

**CLINDACIN P- clindamycin phosphate solution**  
**CLINDACIN PAC- clindamycin phosphate swab**  
**Medimetriks Pharmaceuticals, Inc.**

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**Clindacin•P®**  
**Clindamycin Phosphate Topical Solution**  
**USP, 1% (Pledgets)**

**For External Use**

**R<sub>x</sub> Only**

**DESCRIPTION**

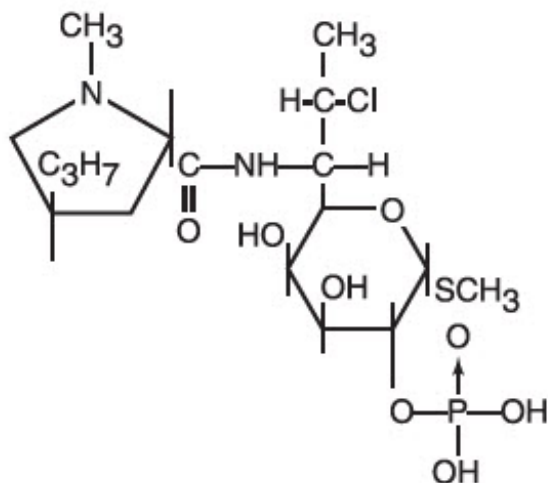
**Clindacin•P®** contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter.

Each **Clindacin•P®** pledget applicator contains approximately 1 mL of topical solution.

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, purified water, and sodium hydroxide (to adjust the pH to between 4.0 - 7.0).

The structural formula is represented below:



The chemical name for clindamycin phosphate is Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidine-carboxamido)-1-thio-L-*threo*- $\alpha$ -D-galactooctopyranoside 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 (0-3 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 0-1490). 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

**Clindacin•P®** is indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudo-membranous colitis, the physician should consider whether other agents are more appropriate (see **CONTRAINDICATIONS, WARNINGS** and **ADVERSE REACTIONS**).

## CONTRAINDICATIONS

**Clindacin•P®** is 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 milligrams 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**

**Clindacin•P**<sup>®</sup> 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 topical products 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 **Clindacin•P**<sup>®</sup>. 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 clindamycin phosphate topical solution USP, 1% 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 topical 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].

Treatment Emergent Adverse Event	Number of Patients Reporting Events		
	Solution n=553 (%)	Gel n=148 (%)	Lotion 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 <sup>†</sup> (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, gastrointestinal disturbances, gram-negative folliculitis, eye pain and contact dermatitis have also been reported in association with the use of topical formulations of clindamycin.

**To report SUSPECTED ADVERSE REACTIONS, contact Medimetriks Pharmaceuticals, Inc., at 1-973-882-7512 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## OVERDOSAGE

Topically applied **Clindacin•P**<sup>®</sup> can be absorbed in sufficient amounts to produce systemic effects (see **WARNINGS**).

## **DOSAGE AND ADMINISTRATION**

Do not use if the seal on jar is broken. Remove pledget from jar just before use. Use a pledget to apply a thin film of Clindamycin Phosphate Topical Solution to the affected area twice daily. More than one pledget may be used. Each pledget should be used only once and then discarded. Keep jar tightly closed when not in use.

## **HOW SUPPLIED**

**Clindacin•P<sup>®</sup>** Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) is available as follows:

A jar containing 69 single-use pledget applicators (NDC 43538-170-69)

## **STORAGE**

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

Manufactured for Medimetriks  
Pharmaceuticals, Inc.  
383 Route 46 West, Fairfield, NJ 07004-2402  
www.medimetriks.com

Product of China  
Mfd. by: Padagis, Yeruham, Israel

IL015-R8  
Rev. Date: 11/22  
74PA4 EK F4

## **PRINCIPAL DISPLAY PANEL - 69 Pledget Jar Label**

R<sub>x</sub> Only

NDC 43538-170-69

For Topical Use Only

Clindacin•P<sup>®</sup>

Clindamycin Phosphate  
Topical Solution USP, 1%\* (Pledgets)

\*equivalent to 1% (10 mg/mL) clindamycin

MEDIMETRIKS  
PHARMACEUTICALS, INC.

69 Pledgets



Lot/Exp/Serialization

**Rx Only** NDC 43538-170-69 **For Topical Use Only**

**Clindacin•P<sup>®</sup>**  
Clindamycin Phosphate  
Topical Solution USP, 1%\* (Pledgets)  
\*equivalent to 1% (10 mg/mL) clindamycin

**MEDIMETRIKS**  
PHARMACEUTICALS, INC. **69 Pledgets**

**USUAL DOSAGE:** See package insert for complete product information. For external use only. Avoid contact with eyes. Store at 20-25°C (68-77°F) (see USP Controlled Room Temperature). Protect from freezing. Instructions for use:  
1. Clean and dry skin areas 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. Discard pledget after single use.

Each Clindacin•P<sup>®</sup> (Clindamycin Phosphate Topical Solution USP, 1%) Pledget contains clindamycin phosphate equivalent to 10 mg/mL clindamycin, isopropyl alcohol 50% v/v, purified water, propylene glycol, and sodium hydroxide (to adjust the pH between 4.0 and 7.0). For lot number and expiration date see container label.

Manufactured by Medimetrix Pharmaceuticals, Inc.  
10000 W. 10th Street, Suite 100  
Denver, CO 80202  
www.medimetrix.com  
Product of China. Mfg. by: Peidings, Yanchuan, Israel  
L01C-R8 Rev. Date 11/22 749M, EN, R1

## PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 43538-171-69

**MEDIMETRIKS**

PHARMACEUTICALS, INC.

*R<sub>x</sub> Only*

**Clindacin<sup>®</sup> pac**

Clindamycin Phosphate

Topical Solution USP, 1%\*

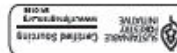
(Pledget) \*equivalent to 1% (10 mg/mL) clindamycin

### CONTENTS:

1-Clindacin•P<sup>®</sup> (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) Jar (69 Pledgets)

1-AcuWash<sup>®</sup> Moisturizing Daily Cleanser Bottle (16 fl. oz.)

IC049-R-3



Expiration Date, lot# and  
Serial# in code, lot# and



NO VARNISH AREA

Made in USA

Manufactured by: Perrigo, Bronx, NY 10457

383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512 • www.medimetrics.com

Manufactured for: Medimetrics Pharmaceuticals, Inc.

Clindamycin Phosphate  
Topical Solution USP, 1%\* (Pledgets)  
\*equivalent to 5.10 mg clindamycin

**Clindacin•P<sup>®</sup>**  
Rx Only

Made in USA

No Animal Testing

383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512 • www.medimetrics.com

Manufactured for: Medimetrics Pharmaceuticals, Inc.

Moisturizing Daily Cleanser  
with Aloe & Green Tea

**AcuWash**



NDC 43538-171-69

CO NEM TS

1 Clindacin•P<sup>®</sup> Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) Jar (69 Pledgets)  
1 AcuWash<sup>®</sup> Moisturizing Daily Cleanser Bottle (16 fl. oz.)



**Clindacin<sup>®</sup> pac**  
Rx Only  
Clindamycin Phosphate  
Topical Solution USP, 1%\*  
(Pledget) \*equivalent to 1% (10 mg/mL) clindamycin

NDC 43538-171-69



NDC 43538-171-69

*Rx Only*  
**Clindacin<sup>®</sup> pac**  
Clindamycin Phosphate  
Topical Solution USP, 1%\*  
(Pledget) \*equivalent to 1% (10 mg/mL) clindamycin

**CONTENTS:**

- 1-Clindacin•P<sup>®</sup> (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) Jar (69 Pledgets)
- 1-AcuWash<sup>®</sup> Moisturizing Daily Cleanser Bottle (16 fl. oz.)

NDC 43538-171-69

Rx Only

# Clindacin<sup>®</sup> pac

Clindamycin Phosphate  
Topical Solution USP, 1%\*  
(Pledget) \*equivalent to 1% (10 mg/mL) clindamycin

**CONTENTS:**

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# Clindacin<sup>®</sup> pac

Rx Only  
Clindamycin Phosphate  
Topical Solution USP, 1%\*  
(Pledget) \*equivalent to 1% (10 mg/mL) clindamycin

**CONTENTS:**

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NDC 43538-171-69

- 1-Clindacin•P<sup>®</sup> (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)) Jar (69 Pledgets)
- 1-AcuWash<sup>®</sup> Moisturizing Daily Cleanser Bottle (16 fl. oz.)

# Clindacin<sup>®</sup> pac

NDC 43538-171-69



AcuWash<sup>®</sup> is a gentle moisturizing cleanser that can be used daily to deeply clean and moisturize sensitive skin on the face, neck, shoulders, chest and back.

**DIRECTIONS:** Wet skin and pump cleanser into hands. Massage gently into skin working into a full lather. Rinse thoroughly and pat dry with a soft towel. For best results, use twice daily.

**CAUTION:** For external use only. Avoid contact with eyes, lips and mucous membranes. If contact occurs, rinse well with water. If rash or irritation develops, discontinue use. Use of other therapeutic moisturizers concurrently may cause irritation. Keep out of reach of children.

**STORAGE:** Store at 19°C-30°C (59°F-86°F). For lot number, see bottom of carton.

Made in USA

**DOSE AND ADMINISTRATION:** Do not use if the seal on jar is broken. Remove pledget from jar just before use. Use a pledget to apply a thin film of Clindamycin Phosphate Topical Solution USP, 1%\* (Pledgets) to the affected area twice daily. More than one pledget may be used. Each pledget should be used only once and the discarded. Keep jar tightly closed when not in use.

**INSTRUCTIONS FOR USE**

1. Do not use if seal under the cap is broken.
2. Clean and dry skin areas to be treated.
3. Apply a thin film of medication to the affected area. Use sparingly, avoid in eyes and mouth. If medication accidentally enters eyes, rinse thoroughly with tap water.
4. Discard pledget after single use.
5. Close tightly after each use.

Each Clindacin•P<sup>®</sup> Pledget contains Clindamycin Phosphate Topical Solution USP, 1%. The solution contains clindamycin phosphate equivalent to clindamycin 10mg/mL, isopropyl alcohol 50% w/v, propylene glycol, purified water, and sodium hydroxide (to adjust the pH to between 4.0-7.0).

For lot number and expiration date, see bottom of carton.

For external use only. Avoid contact with eyes.

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

Protect from freezing.

Made in USA







## CLINDACIN P

clindamycin phosphate solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43538-170
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
clindamycin phosphate (UNII: EH6D7113I8) (clindamycin - UNII:3U02EL437C)	clindamycin	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
isopropyl alcohol (UNII: ND2M416302)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium hydroxide (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-170-69	69 in 1 JAR	11/14/2022	
1		1 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065049	02/20/2011	

## CLINDACIN PAC

clindamycin phosphate swab

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43538-171
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>clindamycin phosphate</b> (UNII: EH6D7113I8) (clindamycin - UNII:3U02EL437C)	clindamycin	10 mg

**Inactive Ingredients**

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<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium hydroxide</b> (UNII: 55X04QC32I)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:43538-171-69	1 in 1 KIT	02/20/2011	12/01/2022
<b>1</b>		69 in 1 JAR; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA065049	02/20/2011	12/01/2022

**Labeler** - Medimetriks Pharmaceuticals, Inc. (019903816)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Padagis		600093611	MANUFACTURE(43538-170, 43538-171)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Marketin Advertising Promotions, Inc.		797063526	PACK(43538-171)

Revised: 11/2023

Medimetriks Pharmaceuticals, Inc.