CLINDAMYCIN PHOSPHATE- clindamycin phosphate solution
CLINDAMYCIN PHOSPHATE- clindamycin phosphate lotion
CLINDAMYCIN PHOSPHATE- clindamycin phosphate gel
Greenstone LLC

Clindamycin Phosphate Topical Solution, USP
Clindamycin Phosphate Topical Gel
Clindamycin Phosphate Topical Lotion

For External Use

DESCRIPTION

Clindamycin phosphate topical solution and clindamycin phosphate topical lotion contain clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Clindamycin phosphate topical gel contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram. Each clindamycin phosphate topical solution pledget applicator contains approximately 1 mL of topical solution.

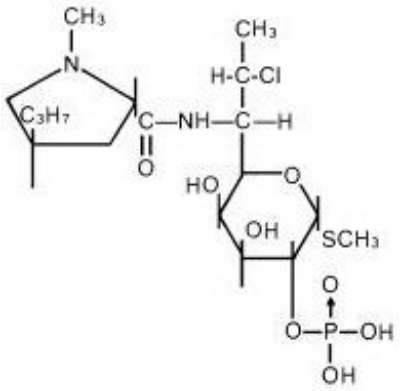
Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

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

Clindamycin phosphate topical solution, clindamycin phosphate topical gel and clindamycin phosphate 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

Clindamycin phosphate topical solution, clindamycin phosphate topical gel and clindamycin phosphate 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

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 products 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 topical product 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 phosphate 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 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 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 topical lotion, clindamycin phosphate topical gel, or use a clindamycin phosphate topical solution pledget for the application of clindamycin phosphate 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

Clindamycin phosphate topical solution containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following sizes:

30 mL applicator bottle—NDC 59762-3728-1
60 mL applicator bottle—NDC 59762-3728-2
Carton of 60 single-use pledget applicators—NDC 59762-3728-3

Clindamycin phosphate topical gel containing clindamycin phosphate equivalent to 10 mg clindamycin per gram is available in the following sizes:

30 gram tube—NDC 59762-3743-1

60 gram tube—NDC 59762-3743-2

Clindamycin phosphate topical lotion containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following size:

60 mL plastic squeeze bottle—NDC 59762-3744-1

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.greenstonellc.com.

GREENSTONE® BRAND

Distributed by:

Greenstone LLC
Peapack, NJ 07977

LAB-0048-12.0
Revised December 2019

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label - Solution

NDC 59762-3728-2
60 mL

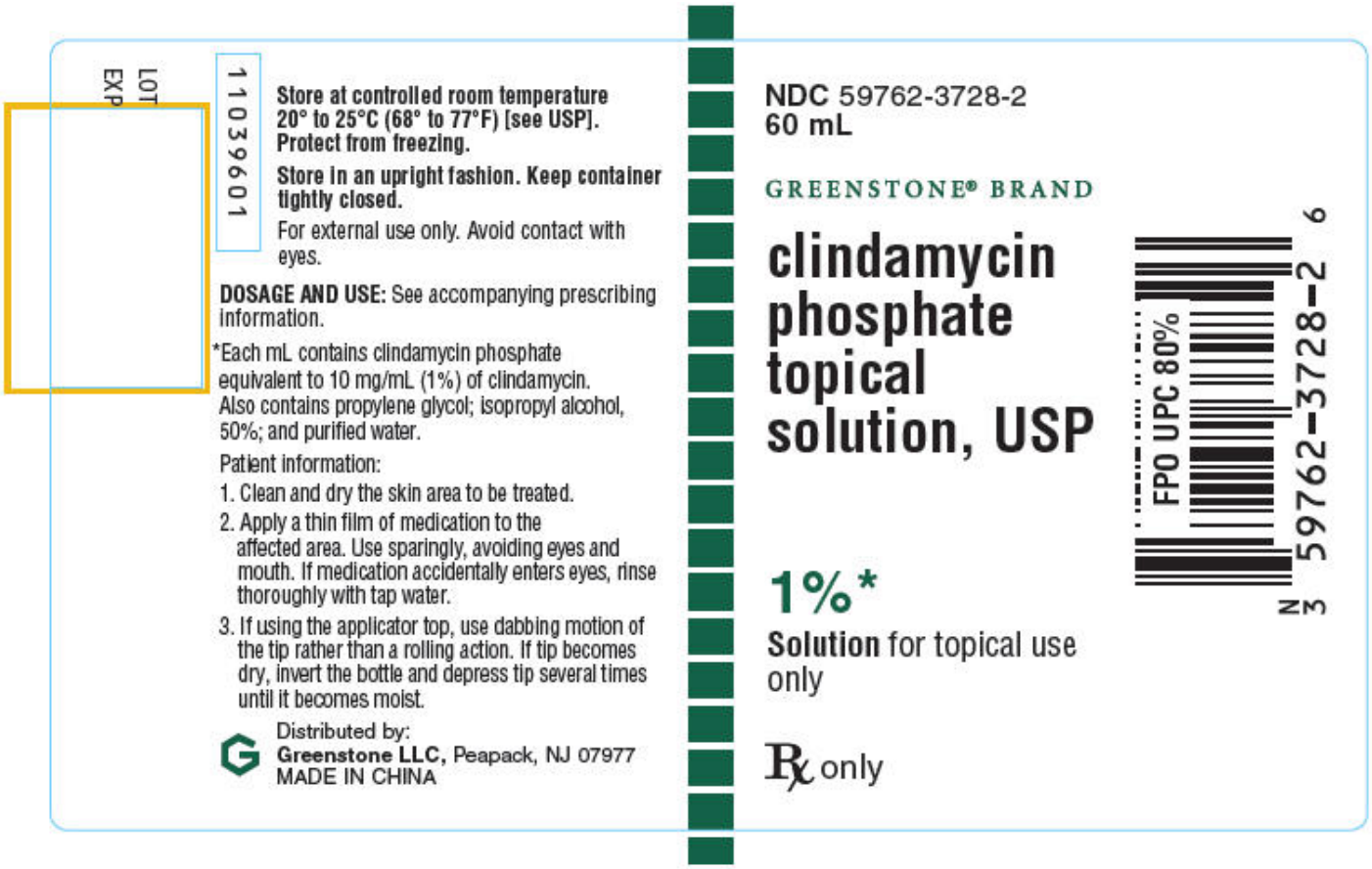
GREENSTONE® BRAND

clindamycin
phosphate
topical
solution, USP

1%*

Solution for topical use
only

Rx only



PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton - Solution

NDC 59762-3728-2
60 mL

GREENSTONE® BRAND

clindamycin
phosphate
topical
solution, USP

1%*

Solution for topical use only

Rx only

clindamycin phosphate topical solution, USP 1%*
GREENSTONE® BRAND
60 mL NDC 59762-3728-2
GTIN: 00359762372826

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12024203

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.

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.

Distributed by:
Greenstone LLC
Peapack, NJ 07977
MADE IN CHINA

NDC 59762-3728-2
60 mL

GREENSTONE® BRAND

clindamycin phosphate topical solution, USP

1%*

Solution for topical use only

℞ only

GREENSTONE

LOT/EXP/SN

IMPRINT AREA
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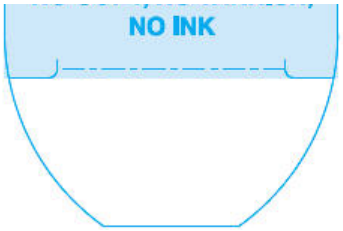

PRINCIPAL DISPLAY PANEL - Pledget Packet

NDC 59762-3728-3
1 Pledget

GREENSTONE® BRAND

clindamycin phosphate topical solution, USP

1%*

Pledget for topical use only

Rx only

PRINCIPAL DISPLAY PANEL - 60 Pledget Packet Carton

NDC 59762-3728-3
60 Pledgets

GREENSTONE® BRAND

clindamycin phosphate topical solution, USP

1%*
Pledget for topical use only

Rx only

NDC 59762-3728-3
60 Pledgets

GREENSTONE® BRAND

clindamycin phosphate topical solution, USP

1%*
Pledget for topical use only

℞ only

GREENSTONE

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NO VARNISH
NO INK

LOT
EXP
SN

1%*
Pledget for topical use only

GTIN: 00359762372833

clindamycin phosphate topical solution, USP

GREENSTONE® BRAND

NDC 59762-3728-3
60 Pledgets

PAA073371

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.

Distributed by:
Greenstone LLC
Peapack, NJ 07977

MADE IN CHINA

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label - Lotion

NDC 59762-3744-1
60 mL

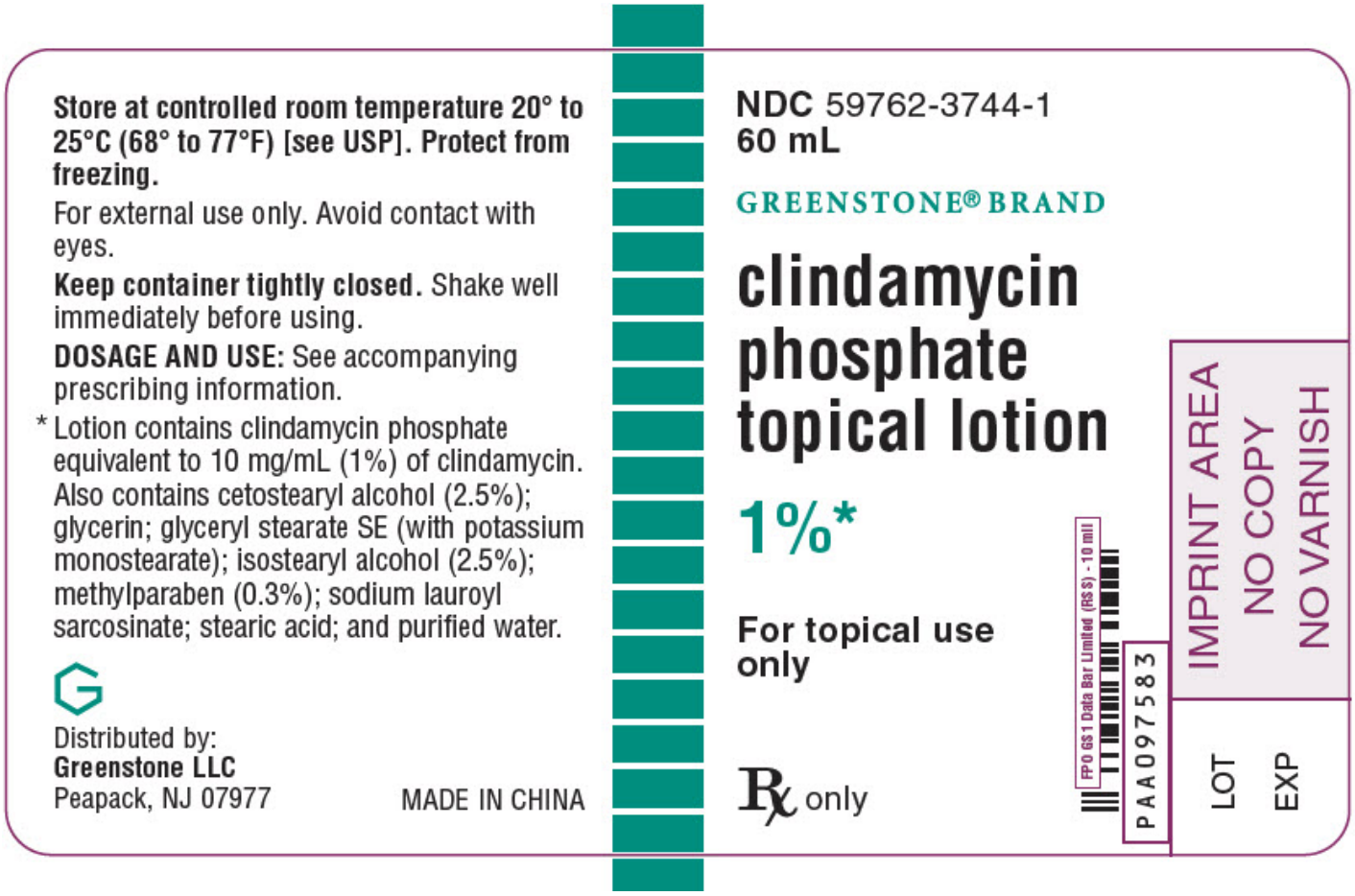
GREENSTONE® BRAND

clindamycin phosphate topical lotion

1%*

For topical use only

Rx only



PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton - Lotion

NDC 59762-3744-1
60 mL

GREENSTONE® BRAND

clindamycin phosphate topical lotion

1%*

For topical use only

Rx only

PRINCIPAL DISPLAY PANEL - 60 gram Tube Label

NDC 59762-3743-2
60 gram

GREENSTONE® BRAND

clindamycin phosphate
topical gel

1%*

For topical use only

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.

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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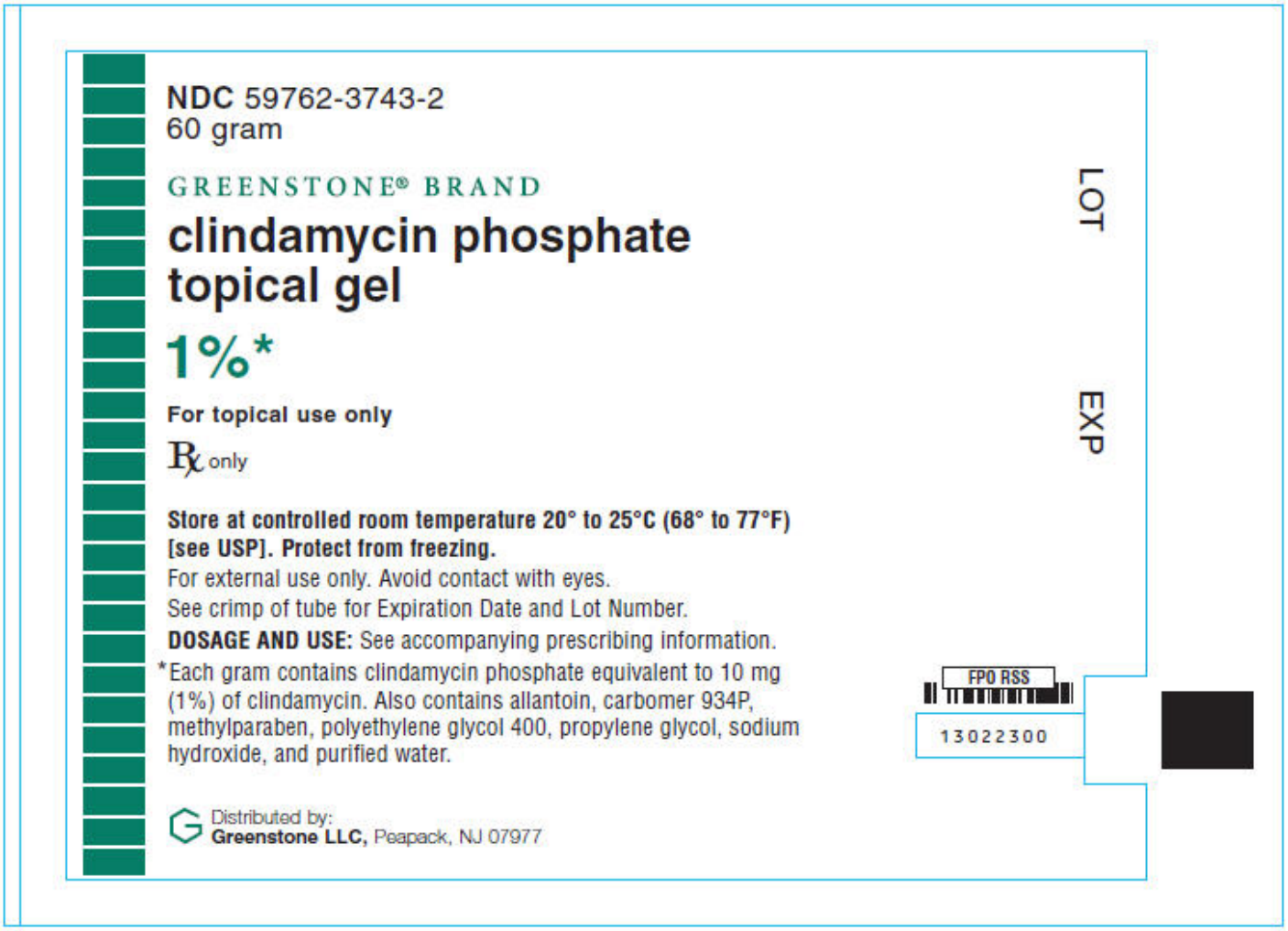
Distributed by:
Greenstone LLC, Peapack, NJ 07977



PRINCIPAL DISPLAY PANEL - 60 gram Tube Carton

NDC 59762-3743-2
60 gram

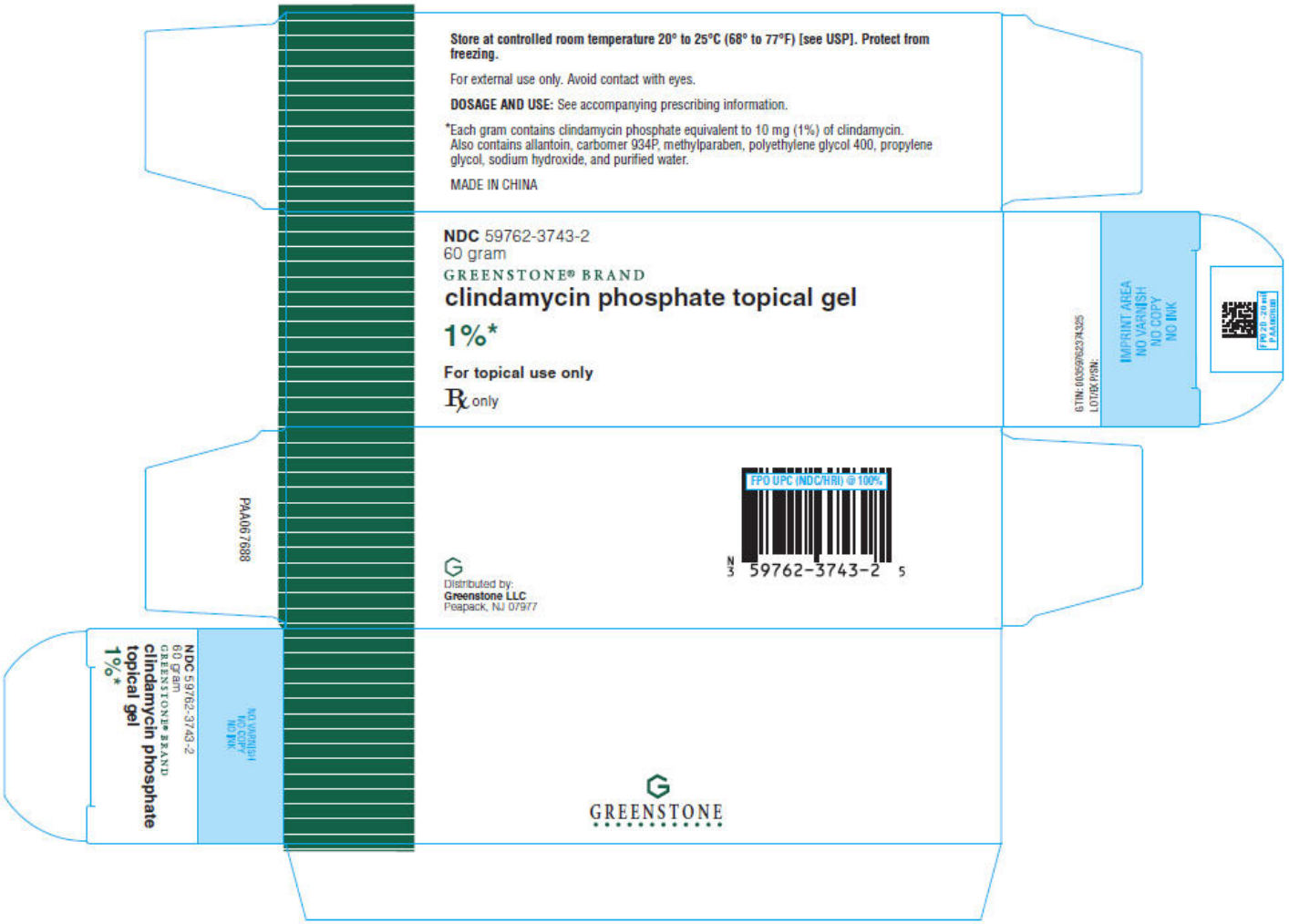
GREENSTONE® BRAND

clindamycin phosphate topical gel

1%*

For topical use only

Rx only



CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59762-3728
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:59762-3728-1	1 in 1 CARTON	06/20/1980	07/31/2018
1		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:59762-3728-2	1 in 1 CARTON	06/20/1980	07/31/2018
2		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:59762-3728-3	60 in 1 CARTON	06/20/1980	12/31/2018
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 AUTHORIZED GENERIC	NDA050537	06/20/1980	12/31/2018

CLINDAMYCIN PHOSPHATE

clindamycin phosphate lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59762-3744
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)	
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:59762-3744-1	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 AUTHORIZED GENERIC	NDA050600	05/31/1989	

CLINDAMYCIN PHOSPHATE

clindamycin phosphate gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59762-3743
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 HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59762-3743-1	1 in 1 CARTON	01/07/1987	

1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59762-3743-2	1 in 1 CARTON	01/07/1987	
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
NDA AUTHORIZED GENERIC	NDA050615	01/07/1987	

Labeler - Greenstone LLC (825560733)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(59762-3728, 59762-3743, 59762-3744) , MANUFACTURE(59762-3728, 59762-3743, 59762-3744) , API MANUFACTURE(59762-3728, 59762-3743, 59762-3744) , PACK(59762-3728, 59762-3743, 59762-3744) , LABEL(59762-3728, 59762-3743, 59762-3744)

Revised: 11/2021 Greenstone LLC