

CLINDAMYCIN PHOSPHATE- clindamycin phosphate solution
Zydus Lifesciences Limited

Clindamycin Phosphate Topical Solution USP, 1%

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1414-2

Clindamycin phosphate topical solution USP, 1%

Rx only

Clindamycin Phosphate Topical Solution, USP
1%*
Solution for topical use only
30 mL
Rx only

Manufactured by:
Zydus Lifesciences Ltd.
 Changodar, Ahmedabad, India

Rev.: 08/24

N 3 72578 08402 8

***Each mL contains clindamycin phosphate, USP equivalent to 10mg/mL (1%) of clindamycin. Also contains isopropyl alcohol 50% v/v, propylene glycol and purified water. Sodium hydroxide or hydrochloric acid may be added to adjust pH between 4.0 to 7.0.**
DOSAGE AND USE: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]. Protect from freezing. Store in an upright fashion.
Keep container tightly closed.
 For external use only. Avoid contact with eyes.
Keep this and all drugs out of the reach of children.
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.

CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1414
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN PHOSPHATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1414-2	1 in 1 CARTON	01/03/2019	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70771-1414-3	1 in 1 CARTON	01/03/2019	
2		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
ANDA	ANDA208767	01/03/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (650650802)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1414) , MANUFACTURE(70771-1414)

Revised: 8/2024

Zydus Lifesciences Limited