NUCARARXPAK- clindamycin phosphate,benzoyl peroxide,cetaphil
NuCare Pharmaceuticals,Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Rx only

For External Use.

DESCRIPTION

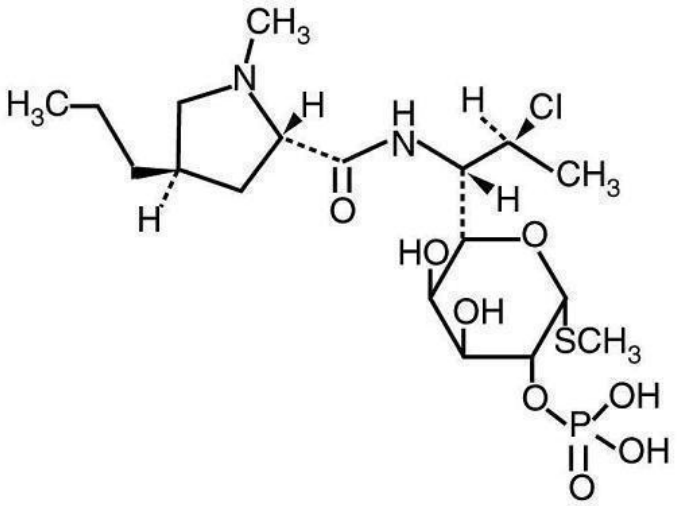
Clindamycin Phosphate Topical Solution and Clindamycin Phosphate Lotion (Clindamycin Phosphate Topical Suspension USP, 1%) contain clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Clindamycin Phosphate Gel contains clindamycin phosphate, USP, at a concentration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



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

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 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

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 human 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 breastfed infant's gastrointestinal flora. If oral or intravenous clindamycin is required by a nursing mother, it is not a reason to discontinue breastfeeding, but an alternate drug may be preferred. Monitor the 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 breastfed child from clindamycin or from the underlying maternal condition.

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 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

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

46206122A/46206123A

R03/18

BENZOYL PEROXIDE (45802-101-96)

ACTIVE INGREDIENT

Benzoyl peroxide 2.5%

PURPOSE

Acne treatmentD

USE

for the treatment of acne

WARNINGS

For external use only

DO NOT USE

if you

have very sensitive skin

are sensitive to benzoyl peroxide

WHEN USING THIS PRODUCT

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

STOP USE AND ASK A DOCTOR IF

- irritation becomes severe

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

DIRECTIONS

- Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily

because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor

- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

OTHER INFORMATION

- store at 20°-25° (68°-77°F)

INACTIVE INGREDIENTS

- carbomer homopolymer, dimethicone, disodium lauryl sulfosuccinate, edetate disodium, glycerin, methylparaben, poloxamer 182, purified water, silicon dioxide, sodium hydroxide

QUESTIONS OR COMMENTS?

1-800-917-9260

ACTIVE INGREDIENTS

Octinoxate 7.5% .....Sunscreen
Octisalate 5% .....Sunscreen
Octocrylene 7% .....Sunscreen
Oxybenzone 6% .....Sunscreen
Titanium Dioxide 5.7% .....Sunscreen

USES

Helps prevent sunburn.

WARNINGS

Skin Cancer/Skin Aging Alert:

Spending time in the sun increases your risk of skin cancer and early aging. This product

has been shown to help prevent sunburn, not skin cancer or early aging.

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Apply liberally 15 minutes before sun exposure. • Use a water resistant sunscreen if swimming or sweating. • Reapply at least every 2 hours. • Children under 6 months: ask a doctor.

INACTIVE INGREDIENTS

Water, Propylene Glycol, Glycerin, Dimethicone, VP/Eicosene Copolymer, Cyclomethicone, Stearic Acid, Dimethiconol, Potassium Cetyl Phosphate, Glyceryl Stearate, PEG-100 Stearate, Aluminum Hydroxide, Disodium EDTA, Tocopherol, Triethanolamine, Phenoxyethanol, Ethylparaben, Chlorphenesin, Cetyl Alcohol, Carbomer, Methylparaben, Xanthan Gum

OTHER INFORMATION

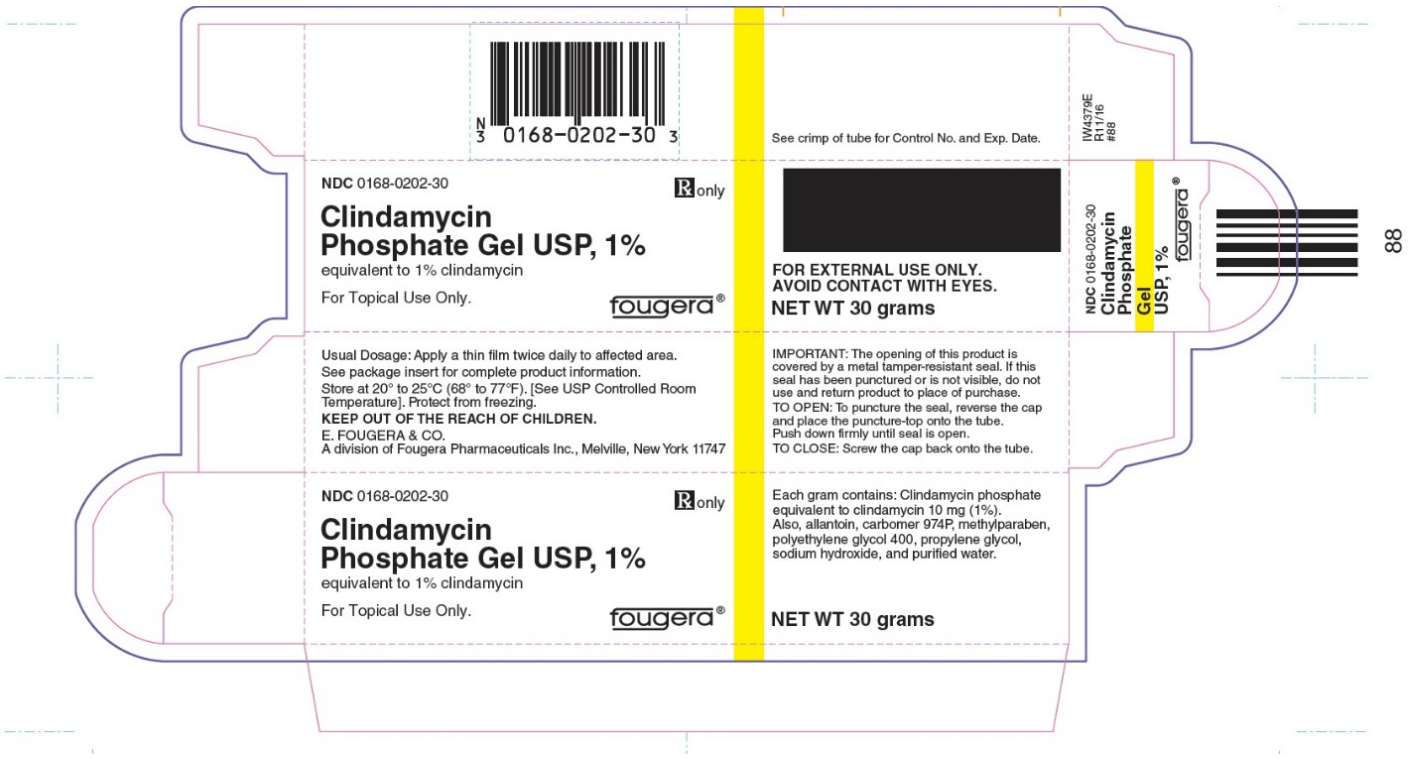
• Protect this product from excessive heat and direct sun.

QUESTIONS

1-866-735-4137

CETAPHIL DAILY FACIAL MOISTURIZER (0299-4930-02)

CLINDAMYCIN PHOSPHATE GEL 30 g(0168-0202-30)



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

BENZOYL PEROXIDE 60g (45802-101-96)

CETAPHIL DAILY FACIAL MOISTURIZER 50mL (0299-4930-02)

NuCaraRXPAK (70859-050-01)

NUCARARXPAK

clindamycin phosphate,benzoyl peroxide,cetaphil kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70859-050

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70859-050-01	1 in 1 KIT	06/10/2019	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 TUBE	30 g
Part 2	1 TUBE	60 g
Part 3	1 TUBE	50 mL

Part 1 of 3

CLINDAMYCIN PHOSPHATE

clindamycin phosphate gel

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0168-0202-30	1 in 1 CARTON		
1		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
ANDA	ANDA064160	06/28/2000	

Part 2 of 3

BENZOYL PEROXIDE

benzoyl peroxide gel

Product Information

Item Code (Source)	NDC:45802-101
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 182 (UNII: JX0HIX6OAG)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DISODIUM LAURYL SULFOSUCCINATE (UNII: P160Q81342)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-101-96	1 in 1 CARTON		
1		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

OTC monograph final	part333D	03/13/2012	

Part 3 of 3

CETAPHIL DAILY FACIAL MOISTURIZER WITH SUNCREEN SPF 50

octinoxate, octisalate, octocrylene, oxybenzone, titanium dioxide lotion

Product Information

Item Code (Source)	NDC:0299-4930
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	57 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
ETHYLPARABEN (UNII: 14255EXE39)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4930-02	1 in 1 CARTON		
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/28/2000	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	manufacture(70859-050)

Revised: 7/2021 NuCare Pharmaceuticals,Inc.