

**CLINDAMYCIN PHOSPHATE- clindamycin phosphate lotion**  
**Encube Ethicals Private Limited**

-----  
**Clindamycin Phosphate Topical Lotion, 1%**

**For External Use**

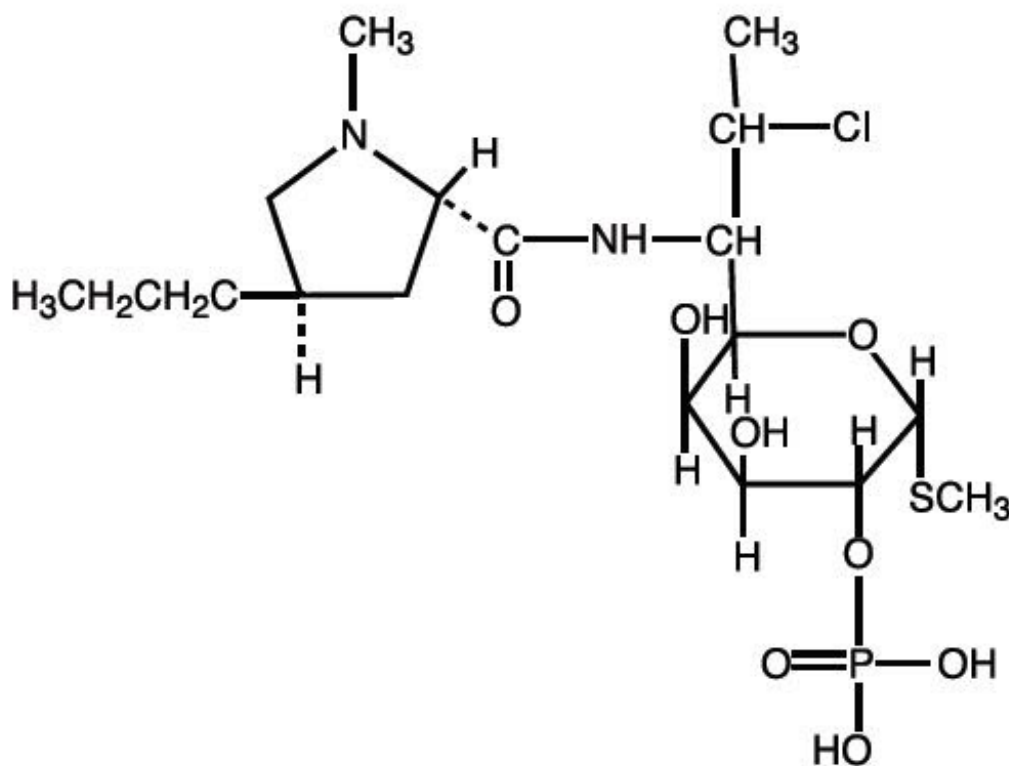
**DESCRIPTION**

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

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*- $\alpha$ -D- *galacto*-octopyranoside 2-(dihydrogen phosphate).

**CLINICAL PHARMACOLOGY**

## Mechanism of Action

The mechanism of action of clindamycin in treating acne vulgaris is unknown.

## Pharmacokinetics

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.

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

## Microbiology

Clindamycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is bacteriostatic.

### Antimicrobial Activity

Clindamycin is active *in vitro* against most isolates of *Propionibacterium acnes*; however, the clinical significance is unknown.

### Resistance

Resistance to clindamycin is most often caused by modification of specific bases of the 23S ribosomal RNA. Cross-resistance between clindamycin and lincomycin is complete. Because the binding sites for these antibacterial drugs overlap, cross-resistance is sometimes observed among lincosamides, macrolides and streptogramin B. Macrolide-inducible resistance to clindamycin occurs in some isolates of macrolide-resistant bacteria.

## INDICATIONS AND USAGE

Clindamycin phosphate topical lotion 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 lotion 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 lotion 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

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 breast milk following use of clindamycin phosphate topical lotion. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Clindamycin has the potential to cause adverse effects on the breast-fed infant's gastrointestinal flora. Monitor the breast-fed infant for possible adverse effects on the gastrointestinal flora, such as diarrhea, candidiasis (thrush, diaper rash) or rarely, blood in the stool indicating possible antibiotic-associated colitis.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breast-fed child from clindamycin or from the underlying maternal condition.

### Clinical Considerations

If used during lactation and clindamycin phosphate topical lotion is applied to the chest, care should be taken to avoid accidental ingestion by the infant.

### **Pediatric Use**

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

### **Geriatric Use**

Clinical studies for clindamycin phosphate 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].

<b>Number of Patients Reporting Events</b>			
<b>Treatment Emergent Adverse Event</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)

# 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 can be absorbed in sufficient amounts to produce systemic effects (see WARNINGS).

## **DOSAGE AND ADMINISTRATION**

Apply a thin film of clindamycin phosphate topical lotion, 1% twice daily to affected area. Shake well immediately before using.

Keep all liquid dosage forms in containers tightly closed.

## **HOW SUPPLIED**

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

**60 mL** plastic squeeze bottle - NDC 16714-246-01

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Protect from freezing.

## **Rx only**

Manufactured for:

### **Encube Ethicals Pvt. Ltd.**

Plot No. C1, Madkaim Industrial Estate, Madkaim,  
Post: Mardol, Ponda, Goa - 403 404, India.

Distributed by:

### **Encube Ethicals, Inc.**

200 Meredith Avenue, Suite 101A  
Durham, NC 27713 USA

Revised: 01/2022

## **PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton Label**

NDC 21922-036-01

# Clindamycin Phosphate Topical Lotion, 1%

For topical use only

60 mL

Rx only



## PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label


NDC 21922-036-01

# Clindamycin Phosphate

**Topical Lotion, 1%**  
**For topical use only**

60 mL

Rx only



**Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].**  
**Protect from freezing.**  
 For external use only. Avoid contact with eyes.  
**Keep container tightly closed.** Shake well immediately before using.  
**DOSAGE AND USE:** See accompanying prescribing information.  
 Each mL contains clindamycin phosphate equivalent to clindamycin 10 mg/mL (1%); 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.

NDC 21922-036-01


**Clindamycin Phosphate**  
**Topical Lotion, 1%**

**For topical use only**

60 mL

Rx only

No varnished Area ( Do Not Print )  
49 x 15 mm



Mfg. Lic. No.: 362  
ECL2A/00

**CLINDAMYCIN PHOSPHATE**

clindamycin phosphate lotion

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:21922-036
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CLINDAMYCIN PHOSPHATE</b> (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN PHOSPHATE	10 ug in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	

<b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	white (white to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21922-036-01	1 in 1 CARTON	01/19/2022	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215607	01/19/2022	

**Labeler** - Encube Ethicals Private Limited (915834105)

### Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	manufacture(21922-036) , analysis(21922-036) , pack(21922-036) , label(21922-036)

Revised: 1/2022

Encube Ethicals Private Limited