Use dabbing motion of the tip rather  
than rolling action. If tip becomes dry  
invert bottle and depress tip several  
times until it becomes moist.

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3 M  
0168-0201-60 3

EXP: LOT:

**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CARTON**

NDC 0168-0201-60

**Fougera**<sup>®</sup>

**CLINDAMYCIN  
PHOSPHATE**  
**Topical Solution  
USP, 1%**

Equivalent to 1%  
(10 mg/mL) clindamycin

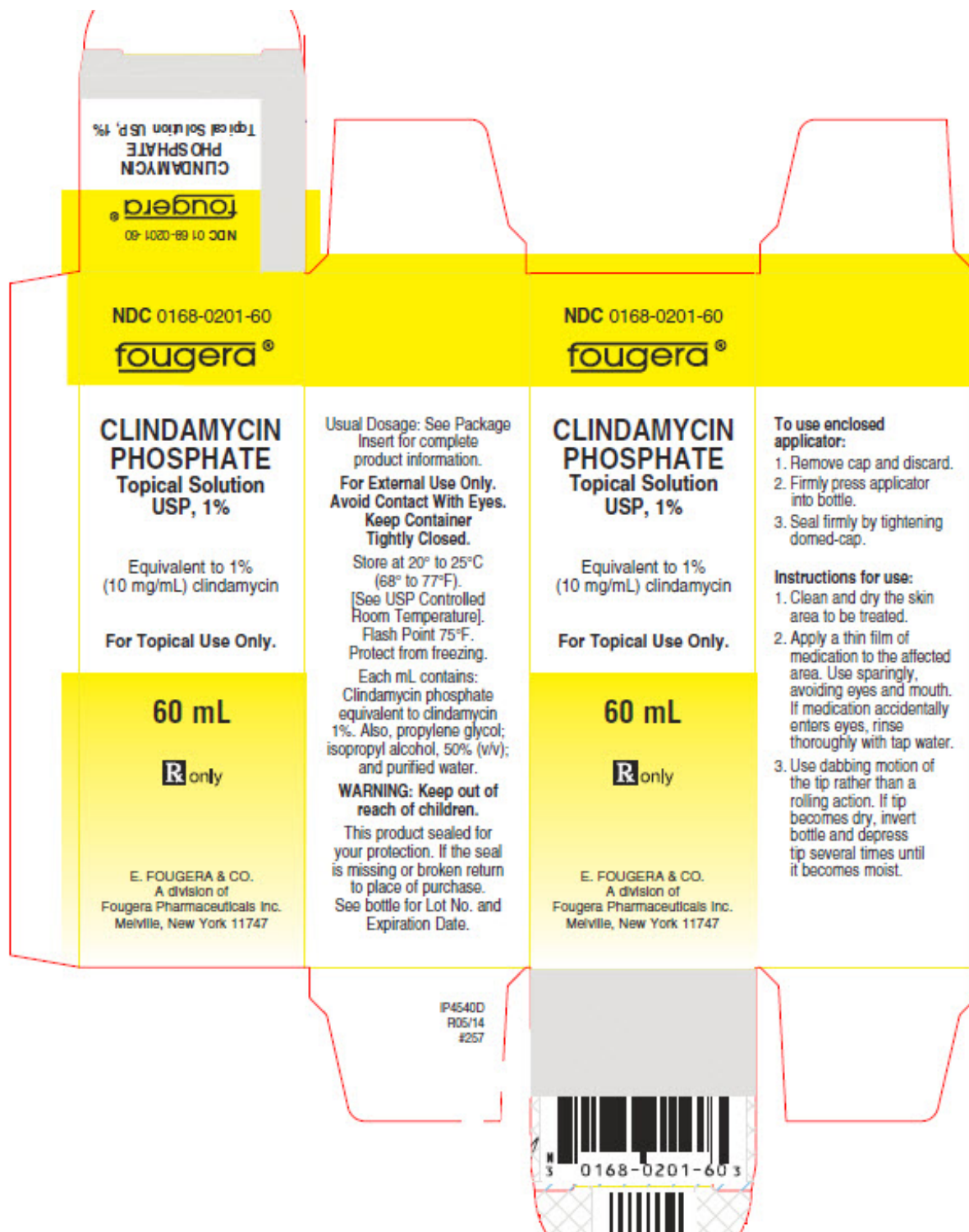
**For Topical Use Only.**

**60 mL**

Rx only

E. FOUGERA & CO.  
A division of  
Fougera Pharmaceuticals Inc.  
Melville, New York 11747





**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 G CONTAINER**

**NDC 0168-0202-30**


**Fougera®**

**CLINDAMYCIN  
PHOSPHATE GEL USP, 1%**  
equivalent to 1% clindamycin

For Topical Use Only.

Rx only

**NET WT 30 grams**

<p>NDC 0168-0202-30</p> <p><b>fougera</b><sup>®</sup></p> <p><b>CLINDAMYCIN PHOSPHATE GEL USP, 1%</b> equivalent to 1% clindamycin</p> <p><b>For Topical Use Only.</b></p> <p>Usual Dosage: Apply a thin film twice daily to affected area. See package insert for complete product information.</p> <p>TO OPEN: Use cap to puncture seal.</p> <p>IMPORTANT: Do not use if seal has been punctured or is not visible.</p> <p><b>WARNING: Keep out of reach of children.</b></p> <p>E. FOUGERA &amp; CO. A division of Fougera Pharmaceuticals Inc. Melville, New York 11747</p>	<p><b>R</b> only</p> <p>Each gram contains: Clindamycin phosphate equivalent to clindamycin 10 mg (1%). Also, allantoin, carbomer 974P, methylparaben, polyethylene glycol 400, propylene glycol, sodium hydroxide, and purified water.</p> <p><b>NET WT 30 grams</b></p> <p>FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. See crimp of tube for Lot No. and Exp. Date. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing.</p> <p>46132721A R07/14</p>  <p>N 3 0168-0202-303</p>	
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**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 G CARTON**

NDC 0168-0202-30

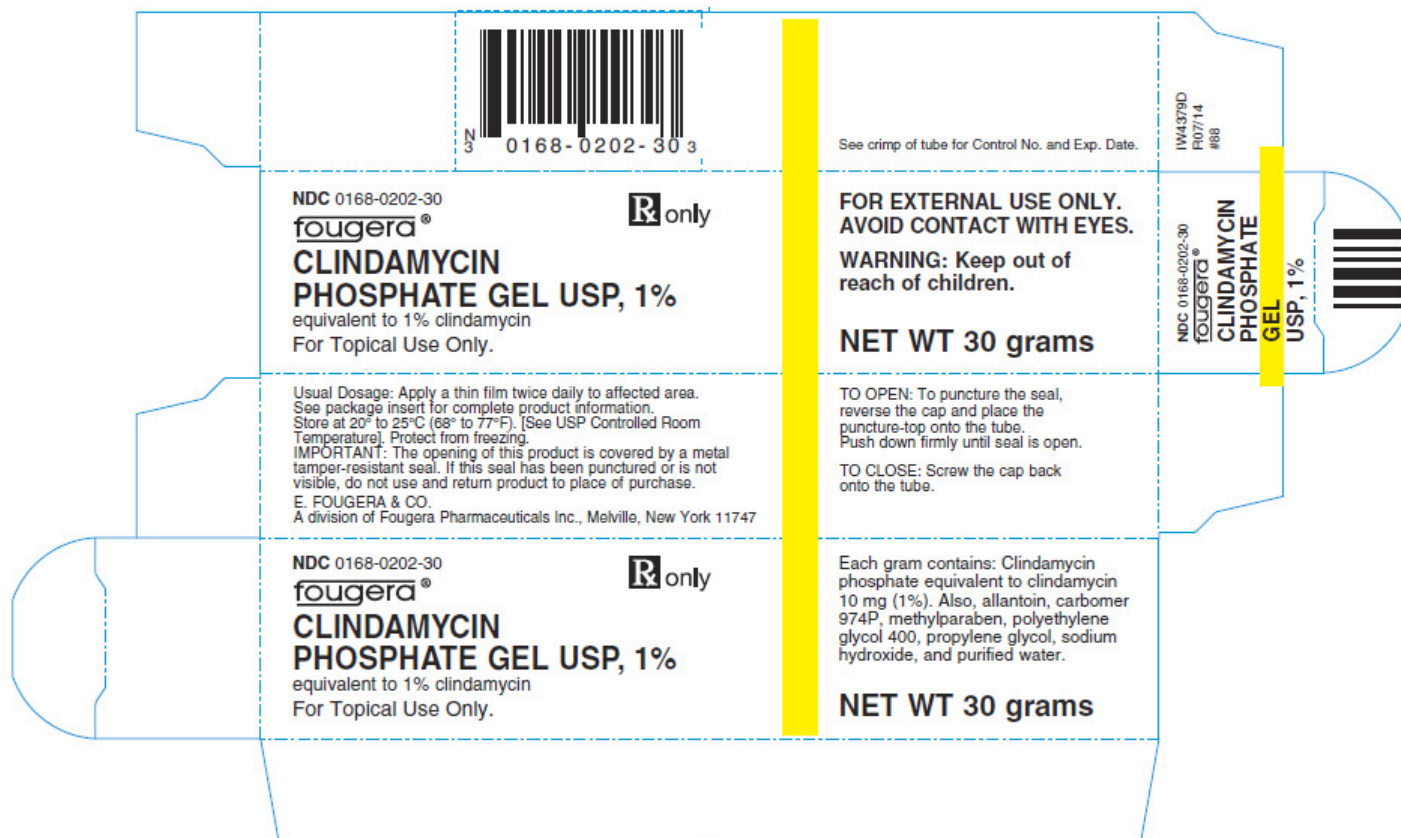
Rx only

**Fougera**<sup>®</sup>

**CLINDAMYCIN  
PHOSPHATE GEL USP, 1%**  
equivalent to 1% clindamycin  
For Topical Use Only.

**FOR EXTERNAL USE ONLY.  
AVOID CONTACT WITH EYES.  
WARNING: Keep out of  
reach of children.**

**NET WT 30 grams**



## CLINDAMYCIN PHOSPHATE

clindamycin phosphate lotion

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG LABEL	<b>Item Code (Source)</b>	NDC:0168-0203
<b>Route of Administration</b>	TOPICAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (CLINDAMYCIN)	CLINDAMYCIN	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL	
GLYCERIN	
GLYCERYL MONOSTEARATE	
ISOSTEARYL ALCOHOL	
METHYLPARABEN	
SODIUM LAUROYL SARCO SINATE	
STEARIC ACID	
WATER	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0203-60	1 in 1 CARTON		
1		60 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065067	01/31/2002	

**CLINDAMYCIN PHOSPHATE**

clindamycin phosphate solution

**Product Information**

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0168-0201
Route of Administration	TOPICAL	DEA Schedule	

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (CLINDAMYCIN)	CLINDAMYCIN	10 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
ISOPROPYL ALCOHOL	
PROPYLENE GLYCOL	
WATER	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0201-30	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		
2	NDC:0168-0201-60	1 in 1 CARTON		
2		60 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064159	06/05/1997	

# CLINDAMYCIN PHOSPHATE

clindamycin phosphate gel

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG LABEL	<b>Item Code (Source)</b>	NDC:0168-0202
<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>
CLINDAMYCIN PHOSPHATE (CLINDAMYCIN)	CLINDAMYCIN	10 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALLANTOIN	
METHYL PARABEN	
POLYETHYLENE GLYCOL 400	
PROPYLENE GLYCOL	
SODIUM HYDROXIDE	
WATER	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0168-0202-30	1 in 1 CARTON		
1		30 g in 1 TUBE		
2	NDC:0168-0202-60	1 in 1 CARTON		
2		60 g in 1 TUBE		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA064160	01/28/2010	

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

Revised: 8/2014

E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.