**CLINDAMYCIN PHOSPHATE - clindamycin phosphate lotion**
**CLINDAMYCIN PHOSPHATE - clindamycin phosphate solution**
**CLINDAMYCIN PHOSPHATE - clindamycin phosphate gel**
**Physicians Total Care, Inc.**

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**Clindamycin Phosphate Topical Solution USP, 1%,**
**Clindamycin Phosphate Gel USP, 1%,**
**Clindamycin Phosphate Lotion**
**(Clindamycin Phosphate Topical Suspension USP, 1%)**

**Rx only**

**For External Use**

## DESCRIPTION

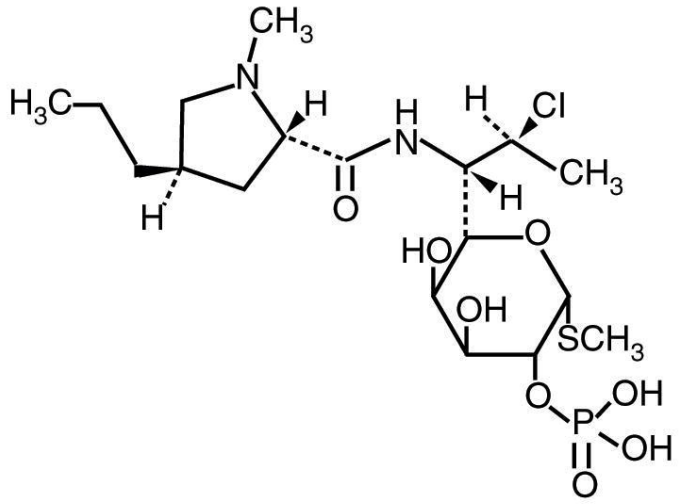
Clindamycin Phosphate Topical Solution and Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension USP, 1%) contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Clindamycin Phosphate Gel contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram. 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 purified 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:




Molecular Formula: $C_{18}H_{34}ClN_2O_8PS$ Molecular Weight: 504.97

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, Clindamycin Phosphate Gel, and Clindamycin Phosphate 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

Clindamycin Phosphate Topical Solution, Clindamycin Phosphate Gel, and Clindamycin Phosphate 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 cultures 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 mg 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 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*. Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin ranging from 100 to 600 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to clindamycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether clindamycin is excreted in human milk following use of clindamycin phosphate. 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 has not been established.

**Geriatric Use**: Clinical studies for topical Clindamycin products 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 response 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].

**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 and gastrointestinal disturbances as well as gram-negative folliculitis 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 Solution, Clindamycin Phosphate Lotion or Clindamycin Phosphate Gel twice daily to affected area.

Lotion: Shake well immediately before using. Keep all liquid dosage forms in containers tightly closed.

## HOW SUPPLIED

Clindamycin Phosphate Topical Solution, USP 1% containing clindamycin phosphate equivalent to 10 mg clindamycin per gram is available in the following sizes:

30 mL applicator bottle NDC 54868-2875-1
60 mL applicator bottle NDC 54868-2875-0

Clindamycin Phosphate Gel, USP 1% containing clindamycin phosphate equivalent to 10 mg clindamycin per gram is available in the following sizes:

30 gram tube NDC 54868-4654-1
60 gram tube NDC 54868-4654-0

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

60 mL bottle NDC 54868-4806-0

Store at 20°-25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing. Keep all liquid dosage forms in containers tightly closed.

November 2007

E. FOUGERA & CO.
A division of Nycomed US Inc.
MELVILLE, NEW YORK 11747

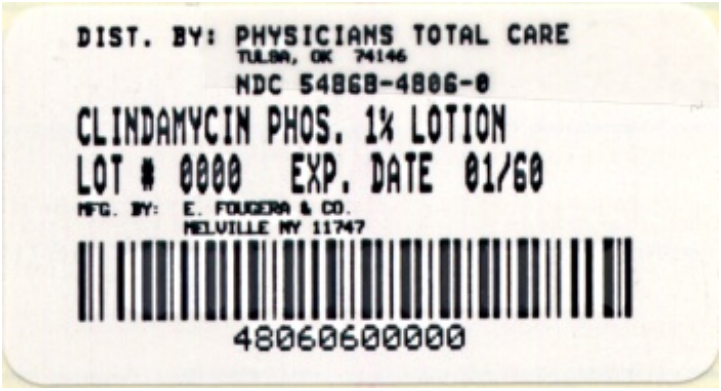
IFI201A

**Relabeling of "Additional Barcode Label" by:**
Physicians Total Care, Inc.
Tulsa, OK 74146

**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 mL CARTON**

**CLINDAMYCIN**
**PHOSPHATE**
**LOTION**
**(Clindamycin Phosphate**
**Topical Suspension**
**USP, 1%)**
equivalent to 1% (10 mg/mL)
clindamycin
**For Topical Use Only**
**60 mL**

Rx only




**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 mL CARTON**

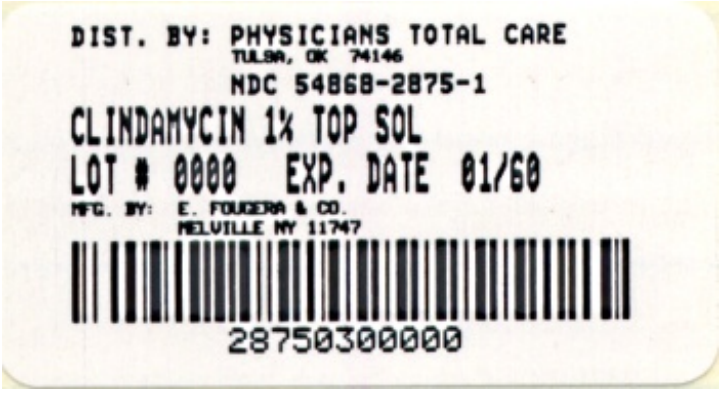
**CLINDAMYCIN**
**PHOSPHATE**
**Topical Solution**
**USP, 1%**

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

**For External Use Only**

**30 mL**

**Rx only**




**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 G CARTON**

**CLINDAMYCIN PHOSPHATE**
**GEL USP, 1%**
**equivalent to 1% clindamycin**
**For Topical Use Only**

**FOR EXTERNAL USE ONLY**
**AVOID CONTACT WITH EYES**
**WARNING: Keep out of reach of children.**

**NET WT 30 grams**

**Rx only**


# CLINDAMYCIN PHOSPHATE

clindamycin phosphate lotion

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:54868-4806(NDC:0168-0203) |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CLINDAMYCIN PHOSPHATE** (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C) | CLINDAMYCIN PHOSPHATE | 10 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S) | |
| **ISOSTEARYL ALCOHOL** (UNII: Q613OCQ44Y) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:54868-4806-0 | 1 in 1 CARTON | | |
| 1 | | 60 mL in 1 BOTTLE | | |

| Marketing Information | | | |
|---|---|---|---|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA065067 | 06/03/2003 | |

# CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

| Product Information | | | |
|---|---|---|---|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:54868-2875(NDC:0168-0201) |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| Ingredient Name | Basis of Strength | Strength |
| **CLINDAMYCIN PHOSPHATE** (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C) | CLINDAMYCIN PHOSPHATE | 10 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| Ingredient Name | Strength |
| **WATER** (UNII: 059QF0KO0R) | |
| **ALLANTOIN** (UNII: 344S277G0Z) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:54868-2875-0 | 1 in 1 CARTON | | |
| 1 | | 60 mL in 1 BOTTLE | | |
| 2 | NDC:54868-2875-1 | 1 in 1 CARTON | | |
| 2 | | 30 mL in 1 BOTTLE | | |

| Marketing Information | | | |
|---|---|---|---|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA064159 | 01/11/2002 | |

# CLINDAMYCIN PHOSPHATE

clindamycin phosphate gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:54868-4654(NDC:0168-0202) |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CLINDAMYCIN PHOSPHATE** (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C) | CLINDAMYCIN PHOSPHATE | 10 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:54868-4654-0 | 1 in 1 CARTON | | |
| **1** | | 60 g in 1 TUBE | | |
| **2** | NDC:54868-4654-1 | 1 in 1 CARTON | | |
| **2** | | 30 g in 1 TUBE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA064160 | 04/07/2005 | |

## Labeler - Physicians Total Care, Inc. (194123980)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Physicians Total Care, Inc. | | 194123980 | relabel |

Revised: 2/2010 Physicians Total Care, Inc.