

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

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1716 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF) | ADAPALENE | 3 mg in 1 g |
| BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM) | BENZOYL PEROXIDE | 25 mg in 1 g |

Inactive Ingredients

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

Product Characteristics

| | | | |
|-----------------|-----------------------------------|---------------------|--|
| Color | WHITE (white to very pale yellow) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

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 |
|----------------------------|---------|-----------|--|
| Zyduz Lifesciences Limited | | 650650802 | ANALYSIS(70771-1716) , MANUFACTURE(70771-1716) |

Revised: 6/2022

Zyduz Lifesciences Limited