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

![Chemical Structure of Clindamycin Phosphate](image)

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].

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Event</th>
<th>Solution n=553(%)</th>
<th>Gel n=148(%)</th>
<th>Lotion n=160(%)</th>
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<tbody>
<tr>
<td>Burning</td>
<td>62 (11)</td>
<td>15 (10)</td>
<td>17 (11)</td>
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<tr>
<td>Itching</td>
<td>36 (7)</td>
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<td>Burning/Itching</td>
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<td># (–)</td>
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<td>Dryness</td>
<td>105 (19)</td>
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<td>Erythema</td>
<td>86 (16)</td>
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<td>22 (14)</td>
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<tr>
<td>Oiliness/Oily Skin</td>
<td>8 (1)</td>
<td>26 (18)</td>
<td>12* (10)</td>
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<tr>
<td>Peeling</td>
<td>61 (11)</td>
<td># (–)</td>
<td>11 (7)</td>
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</table>

# 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.

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

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
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
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

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 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.

Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc
NY, NY 10017
MADE IN CHINA
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 cetyl stearyl alcohol (2.5%); glycerin; glyceryl stearate SE with potassium monostearate; isostearyl alcohol (2.5%); methylparaben (0.3%); sodium lauryl sarcosinate, stearic acid; and purified water.

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

Pfizer
Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc, NY, NY 10017
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.

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
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

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### Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>CLINDAMYCIN PHOSPHATE (UNII: EH6D71131B)</td>
<td>CLINDAMYCIN</td>
<td>10 mg in 1 mL</td>
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<tr>
<td>CLINDAMYCIN (UNII: 3U02EL437C)</td>
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### Inactive Ingredients

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<td>ISOPROPYL ALCOHOL (UNII: ND2M416302)</td>
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### Packaging

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### CLEOCIN T

clindamycin phosphate lotion

### Product Information

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### Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
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<tbody>
<tr>
<td>CLINDAMYCIN PHOSPHATE (UNII: EH6D711318) (CLINDAMYCIN - UNII:3U02EL437C)</td>
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<td>10 mg in 1 mL</td>
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### Inactive Ingredients

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<th>Ingredient Name</th>
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<tr>
<td>CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)</td>
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<td>GLYCERIN (UNII: PDC6A3C00X)</td>
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<td>METHYLPARABEN (UNII: A2BC7H9T)</td>
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# CLEOCIN T
clindamycin phosphate gel

## Product Information

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<th>Basis of Strength</th>
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<tr>
<td>CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)</td>
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## Inactive Ingredients

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<td>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)</td>
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Pharmacia and Upjohn Company LLC