CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE - clindamycin phosphate and benzoyl peroxide gel
Zydus Lifesciences Limited

CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE GEL

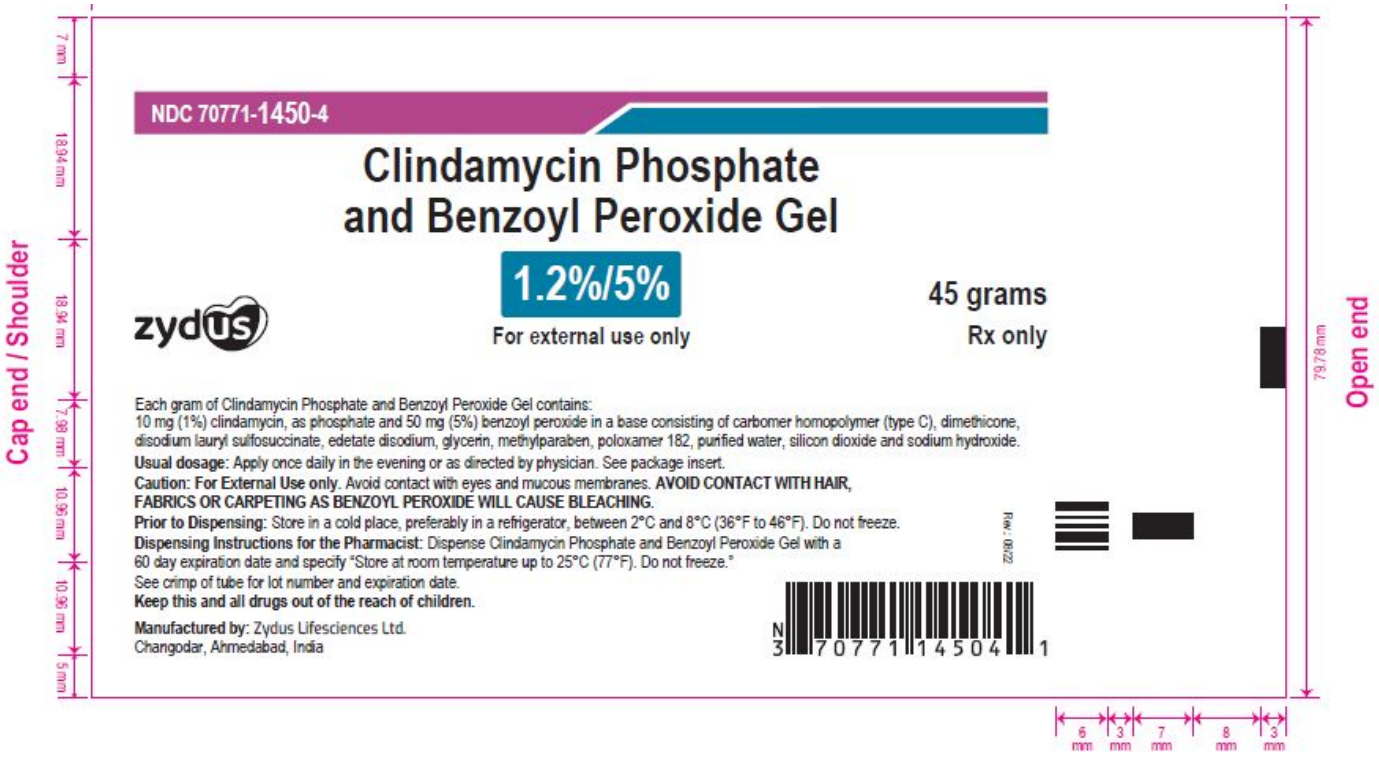
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

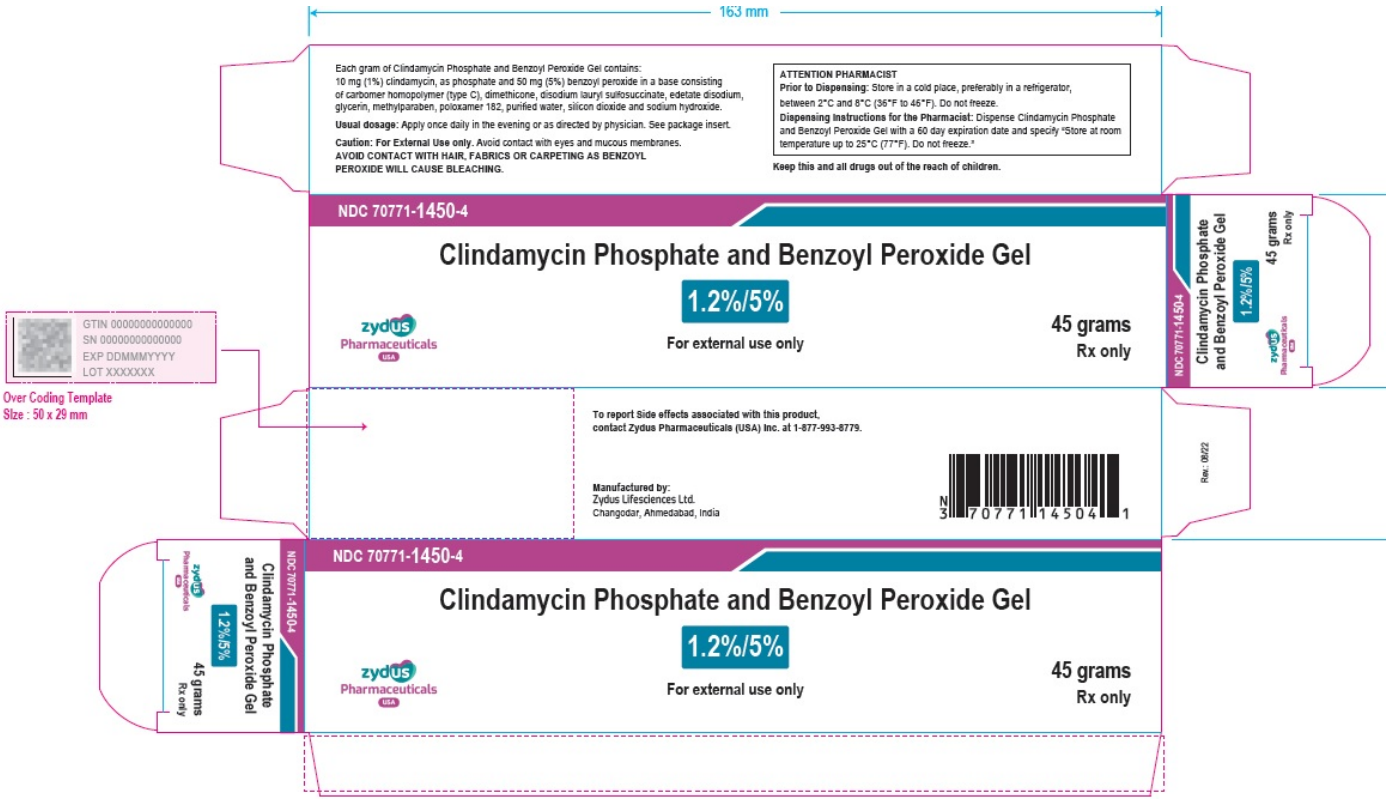
NDC 70771-1450-4

Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/5%

Rx only

45 g





CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE

clindamycin phosphate and benzoyl peroxide gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1450
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 g
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISODIUM LAURYL SULFOSUCCINATE (UNII: P160Q81342)	
EDETATE SODIUM (UNII: MP1J8420LU)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
WATER (UNII: 059QF0KO0R)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1450-4	1 in 1 CARTON	03/07/2019	
1		45 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	ANDA210794	03/07/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1450) , MANUFACTURE(70771-1450)

Revised: 8/2022 Zydus Lifesciences Limited