

**ADAPALENE AND BENZOYL PEROXIDE- adapalene and benzoyl peroxide gel**  
**Zydus Lifesciences Limited**

**ADAPALENE and BENZOYL PEROXIDE topical gel**

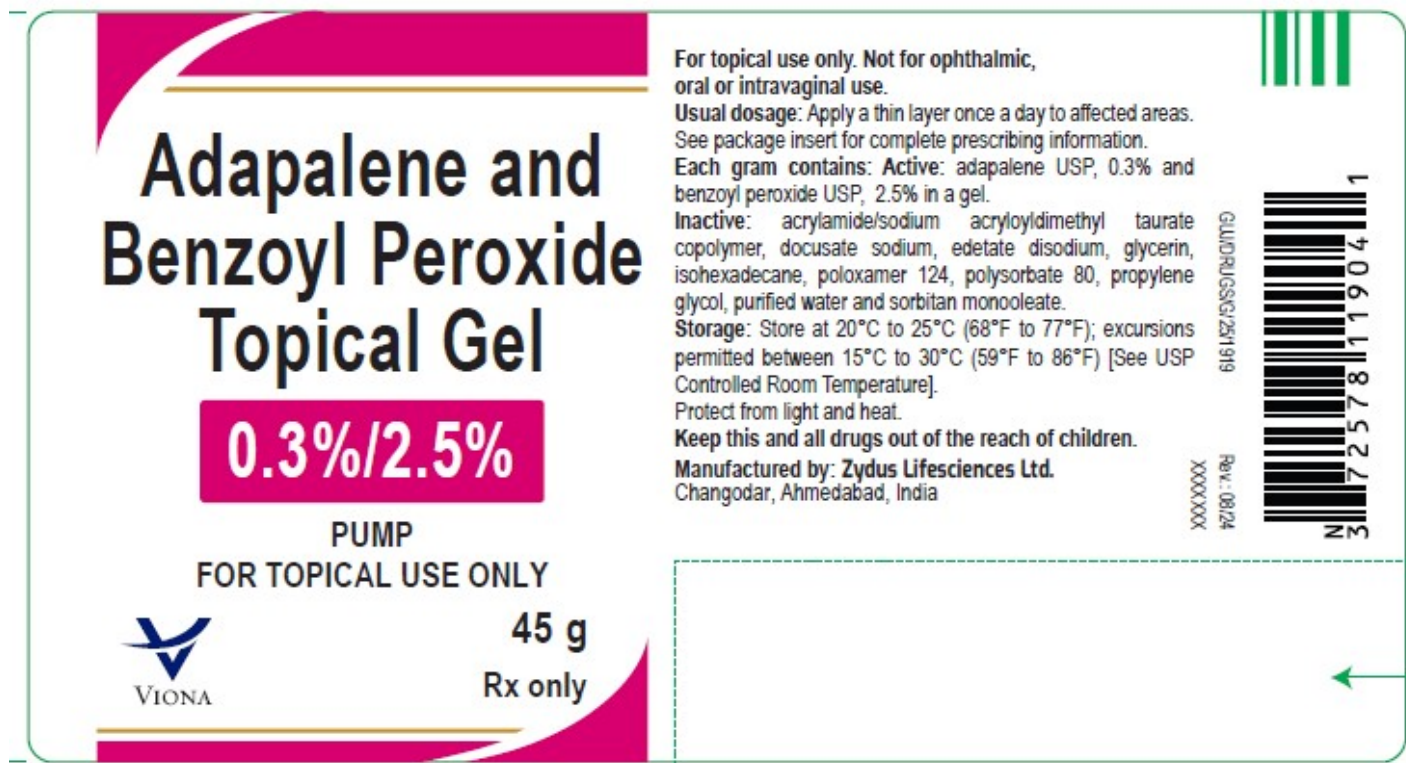
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Adapalene and benzoyl peroxide gel 0.3%/2.5%

NDC 70771-1716-4

45 g

Rx only



**ADAPALENE AND BENZOYL PEROXIDE**

adapalene and benzoyl peroxide gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1716
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

		<b>Ratio of</b>	
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Ingredient Name	Basis of Strength	Strength
<b>ADAPALENE</b> (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	3 mg in 1 g
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	25 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>POLOXAMER 124</b> (UNII: 1S66E28KXA)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S)</b> (UNII: 5F4963KLHS)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	WHITE (white to very pale yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1716-4	1 in 1 BOTTLE, PUMP	06/06/2022	
1		45 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:70771-1716-3	1 in 1 BOTTLE, PUMP	06/06/2022	
2		60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214553	06/06/2022	

**Labeler** - Zydus Lifesciences Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1716) , MANUFACTURE(70771-1716)

Revised: 8/2024

Zydus Lifesciences Limited