CLINDAMYCIN PHOSPHATE- clindamycin phosphate topical solution
Carnegie Pharmaceuticals, LLC

Clindamycin Phosphate Topical Solution, USP 1% (Pledgets)

For External Use

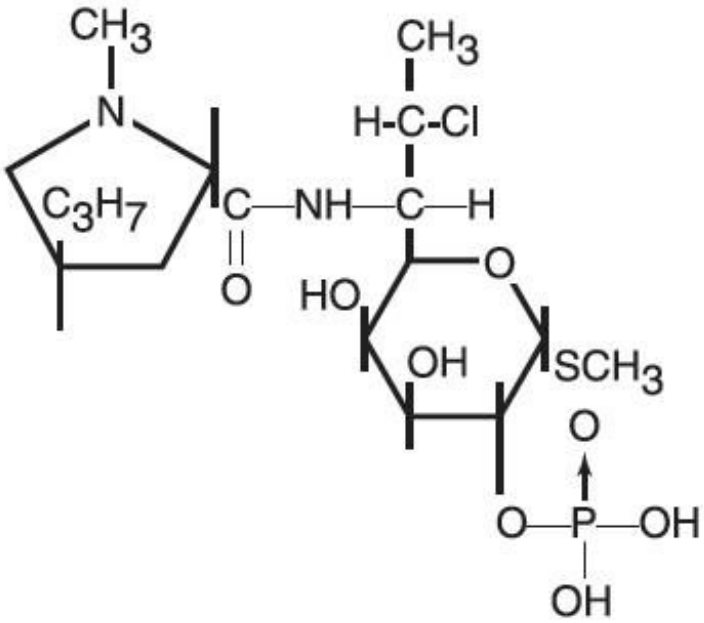
DESCRIPTION

Clindamycin Phosphate Topical Solution, USP contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Each Clindamycin Phosphate Topical Solution, USP pledget applicator contains approximately 1 mL of topical solution.

Clindamycin phosphate is a water soluble ester of the semi-synthetic antibacterial drug produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent compound lincomycin.

The solution contains isopropyl alcohol 50% v/v, propylene glycol, sodium hydroxide pellets, and water.

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

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 (0–3 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 Solution 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 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 systemic absorption 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 *Clostridioides 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 *Clostridioides 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 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 Solution 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 Solution. 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 Solution 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 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 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 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* (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 Carnegie Pharmaceuticals, LLC at 1-732-783-7010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Use a Clindamycin Phosphate Topical Solution pledget for the application of Clindamycin Phosphate Topical Solution twice daily to affected area. More than one pledget may be used. Each pledget should be used only once and then be discarded.

Clindamycin Phosphate Topical Solution is flammable. Avoid fire, flame, and smoking during and immediately following application.

Pledget: Do not use if the seal is broken. Discard after single use.

Keep the jar tightly closed after each use.

HOW SUPPLIED

Clindamycin Phosphate Topical Solution, USP containing clindamycin phosphate, USP equivalent to 10 mg clindamycin per milliliter is available in a jar containing 60 single-use pledget applicators (NDC 80005-131-09) and a jar containing 69 single-use pledget applicators (NDC 80005-131-38).

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Protect from freezing.

Clindamycin Phosphate Topical Solution, USP is flammable. Keep away from heat, sparks or open flames.

Rx only

Manufactured and Distributed by:

Carnegie Pharmaceuticals, LLC

Delran, NJ 08075, USA

Made In USA

Rev. 12/2025

PRINCIPAL DISPLAY PANEL

NDC 80005-**131**-09

Clindamycin Phosphate Topical Solution, USP

1%*

(Pledgets)

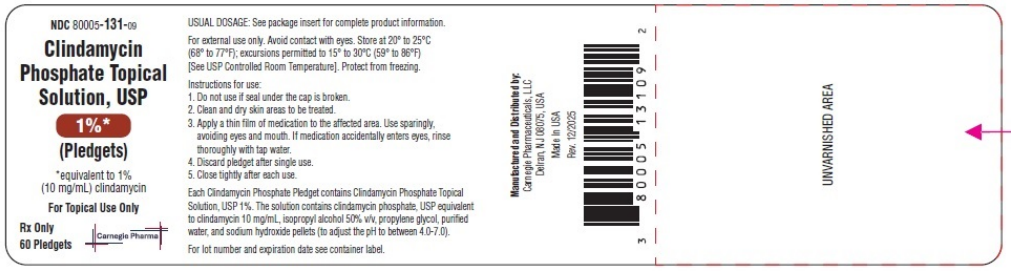
*equivalent to 1% (10 mg/mL) clindamycin

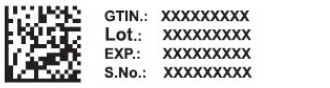
For Topical Use Only

Rx Only

60 Pledgets

Carnegie Pharma





Batch Details along with variable data & Unique serial number on each Label with 2d data Matrix shall be printed during packing

PRINCIPAL DISPLAY PANEL

NDC 80005-**131**-38

Clindamycin Phosphate Topical Solution, USP

1%*

(Pledgets)

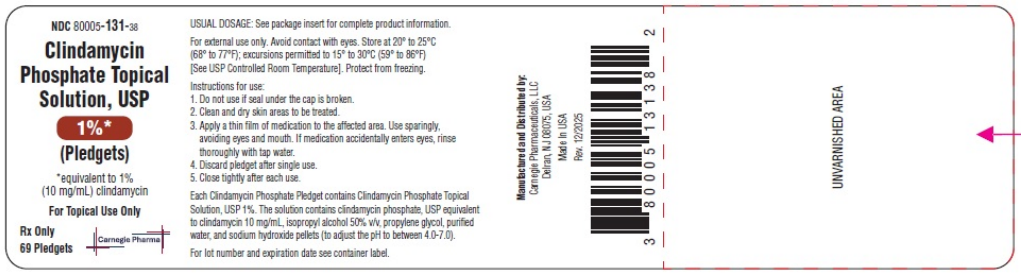
*equivalent to 1% (10 mg/mL) clindamycin

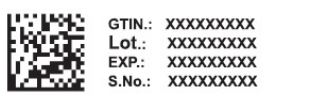
For Topical Use Only

Rx Only

69 Pledgets

Carnegie Pharma





Batch Details along with variable data & Unique serial number on each Label with 2d data Matrix shall be printed during packing

CLINDAMYCIN PHOSPHATE

clindamycin phosphate topical solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80005-131
Route of Administration	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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80005-131-09	60 in 1 JAR	06/16/2025	
1		1 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:80005-131-38	69 in 1 JAR	12/15/2025	
2		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	ANDA219612	06/16/2025	

Labeler - Carnegie Pharmaceuticals, LLC (079839141)

Registrant - Carnegie Pharmaceuticals, LLC (079839141)

Establishment

Name	Address	ID/FEI	Business Operations
Carnegie Pharmaceuticals, LLC		079839141	manufacture(80005-131)