CLINDACIN ETZ- clindamycin phosphate swab
CLINDACIN ETZ- clindamycin phosphate
Medimetriks Pharmaceuticals, Inc.

Clindacin® ETZ
Clindamycin Phosphate Topical Solution
USP, 1% (Pledgets)

R_x Only

For External Use

DESCRIPTION

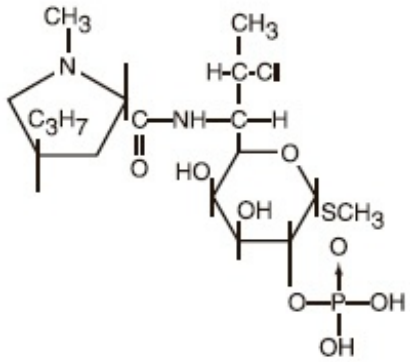
Clindacin® ETZ contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter.

Each **Clindacin® ETZ** 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, purified water, and sodium hydroxide (to adjust the pH to between 4.0 - 7.0).

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

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

Clindacin® ETZ is 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

Clindacin® ETZ is 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

Clindacin® ETZ 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

Pregnancy Category B

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 **Clindacin® ETZ**. 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 have not been established.

Geriatric Use

Clinical studies for clindamycin phosphate topical solution USP, 1% 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 topical 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.

To report SUSPECTED ADVERSE REACTIONS, contact Medimetriks Pharmaceuticals, Inc., at 1-973-882-7512 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Topically applied **Clindacin® ETZ** can be absorbed in sufficient amounts to produce systemic effects (see **WARNINGS**).

DOSAGE AND ADMINISTRATION

Do not use if the unit-dose pouch seal is broken. Remove pledget just before use. Use

pledget to apply a thin film of Clindamycin Phosphate Topical Solution to the affected area twice daily. More than one pledget may be used. Each pledget should be used only once and then discarded.

HOW SUPPLIED

Clindacin® ETZ (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)) is available as follows:

A carton containing 60 individually wrapped single-use pledget applicators (NDC 43538-172-60)

STORAGE

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

Manufactured by: Ferndale Laboratories, Ferndale, MI 48220

Rev 09/22
IP032-R4
61H72 EK J1

PRINCIPAL DISPLAY PANEL - 60 Pledget Carton

NDC 43538-172-60

For Topical Use Only

R_x Only

Clindacin® ETZ
Clindamycin Phosphate
Topical Solution USP, 1%* (Pledgets)
*equivalent to 1% (10 mg/mL) clindamycin

60 Individual Pledgets

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-172-60

For Topical Use Only

Rx Only

Clindacin® ETZ

Clindamycin Phosphate
Topical Solution USP, 1%* (Pledgets)

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

60 *Individual Pledgets*

MEDIMETRIKS PHARMACEUTICALS, INC.

NDC 43538-172-60

For Topical Use Only

Rx Only

Clindacin® ETZ

Clindamycin Phosphate
Topical Solution USP, 1%* (Pledgets)

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

60 *Individual Pledgets*

MEDIMETRIKS PHARMACEUTICALS, INC.

P16690

USUAL DOSAGE: See package insert for complete product information.

For external use only. Avoid contact with eyes.

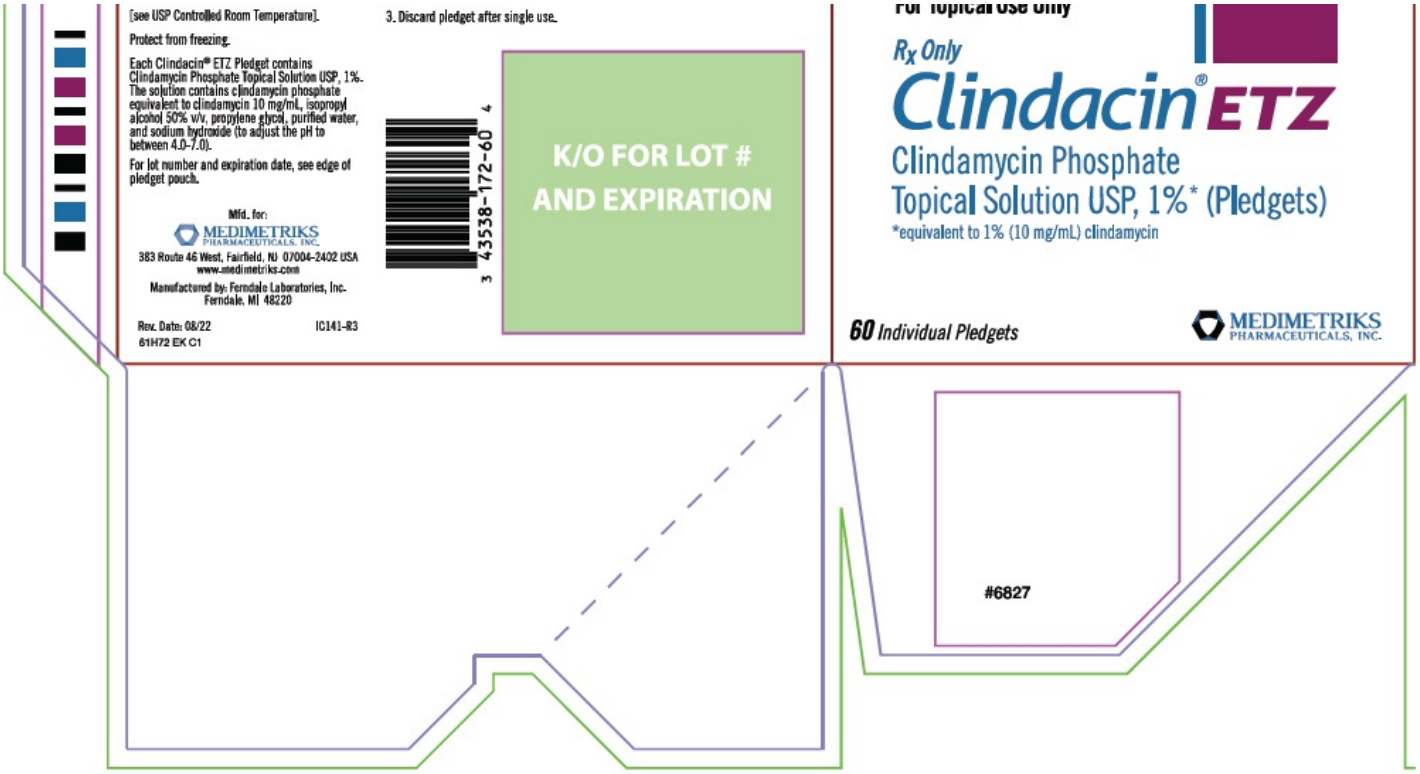
Store at 20-25°C (68-77°F)

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.

NDC 43538-172-60

For Topical Use Only



PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 43538-173-60

R_x Only

Clindacin® ETZ
KIT

Clindamycin Phosphate
Topical Solution USP, 1%*
(Pledgets)
*equivalent to 1% (10 mg/mL) clindamycin

CONTENTS:
Clindacin® ETZ Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)
1 - Carton (60 Pledgets)

AcuWash® Moisturizing Daily Cleanser
1 - Bottle (16 fl. oz.)

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-173-60

R_x Only

Clindacin® ETZ

Clindamycin Phosphate Topical Solution USP, 1%* (Pledgets) KIT

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

CONTENTS:

Clindacin® ETZ Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)
1 - Carton (60 Pledgets)

AcuWash® Moisturizing Daily Cleanser
1 - Bottle (16 fl. oz.)

MEDIMETRIKS PHARMACEUTICALS, INC.

NDC 43538-173-60

R_x Only

Clindacin® ETZ

Clindamycin Phosphate Topical Solution USP, 1%* KIT

(Pledgets) *equivalent to 1% (10 mg/mL) clindamycin

MEDIMETRIKS PHARMACEUTICALS, INC.

CONTENTS:

Clindacin® ETZ Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)
1 - Carton (60 Pledgets)

AcuWash® Moisturizing Daily Cleanser
1 - Bottle (16 fl. oz.)

NDC 43538-173-60

R_x Only

Clindacin® ETZ

Clindamycin Phosphate Topical Solution USP, 1%* (Pledgets)

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

Manufactured for: Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512 • www.medimetriks.com
Manufactured by: Ferndale Laboratories, Inc., Ferndale, MI 48220
Made in USA

AcuWash®

Moisturizing Daily Cleanser
with Aloe & Green Tea

Manufactured for: Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512 • www.medimetriks.com
No Animal Testing
Made in USA

NO VARNISH AREA

Serialization code, Lot # and
Expiration Date imprint goes here

IC119-R3
REV. 2/2023


NDC 43538-173-60
Rx Only
Clindacin® ETZ
Clindamycin Phosphate
Topical Solution USP, 1%*
(Pledgets) *equivalent to 1% (10 mg/mL) clindamycin
KIT
CONTENTS:
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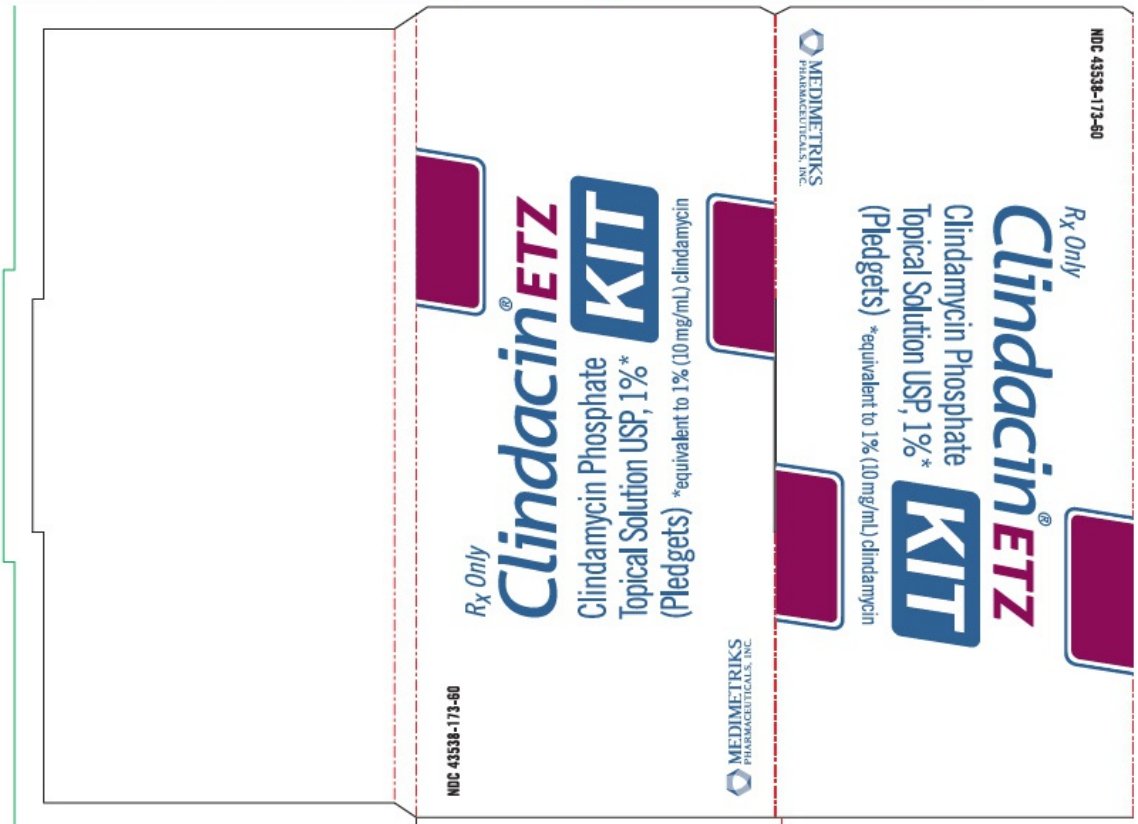
1 - Carton (60 Pledgets)
AcuWash® Moisturizing Daily Cleanser
1 - Bottle (16 fl. oz.)
MEDIMETRIKS PHARMACEUTICALS, INC.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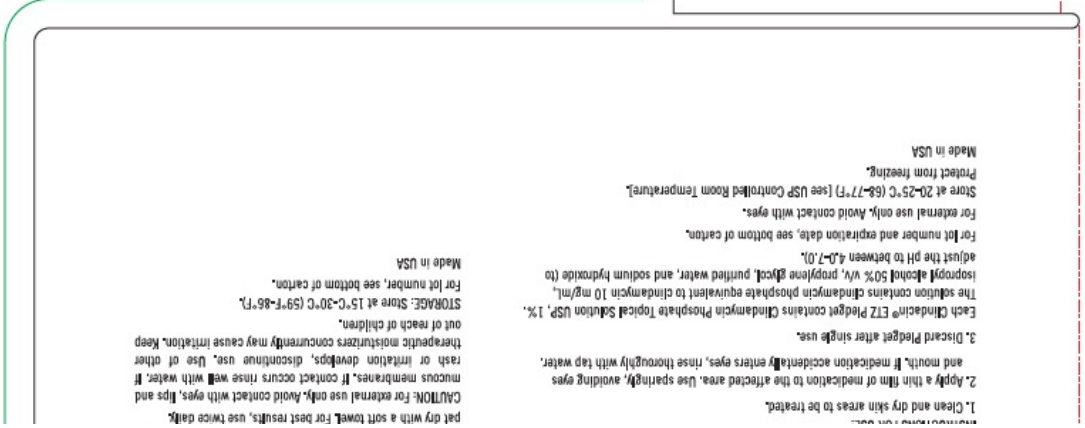
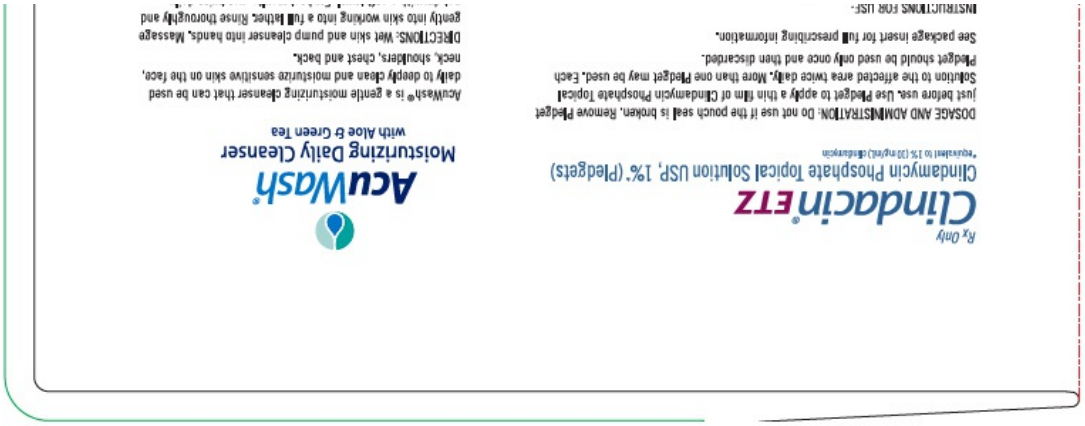
MEDIMETRIKS PHARMACEUTICALS, INC.


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.
Each Clindacin® ETZ Pledget contains Clindamycin Phosphate Topical Solution USP, 1%. The solution contains clindamycin phosphate equivalent to clindamycin 10 mg/mL, isopropyl alcohol 50% v/v, propylene glycol, purified water, and sodium hydroxide to adjust the pH to between 4.0–7.0).
For external use only. Avoid contact with eyes.
Store at 20–25°C (68–77°F) [see USP Controlled Room Temperature].
Protect from freezing.
Made in USA
pat dry with a soft towel. For best results, use twice daily.
CAUTION: For external use only. Avoid contact with eyes, lips and mucous membranes. If contact occurs rinse well with water. If rash or irritation develops, discontinue use. Use of other therapeutic moisturizers concurrently may cause irritation. Keep out of reach of children.
STORAGE: Store at 15°C-30°C (59°F–86°F).
For lot number, see bottom of carton.
Made in USA



CLINDACIN ETZ

clindamycin phosphate swab

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-172
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
clindamycin phosphate (UNII: EH6D7113I8) (clindamycin - UNII:3U02EL437C)	clindamycin	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
isopropyl alcohol (UNII: ND2M416302)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43538-172-60	60 in 1 CARTON	06/15/2013	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065049	06/15/2013	

CLINDACIN ETZ

clindamycin phosphate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-173

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43538-173-60	1 in 1 CARTON	06/15/2013	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 CARTON	60
Part 2	1 BOTTLE	473 mL

Part 1 of 2

CLINDACIN ETZ

clindamycin phosphate swab

Product Information	
Item Code (Source)	NDC:43538-172
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
clindamycin phosphate (UNII: EH6D7113I8) (clindamycin - UNII:3U02EL437C)	clindamycin	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
isopropyl alcohol (UNII: ND2M416302)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging			
#	**Item Code**	**Package Description**	**Marketing Start**	**Marketing End**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-172-01	60 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065049	06/15/2013	

Part 2 of 2

ACUWASH

cleansing (cold creams, cleansing lotions, liquids, and pads) cream

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**water** (UNII: 059QF0KO0R)	
INGR	**cetyl alcohol** (UNII: 936JST6JCN)	
INGR	**laureth-12** (UNII: OAH19558U1)	
INGR	**sodium coco-sulfate** (UNII: 3599J29ANH)	
INGR	**sodium lauroamphoacetate** (UNII: SLK428451L)	
INGR	**propylene glycol** (UNII: 6DC9Q167V3)	
INGR	**aloe vera leaf** (UNII: ZY81Z83H0X)	
INGR	**glycerin** (UNII: PDC6A3C0OX)	
INGR	**magnesium aluminum silicate** (UNII: 6M3P64V0NC)	
INGR	**edetate disodium** (UNII: 7FLD91C86K)	
INGR	**xanthan gum** (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		473 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
Cosmetic		06/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065049	06/15/2013	

Labeler - Medimetriks Pharmaceuticals, Inc. (019903816)

Establishment

Name	Address	ID/FEI	Business Operations
Perrigo Inc.		078846912	MANUFACTURE(43538-172, 43538-173)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories Inc		005320536	MANUFACTURE(43538-172) , PACK(43538-172) , LABEL(43538-172) , ANALYSIS(43538-172)

Establishment

Name	Address	ID/FEI	Business Operations
Marketin Advertising Promotions, Inc.		797063526	PACK(43538-173)

Revised: 11/2023 Medimetriks Pharmaceuticals, Inc.