

CLEOCIN T- clindamycin phosphate solution
CLEOCIN T- clindamycin phosphate lotion
CLEOCIN T- clindamycin phosphate gel
Pharmacia and Upjohn Company LLC

Cleocin T®
(clindamycin phosphate topical solution, USP)
(clindamycin phosphate topical gel)
(clindamycin phosphate topical lotion)

For External Use

DESCRIPTION

CLEOCIN T Topical Solution and CLEOCIN T Topical Lotion contain clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. CLEOCIN T Topical Gel contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram. Each CLEOCIN T Topical Solution pledget applicator contains approximately 1 mL of topical solution.

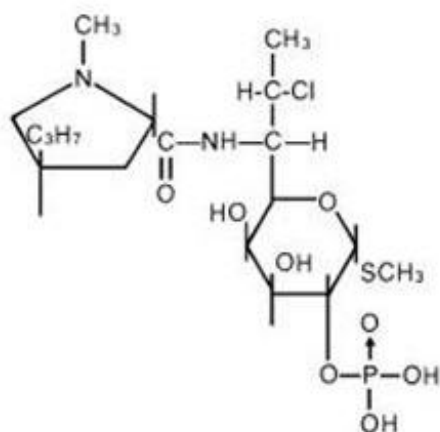
Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

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

The gel contains allantoin, carbomer 934P, 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:



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

CLEOCIN T Topical Solution, CLEOCIN T Topical Gel and CLEOCIN T Topical 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

CLEOCIN T Topical Solution, CLEOCIN T Topical Gel and CLEOCIN T Topical 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 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

CLEOCIN T 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.

CLEOCIN T 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 CLEOCIN T. 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 CLEOCIN T 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 CLEOCIN T 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 CLEOCIN T 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.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Apply a thin film of CLEOCIN T Topical Solution, CLEOCIN T Topical Lotion, CLEOCIN T Topical Gel, or use a CLEOCIN T Topical Solution pledget for the application of CLEOCIN T twice daily to affected area. More than one pledget may be used. Each pledget should be used only once and then be discarded.

Lotion: Shake well immediately before using.

Pledget: Remove pledget from foil just before use. Do not use if the seal is broken. Discard after

single use.

Keep all liquid dosage forms in containers tightly closed.

HOW SUPPLIED

CLEOCIN T Topical Solution containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following sizes:

30 mL applicator bottle—NDC 0009-3116-01

60 mL applicator bottle—NDC 0009-3116-02

Carton of 60 single-use pledget applicators—NDC 0009-3116-14

CLEOCIN T Topical Gel containing clindamycin phosphate equivalent to 10 mg clindamycin per gram is available in the following sizes:

60 gram tube—NDC 0009-3331-01

30 gram tube—NDC 0009-3331-02

CLEOCIN T Topical Lotion containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following size:

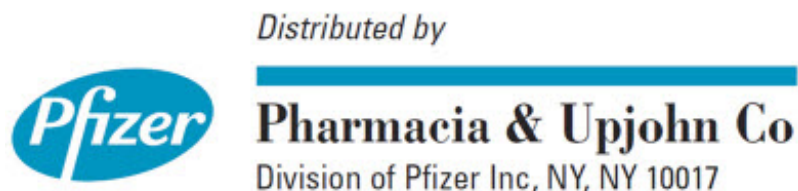
60 mL plastic squeeze bottle—NDC 0009-3329-01

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

Protect from freezing.

Rx only

This product's label may have been updated. For current full prescribing information, please visit www.pfizer.com.



LAB-0042-10.0

Revised 12/2019

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

Pfizer

NDC 0009-3116-01

Cleocin T[®]


clindamycin phosphate
topical solution, USP

1%*

Solution for topical use only

30 mL

Rx only

LOT EXP	14245100	<p>Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Protect from freezing. Store in an upright fashion. Keep container tightly closed.</p> <p>For external use only. Avoid contact with eyes.</p> <p>DOSAGE AND USE: See accompanying prescribing information.</p> <p>*Each mL contains clindamycin phosphate equivalent to 10 mg/mL (1%) of clindamycin. Contains isopropyl alcohol, 50%.</p> <p>Patient information:</p> <ol style="list-style-type: none"> 1. Clean and dry the 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. If using the applicator top, use dabbing motion of the tip rather than a rolling action. If tip becomes dry, invert the bottle and depress tip several times until it becomes moist. 	NDC 0009-3116-01
	PROEST Data Bar Limited (PSS) - 8 ml N 0 03 0009 -3116-01-6	<p>Distributed by Pharmacia & Upjohn Co Division of Pfizer Inc, NY, NY 10017</p> <p style="text-align: right;">MADE IN CHINA</p>	 <p>Cleocin T[®] clindamycin phosphate topical solution, USP</p> <p>1%*</p> <p>Solution for topical use only</p> <p>30 mL Rx only</p>

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

Pfizer

NDC 0009-3116-01

Cleocin T[®]
clindamycin
phosphate
topical solution,
USP

1%*

Solution for topical
use only

30 mL

Rx only



11977503
 PO 128 - 10 ml

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 READS THIS WAY
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LOT/EXP
 30 mL
 Solution for topical use only
 1%*
 clindamycin phosphate
 topical solution, USP
Cleocin T
 NDC 0009-3116-01

11977503

Pfizer NDC 0009-3116-01

Cleocin T[®]
 clindamycin
 phosphate
 topical solution,
 USP

1%*

Solution for topical
 use only

30 mL

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

Keep container tightly closed.
 For external use only.
 Avoid contact with eyes.

DOSAGE AND USE:
 See accompanying prescribing
 information.

* Each mL contains clindamycin
 phosphate equivalent to
 10 mg/mL (1%) of clindamycin.
 Also contains propylene glycol,
 isopropyl alcohol, 50%; and
 purified water.

To use enclosed applicator:

1. Remove cap and discard.
2. Firmly press applicator into
 bottle.
3. Seal firmly by tightening
 domed-cap.

Patient information:

1. Clean and dry the 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. If using the applicator top,
 use dabbing motion of the tip
 rather than a rolling action. If
 tip becomes dry, invert the
 bottle and depress tip several
 times until it becomes moist.

Pfizer NDC 0009-3116-01

Cleocin T[®]
 clindamycin
 phosphate
 topical solution,
 USP

1%*

Solution for topical
 use only

30 mL

Rx only



N 0009-3116-01 6

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 Division of Pfizer Inc
 NY, NY 10017
 MADE IN CHINA

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 NO INK

Pfizer

NDC 0009-3116-14

Cleocin T[®]

clindamycin phosphate
topical solution, USP

1%*

Pledget for topical use only

1 Pledget

Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc, NY, NY 10017
MADE IN CHINA

Rx only

Pfizer NDC 0009-3116-14

Cleocin T[®]
clindamycin phosphate
topical solution, USP

1%*

Pledget for topical use only

1 Pledget

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Pharmacia & Upjohn Co
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MADE IN CHINA **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.

DOSAGE AND USE:
See accompanying prescribing information.
Instructions for use:

1. Clean and dry the 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. Do not use if the seal is broken.

*Solution contains clindamycin phosphate equivalent to 10 mg/mL (1%) of clindamycin. Also contains isopropyl alcohol 50% v/v, propylene glycol, and purified water.

PAA041056

FPO: RSS
N10300093116143

PRINCIPAL DISPLAY PANEL - 60 Pledget Packet Carton

NDC 0009-3116-14

Pfizer

Cleocin T[®]

1%*

clindamycin phosphate
topical solution, USP

Pledget for topical use only

60 Pledgets

Rx only



Cleocin T[®]

clindamycin phosphate
topical solution, USP

NDC 0009-3116-14

1%*

Pledget for topical use only

60 Pledgets

Rx only



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MADE IN CHINA



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LOT/EXPIRS N
GTIN : 000009118148

60 Pledgets
Pledget for topical use only

clindamycin phosphate
topical soluton, USP

1%*

Cleocin T[®]



PAA072949



Cleocin T[®]

clindamycin phosphate
topical solution, USP

1%*

Pledget for topical use only

60 Pledgets

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.

DOSAGE AND USE:

See accompanying prescribing information.

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. Do not use if the seal
is broken.

*Solution contains clindamycin phosphate equivalent to
10 mg/mL (1%) of clindamycin. Also contains Isopropyl
alcohol 50% v/v, propylene glycol, and purified water.

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

Pfizer
NDC 0009-3329-01

Cleocin T®
clindamycin
phosphate
topical lotion

1%*

For topical use only

60 mL
Rx only

Pfizer NDC 0009-3329-01

Cleocin T®
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.

* Lotion contains clindamycin phosphate equivalent to 10 mg/mL (1%) of clindamycin. Also 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.

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Pharmacia & Upjohn Co
Division of Pfizer Inc
NY, NY 10017
MADE IN CHINA

FPO GS 1 Delta Bar Limited (RSS) - 10 mil
N 0 03 0009-3329-01-0
PAA097517

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EXP

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

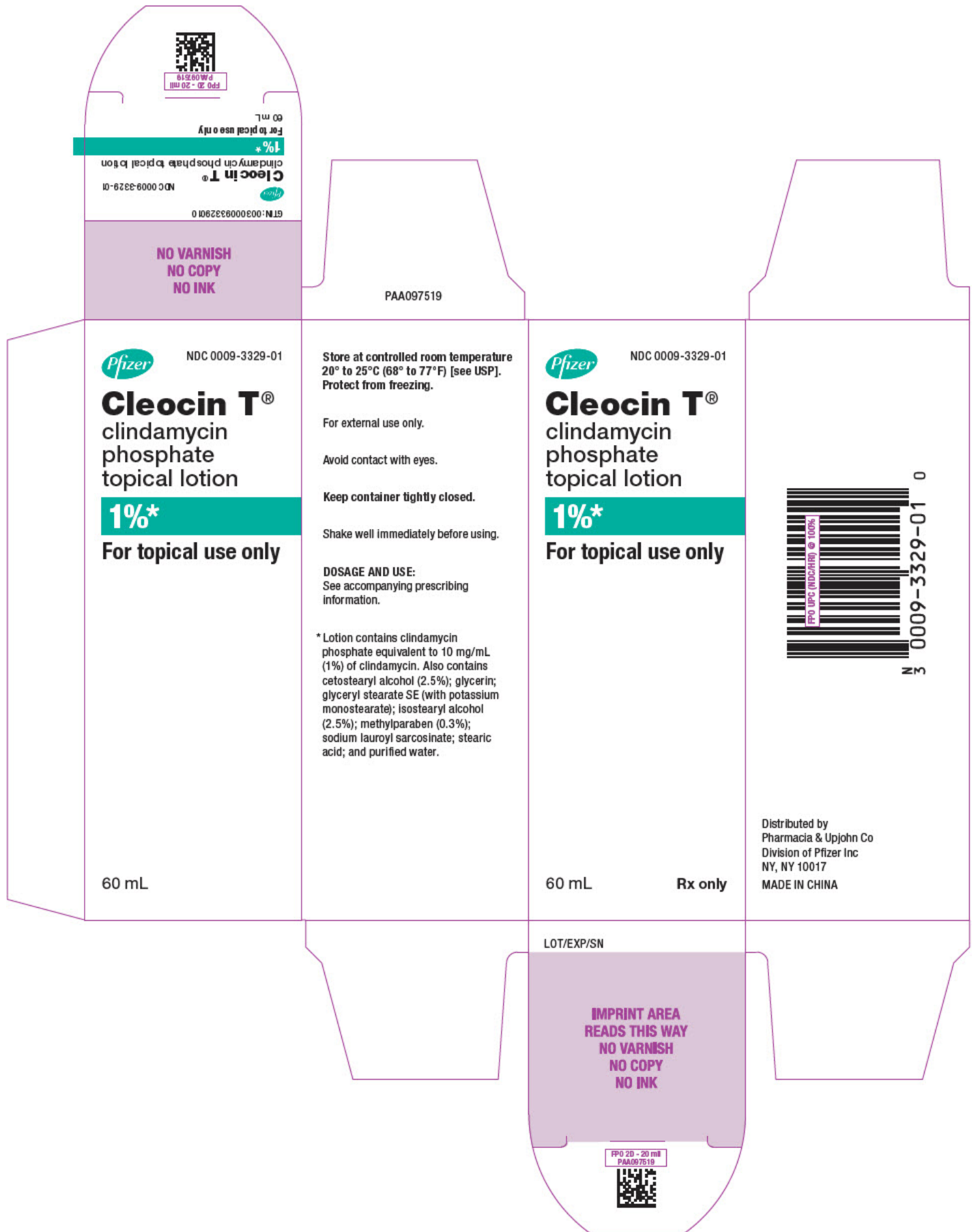
Pfizer
NDC 0009-3329-01

Cleocin T®
clindamycin
phosphate
topical lotion

1%*

For topical use only

60 mL
Rx only



PRINCIPAL DISPLAY PANEL - 60 gram Tube Label

NDC 0009-3331-01

60 gram

Rx only

Cleocin T[®]

clindamycin phosphate topical gel

For topical use only

1%*

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.

See crimp of tube for Expiration Date and Lot Number.

DOSAGE AND USE: See accompanying prescribing information.

* Each gram contains clindamycin phosphate equivalent to 10 mg (1%) of clindamycin. Also contains allantoin, carbomer 934P, methylparaben, polyethylene glycol 400, propylene glycol, sodium hydroxide, and purified water.

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NDC 0009-3331-01

60 gram

Rx only

LOT

EXP

Cleocin T[®]

clindamycin phosphate topical gel

For topical use only

1%*

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.

See crimp of tube for Expiration Date and Lot Number.

DOSAGE AND USE: See accompanying prescribing information.

*Each gram contains clindamycin phosphate equivalent to 10 mg (1%) of clindamycin. Also contains allantoin, carbomer 934P, methylparaben, polyethylene glycol 400, propylene glycol, sodium hydroxide, and purified water.



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PRINCIPAL DISPLAY PANEL - 60 gram Tube Carton

NDC 0009-3331-01

Pfizer

Cleocin T[®]

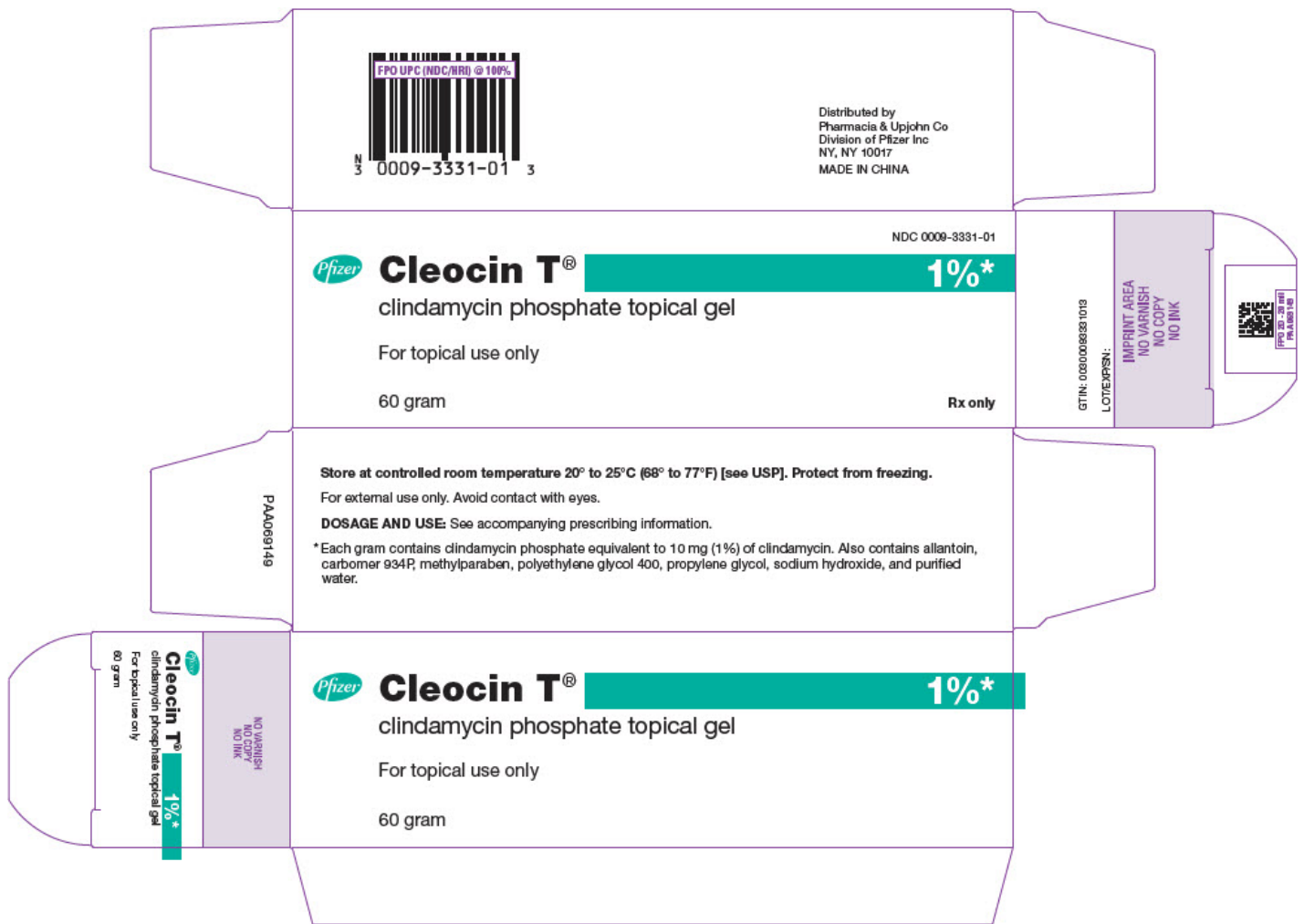
1%*

clindamycin phosphate topical gel

For topical use only

60 gram

Rx only



PRINCIPAL DISPLAY PANEL - 30 gram Tube Label

NDC 0009-3331-02

30 gram

Rx only

Cleocin T[®]

clindamycin phosphate topical gel

For topical use only

1%*

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.

See crimp of tube for Expiration Date and Lot Number.

DOSAGE AND USE: See accompanying prescribing information.

* Each gram contains clindamycin phosphate equivalent to 10 mg (1%) of clindamycin. Also contains allantoin, carbomer 934P, methylparaben, polyethylene glycol 400, propylene glycol, sodium hydroxide, and purified water.

Pfizer

Distributed by

Pharmacia & Upjohn Co

NDC 0009-3331-02


30 gram **Rx only**

Cleocin T[®]
clindamycin phosphate topical gel

For topical use only

1%*

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.
See crimp of tube for Expiration Date and Lot Number.
DOSAGE AND USE: See accompanying prescribing information.
* Each gram contains clindamycin phosphate equivalent to 10 mg
(1%) of clindamycin. Also contains allantoin, carbomer 934P,
methylparaben, polyethylene glycol 400, propylene glycol, sodium
hydroxide, and purified water.

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 **Pharmacia & Upjohn Co**
Division of Pfizer Inc, NY, NY 10017


13022000

FPO: RSS 10 mil

N 0 03 0009-3331-02-0

LOT

EXP



PRINCIPAL DISPLAY PANEL - 30 gram Tube Carton

NDC 0009-3331-02

Pfizer

Cleocin T[®]

1%*

clindamycin phosphate topical gel

For topical use only

30 gram

Rx only



CLEOCIN T			
clindamycin phosphate solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0009-3116
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)			
WATER (UNII: 059QF0KO0R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0009-3116-01	1 in 1 CARTON	06/20/1980	
1		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0009-3116-02	1 in 1 CARTON	06/20/1980	06/30/2018
2		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:0009-3116-14	60 in 1 CARTON	06/20/1980	03/31/2019
3		1 mL in 1 PACKET; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050537	06/20/1980	

CLEOCIN T

clindamycin phosphate lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0009-3329
Route of Administration	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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0009-3329-01	1 in 1 CARTON	05/31/1989	
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	
NDA	NDA050600	05/31/1989		

CLEOCIN T				
clindamycin phosphate gel				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0009-3331	
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 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	ALLANTOIN (UNII: 344S277G0Z)			
	CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)			
	METHYL PARABEN (UNII: A2I8C7HI9T)			
	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	SODIUM HYDROXIDE (UNII: 55X04QC32I)			
	WATER (UNII: 059QF0K00R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0009-3331-01	1 in 1 CARTON	01/07/1987	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0009-3331-02	1 in 1 CARTON	01/07/1987	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA050615	01/07/1987		

Labeler - Pharmacia and Upjohn Company LLC (618054084)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia and Upjohn Company LLC		618054084	ANALYSIS(0009-3116, 0009-3329, 0009-3331) , API MANUFACTURE(0009-3116, 0009-3329, 0009-3331) , LABEL(0009-3116, 0009-3329, 0009-3331) , MANUFACTURE(0009-3116, 0009-3329, 0009-3331) , PACK(0009-3116, 0009-3329, 0009-3331)

Revised: 12/2019

Pharmacia and Upjohn Company LLC