**TRETINOIN- tretinoin cream**
**Zydus Lifesciences Limited**

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**Tretinoin Cream, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1873-2

Tretinoin cream USP, 0.1%

20 grams

Rx


| **TRETINOIN**<br>tretinoin cream | | | |
|---|---|---|---|
| **Product Information** | | | |
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1873 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **TRETINOIN** (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R) | TRETINOIN | 1 mg in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K) | |
| **ISOPROPYL MYRISTATE** (UNII: 0RE8K4LNJS) | |
| **POLYOXYL 40 STEARATE** (UNII: 13A4J4NH9I) | |
| **SORBIC ACID** (UNII: X045WJ989B) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1873-2 | 1 in 1 CARTON | 04/30/2024 | |
| **1** | | 20 g in 1 TUBE; Type 0: Not a Combination Product | | |
| **2** | NDC:70771-1873-4 | 1 in 1 CARTON | 04/30/2024 | |
| **2** | | 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 | ANDA218561 | 04/30/2024 | |

## Labeler - Zydus Lifesciences Limited (918596198)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Zydus Lifesciences Limited | | 650650802 | ANALYSIS(70771-1873) , MANUFACTURE(70771-1873) |

Revised: 4/2024 Zydus Lifesciences Limited