

CLINDAVIX- clindamycin phosphate, dimethicone
Primary Pharmaceuticals, Inc.

Clindavix

For External Use

Rx Only

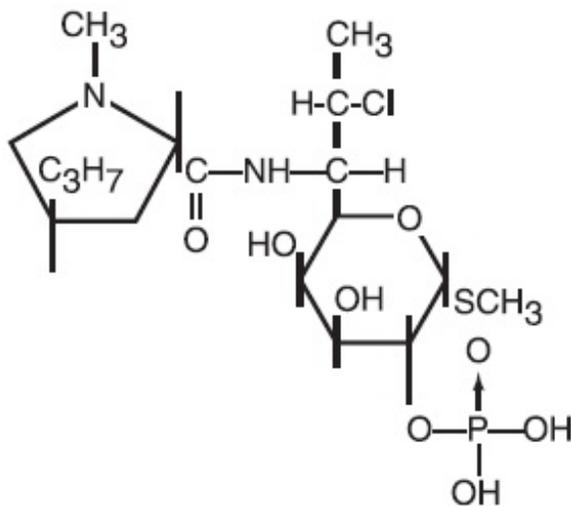
DESCRIPTION

Clindamycin Phosphate Topical Solution USP, 1% contains clindamycin phosphate USP at a concentration equivalent to 10 mg clindamycin per milliliter.

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

Clindamycin Phosphate Topical Solution USP, 1% 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

Clindamycin Phosphate Topical Solution USP, 1% 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 -

Clindamycin Phosphate Topical Solution USP, 1% 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 Clindamycin Phosphate Topical Solution USP, 1%. 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].

Treatment Emergent Adverse Event	Number of Patients Reporting Events		
	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 Topical Solution USP, 1% can be absorbed in sufficient amounts to produce systemic effects (see **WARNINGS**).

DOSAGE AND ADMINISTRATION

Apply a thin film of Clindamycin Phosphate Topical Solution USP, 1% to the affected area twice daily. Keep container tightly closed.

HOW SUPPLIED

Clindamycin Phosphate Topical Solution USP, 1% is available as follows:

60 mL applicator bottle (NDC 45802- 562-02)

STORAGE

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

Manufactured By

Perrigo

Bronx, NY 10457

Distributed By Perrigo

Allegan, MI 49010

www.perrigo.com

Rev 05-18

: 7F100 RC J4

Dynasield -Active Ingredients

Active Ingredient Purpose

Zinc Oxide 2% Diaper Rash

Dimethicone 1.8% Skin Protectant

Dynasield-When using

For External Use Only.

Do not get in eyes.

Dynas hield-Stop Use

- condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician
- over large areas of the body
- if you are allergic to any of these ingredients

Dynas hield- Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Dynas hield- Purpose

- Helps treat and prevent diaper rash
- Dries the oozing and weeping of;
- poison ivy
- poison oak
- poison sumac

Dynas hield-Dos age

For poison ivy, oak and sumac:

- Apply ointment liberally as often as needed

For diaper Rash:

- change wet and soiled diapers promptly
- clean the diaper area and allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Dynas hield-Other Information

- Do not use if seal is punctured or not visible
- Store at room temperature 15 0 °- 30 0 °C (59 0 °- 86 0 °F)
- avoid excessive heat
- contains color additives including FDC yellow # 5 (Tartrazine)

Dynas hield-Indications

Indications: For use as a general skin protectant and diaper rash.

Dynas hield-Inactive

Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-20, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender perfume, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Trolamine, Vitamin A, Water

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - CARTON



CLINDAVIX

clindamycin phosphate, dimethicone kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72275-741
---------------------	-------------------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72275-741-77	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	12/01/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 BOTTLE, WITH APPLICATOR	1 mL
Part 2	0 TUBE	1 g in 114

Part 1 of 2

CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

Product Information

Item Code (Source)	NDC:45802-562
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113B8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 mL in 1 BOTTLE, WITH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064050	09/17/2013	

Part 2 of 2

DYNASHIELD WITH DIMETHICONE

zinc oxide ointment

Product Information

Route of Administration	TOPICAL
-------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.8 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PETROLATUM (UNII: 4T6H12BN9U)	
TROLAMINE (UNII: 9O3K93S3TK)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETETH-20 (UNII: I835H2IHHX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
VITAMIN A (UNII: 81G40H8B0T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		114 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064050	09/17/2013	

Labeler - Primary Pharmaceuticals, Inc. (066126126)

Establishment

Name	Address	ID/FEI	Business Operations
Rainbow Gold		800695152	repack(72275-741)

