

CLINDAMYCIN PHOSPHATE- clindamycin phosphate lotion
CLINDAMYCIN PHOSPHATE- clindamycin phosphate solution
CLINDAMYCIN PHOSPHATE- clindamycin phosphate gel
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.
Reference Label Set Id: d4371159-b58a-40a4-8060-d345843b5468

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

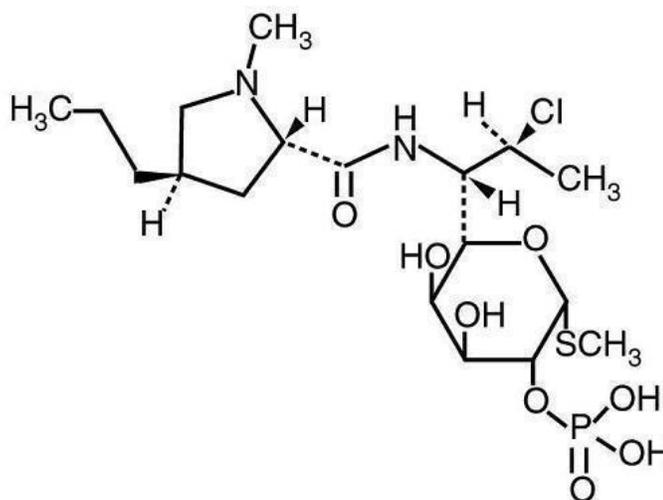
Clindamycin Phosphate Topical Solution and Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension USP, 1%) contain clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Clindamycin Phosphate Gel contains clindamycin phosphate, USP, at a concentration 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 974P, 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-galactooctopyranoside 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 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 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 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

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. 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 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 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 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].

Number of Patients Reporting Events

Treatment Emergent Adverse Event	Solution		Gel		Lotion	
	n=553	(%)	n=148	(%)	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 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 milliliter is available in the following sizes:

30 mL applicator bottle NDC 0168-0201-30

60 mL applicator bottle NDC 0168-0201-60

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 0168-0202-30

60 gram tube NDC 0168-0202-60

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 0168-0203-60

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

Protect from freezing.

**Fougera
PHARMACEUTICALS INC.**

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.
MELVILLE, NEW YORK 11747

46263755A

R01/2020

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 60 mL CONTAINER

NDC 0168-0203-60

Fougera®

**CLINDAMYCIN
PHOSPHATE LOTION
(Clindamycin Phosphate
Topical Suspension
USP, 1%)**

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

**FOR TOPICAL USE ONLY.
60 mL**

Rx only

E. FOUGERA & CO.

A division of
Fougera Pharmaceuticals Inc.
Melville, New York 11747

NDC 0168-0203-60

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

Equivalent to 1% (10 mg/mL)
clindamycin

Rx only

**FOR TOPICAL
USE ONLY.**

60 mL

fougera[®]

USUAL DOSAGE: Apply a thin film twice daily to affected area. See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing.

**FOR EXTERNAL USE ONLY.
AVOID CONTACT WITH EYES.**

Keep container tightly closed.
**SHAKE WELL IMMEDIATELY
BEFORE USING.**

KEEP OUT OF THE REACH OF CHILDREN.

Each mL contains clindamycin phosphate, USP, equivalent to clindamycin 10 mg/mL, 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.

This product sealed for your protection. If the seal is missing or broken return to place of purchase.

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747

46275774A R11/2020



EXP:

LOT:

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 60 mL CARTON

NDC 0168-0203-60

Fougera[®]

**CLINDAMYCIN
PHOSPHATE
LOTION
(Clindamycin
Phosphate Topical
Suspension
USP, 1%)**

Equivalent to 1%
(10 mg/mL) clindamycin

FOR TOPICAL USE ONLY.

60 mL

Rx only

E. FOUGERA & CO.

A division of
Fougera Pharmaceuticals Inc.

Melville, New York 11747

fougera
Clindamycin Phosphate Lotion
Clindamycin Phosphate Topical Suspension USP, 1%
NDC 0168-0203-60

NDC 0168-0203-60

Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension USP, 1%)

Equivalent to 1% (10 mg/mL) clindamycin

USUAL DOSAGE: Apply a thin film twice daily to affected area.

See package insert for complete product information.

FOR EXTERNAL USE ONLY.

AVOID CONTACT WITH EYES.

Keep container tightly closed.

SHAKE WELL IMMEDIATELY BEFORE USING.

NDC 0168-0203-60

Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension USP, 1%)

Equivalent to 1% (10 mg/mL) clindamycin

Each mL contains clindamycin phosphate, USP, equivalent to clindamycin 10 mg/mL, 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.

This product sealed for your protection. If the seal is missing or broken return to place of purchase.

R only

FOR TOPICAL USE ONLY.

60 mL

fougera

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Protect from freezing.

KEEP OUT OF THE REACH OF CHILDREN.

See bottle for Lot No. and Expiration Date.

E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747

R only

FOR TOPICAL USE ONLY.

60 mL

fougera

46275770A
R11/2020
#175



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 60 mL CONTAINER

NDC 0168-0201-60

Fougera®

**CLINDAMYCIN
PHOSPHATE**

Topical Solution USP, 1%

Equivalent to 1%
(10 mg/mL) clindamycin

For Topical Use Only.

Rx only

60 mL

E. FOUGERA & CO.

A division of

Fougera Pharmaceuticals Inc.

Melville, New York 11747

NDC 0168-0201-60

**Clindamycin
Phosphate
Topical Solution
USP, 1%**

R only

**Solution for
topical use only**

60 mL

fougera®

This product sealed for your protection. If the seal is missing or broken return to place of purchase.

DOSAGE AND USE: See accompanying prescribing information.

For external use only.

Avoid contact with eyes.

Store at controlled room temperature

20° to 25°C (68° to 77°F) [see USP].

Protect from freezing.

Keep container tightly closed.

Store in an upright fashion.

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

Patient information:

1. Clean and dry 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.

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A division of Fougera Pharmaceuticals Inc.

Melville, New York 11747

46275776A R12/20

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 60 mL CARTON

NDC 0168-0201-60

Fougera[®]

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

Equivalent to 1%
(10 mg/mL) clindamycin

For Topical Use Only.

60 mL

Rx only

E. FOUGERA & CO.
A division of
Fougera Pharmaceuticals Inc.
Melville, New York 11747

fougera®

Solution for topical use only
Clindamycin Phosphate Topical Solution USP, 1%
NDC 0168-0201-60

NDC 0168-0201-60

Clindamycin Phosphate Topical Solution USP, 1%

DOSAGE AND USE:
See accompanying prescribing information.

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

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

NDC 0168-0201-60

Clindamycin Phosphate Topical Solution USP, 1%

Each mL contains clindamycin phosphate USP, 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.

R only

Solution for topical use only

60 mL

fougera®

This product sealed for your protection. If the seal is missing or broken return to place of purchase.

See bottle for Lot No. and Expiration Date.

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A division of
Fougera Pharmaceuticals Inc.
Melville, New York 11747

R only

Solution for topical use only

60 mL

fougera®

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.

46275772A
R12/20
#257



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 30 G CONTAINER

NDC 0168-0202-30

Fougera®

**CLINDAMYCIN
PHOSPHATE GEL USP, 1%**
equivalent to 1% clindamycin

For Topical Use Only.

Rx only

NET WT 30 grams

<p>NDC 0168-0202-30</p> <p>Clindamycin Phosphate Gel USP, 1% equivalent to 1% clindamycin</p> <p>For Topical Use Only.</p> <p>fougera®</p> <p>Usual Dosage: Apply a thin film twice daily to affected area. See package insert for complete product information. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing. KEEP OUT OF THE REACH OF CHILDREN. TO OPEN: Use cap to puncture seal. IMPORTANT: Do not use if seal has been punctured or is not visible. E. FOUGERA & CO. A division of Fougera Pharmaceuticals Inc. Melville, New York 11747</p>	<p>R only</p> <p>Each gram contains: Clindamycin phosphate, USP equivalent to clindamycin 10 mg (1%). Also, allantoin, carbomer 974P, methylparaben, polyethylene glycol 400, propylene glycol, sodium hydroxide, and purified water.</p> <p>NET WT 30 grams</p> <p>FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. See crimp of tube for Lot No. and Exp. Date.</p> <p>46275766A R11/2020</p>  <p>N 3 0168-0202-30 3</p>	
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PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 30 G CARTON

NDC 0168-0202-30

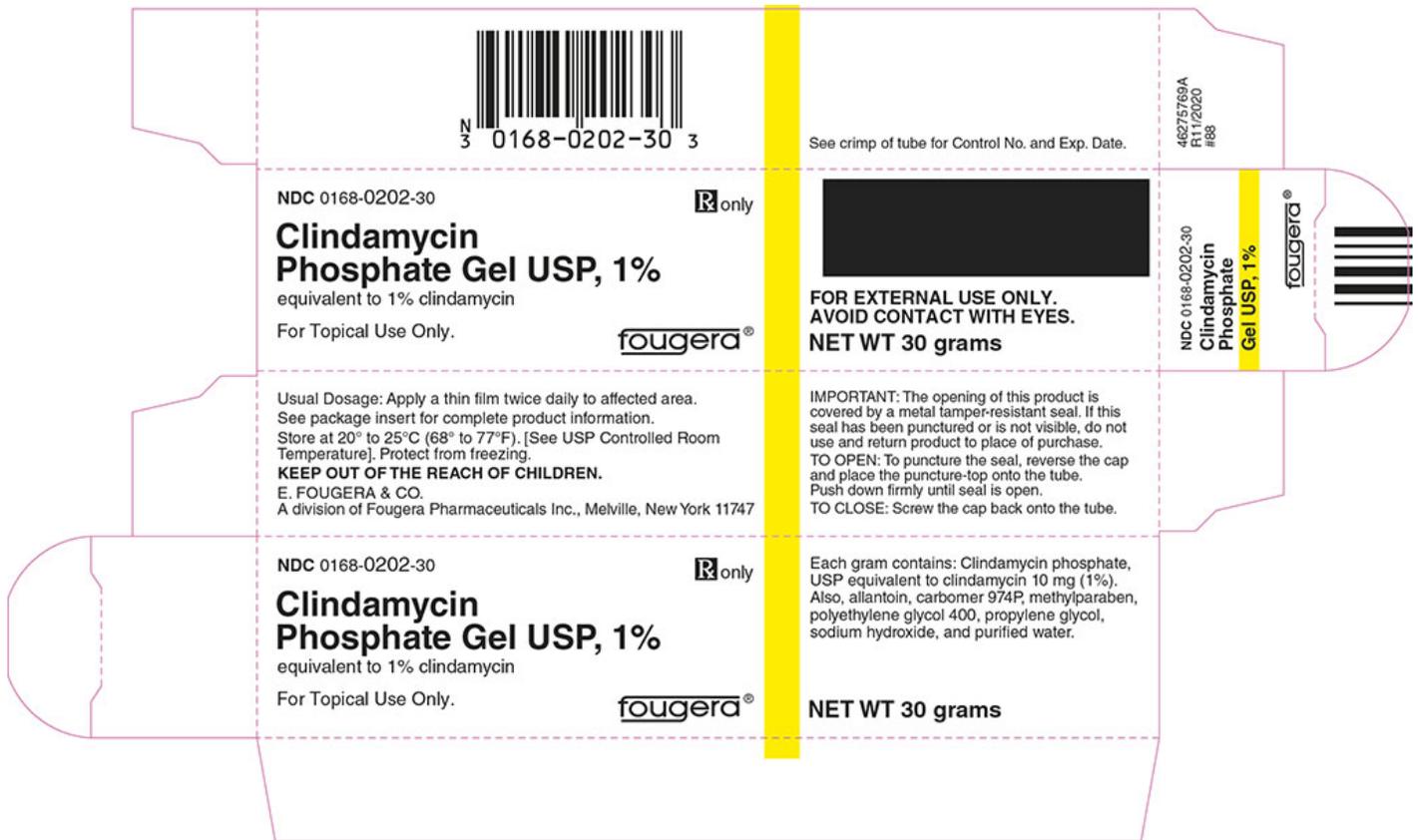
Rx only

Fougera®

**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



CLINDAMYCIN PHOSPHATE

clindamycin phosphate lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)

STEARIC ACID (UNII: 4ELV7Z65AP)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0203-60	1 in 1 CARTON	01/31/2002	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065067	01/31/2002	

CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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	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:0168-0201-30	1 in 1 CARTON	06/05/1997	
1		30 mL in 1 BOTTLE; Type 1: Convenience Kit of		

1		Co-Package	
2	NDC:0168-0201-60	1 in 1 CARTON	06/05/1997
2		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064159	06/05/1997	

CLINDAMYCIN PHOSPHATE

clindamycin phosphate gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0202-30	1 in 1 CARTON	01/28/2000	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0168-0202-60	1 in 1 CARTON	01/28/2000	

2

60 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
ANDA	ANDA064160	01/28/2000	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 2/2022

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