

**CLINDAMYCIN PHOSPHATE- clindamycin phosphate solution**  
**RPK Pharmaceuticals, Inc.**

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**Clindamycin Phosphate Topical Solution USP, 1%**

**For External Use**

**Rx Only**

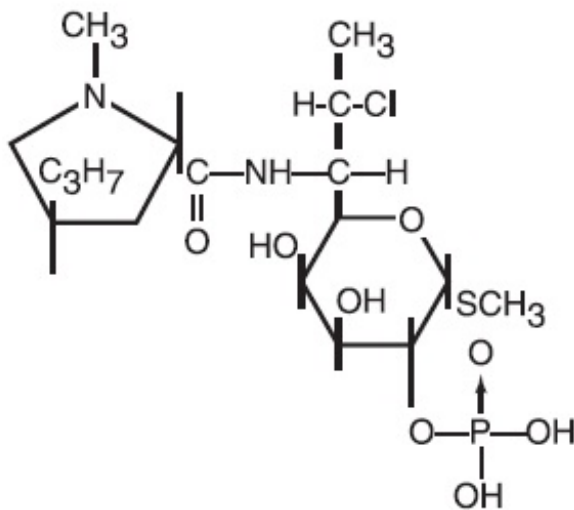
**DESCRIPTION**

Clindamycin Phosphate Topical Solution USP, 1% contains clindamycin phosphate USP at a concentration equivalent to 10 mg clindamycin per milliliter.

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-pyrrolidinecarboxamido)-1-thio-L-*threo*- α-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 (0–3 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

Clindamycin Phosphate Topical Solution USP, 1% is 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 USP, 1% 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 -

Clindamycin Phosphate Topical Solution USP, 1% 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 Clindamycin Phosphate Topical Solution USP, 1%. 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].

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<b>Treatment Emergent Adverse Event</b>	<b>Number of Patients Reporting Events</b>		
	<b>Solution n=553 (%)</b>	<b>Gel n=148 (%)</b>	<b>Lotion n=160 (%)</b>
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)

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# 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.

## **OVERDOSAGE**

Topically applied Clindamycin Phosphate Topical Solution USP, 1% can be absorbed in sufficient amounts to produce systemic effects (see **WARNINGS**).

## **DOSAGE AND ADMINISTRATION**

Apply a thin film of Clindamycin Phosphate Topical Solution USP, 1% to the affected area twice daily. Keep container tightly closed.

## **HOW SUPPLIED**

Product: 53002-8370

NDC: 53002-8370-1 30 mL in a BOTTLE, WITH APPLICATOR / 1 in a CARTON

## **STORAGE**

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

Manufactured By

Perrigo

Bronx, NY 10457

Distributed By Perrigo

Allegan, MI 49010

[www.perrigo.com](http://www.perrigo.com)

Rev 05-18

: 7F100 RC J4

## **Clindamycin 1% Topical Solution**

NDC# 53002-8370-1  
 LIST# 45802-062-01  
**CLINDAMYCIN 1% TOPICAL SOLUTION**  
 30 mL Bottle  
 LOTS# 18275-043  
 EXPIR DATE: 93-31-2020  
 Shape & Color Markings

30 mL Bottle PATIENT NAME: \_\_\_\_\_  
**CLINDAMYCIN 1% TOPICAL SOLN**  
 PEREGO Ref# 182870091000 ITEM# 8370 837-01

**APPLY TO AFFECTED AREA TWICE A DAY OR AS DIRECTED.**

CLINIC NAME GOES HERE

IMPORTANT: THIS DRUG IS AN ANTIBIOTIC FOR TOPICAL USE ONLY. READ INCLUDED PATIENT INFORMATION CAREFULLY BEFORE USING.

Prescribe Name \_\_\_\_\_  
 Date Dispensed \_\_\_\_\_

100% AND 100% (100% OF THE 8370-01) ARE IDENTICAL TO THE 8370-01. THIS DRUG IS NOT FOR INJECTION. IT IS FOR TOPICAL USE ONLY. READ THE PATIENT INFORMATION CAREFULLY BEFORE USING.



REF# 182870091000 ITEM# 8370

APP AFF AREA BID OR QID  
 LOTS# 18275-043 EXP 08-31-2020  
 Ref# 182870091 000 FDA- 8370  
 30 mL CLINDAMYCIN 1% TOPICAL SOLN

**CLINDAMYCIN 1% TOPICAL SOLUTION**  
 30 mL Bottle

BILLING NDC# 45802-062-01  
 Ref# 182870091 000  
 30 mL CLINDAMYCIN 1% TOPICAL SOLN

DISCARD BY 05-31-2020  
 NDC# 53002-8370-1  
 Ref# 182870091 000

BILLING NDC# 45802-062-01  
 Ref# 182870091 000  
 30 mL CLINDAMYCIN 1% TOPICAL SOLN

Clinic Name Here

BILLING NDC# 45802-062-01  
 Ref# 182870091 000  
 30 mL CLINDAMYCIN 1% TOPICAL SOLN

# CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:53002-8370(NDC:45802-562)
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113B) (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:53002-8370-1	1 in 1 CARTON	10/01/2018	
1		30 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064050	09/17/2013	

**Labeler** - RPK Pharmaceuticals, Inc. (147096275)

**Establishment**

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-8370)

Revised: 12/2020

RPK Pharmaceuticals, Inc.