**IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / TRETINOIN 0.05%-**
**imiquimod 5% / levocetirizine dihydrochloride 1% / tretinoin 0.05% gel**
**Sincerus Florida, LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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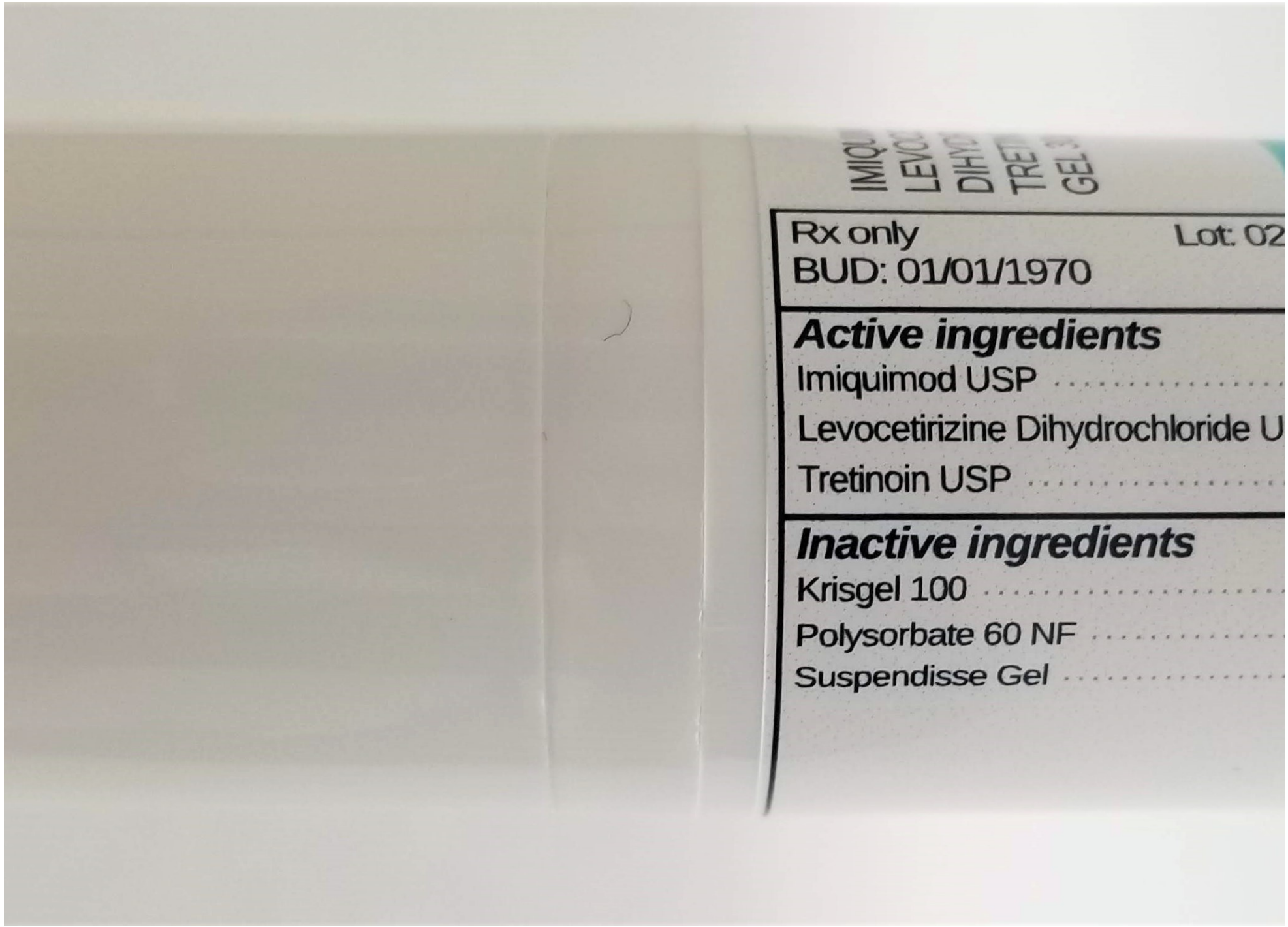
**IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / TRETINOIN 0.05%**

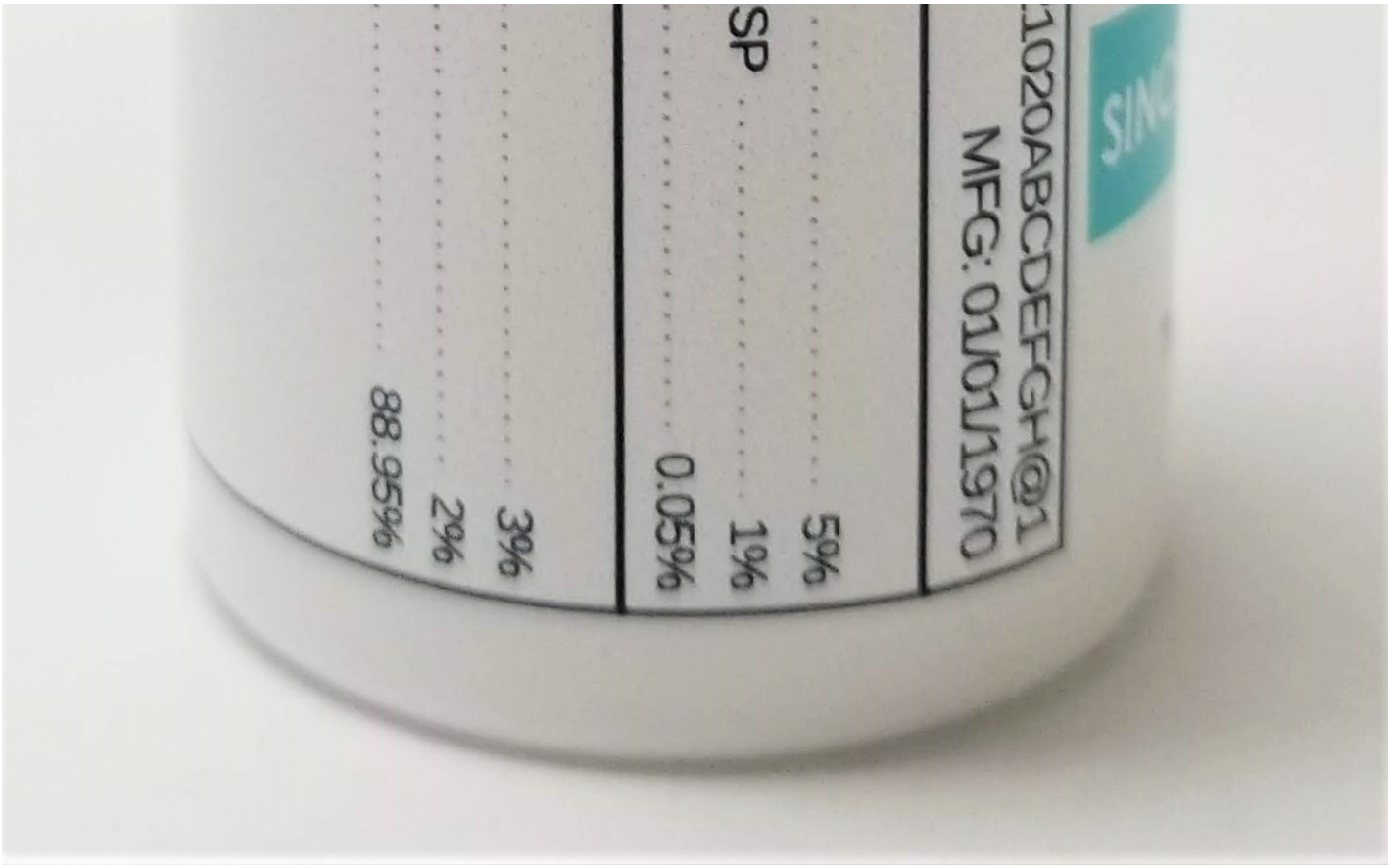
**Directions for use**

**Sincerus Florida, LLC adverse reactions.**


Direction
As directed b
Apply topical
Store at cont
Sincerus Flo
3265 W McN
To report sus
Sincerus Flo
at www.FDA.
C

**Active, inactive**


IMIQ
LEVO
DIHY
TRET
GEL
Rx only
Lot: 02
BUD: 01/01/1970
Active ingredients
Imiquimod USP
Levocetirizine Dihydrochloride U
Tretinoin USP
Inactive ingredients
Krisgel 100
Polysorbate 60 NF
Suspendisse Gel




**NDC 72934-1126-2 IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / TRETINOIN 0.05% gel 30gm**

Rx only

BUD: 01/01/2070

Lot: 021020ABCD

NDC 72934-1126-2

IMIQUIMOD USP 5%
LEVOCETIRIZINE
DIHYDROCHLORIDE USP 1%
TRETINOIN USP 0.05%
GEL 30gm

SINCERUS FLORIDA


# IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / TRETINOIN 0.05%

imiquimod 5% / levocetirizine dihydrochloride 1% / tretinoin 0.05% gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:72934-1126 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **TRETINOIN** (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R) | TRETINOIN | 0.05 g in 100 g |
| **LEVOCETIRIZINE DIHYDROCHLORIDE** (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O) | LEVOCETIRIZINE DIHYDROCHLORIDE | 1 g in 100 g |
| **IMIQUIMOD** (UNII: P1QW714R7M) (IMIQUIMOD - UNII:P1QW714R7M) | IMIQUIMOD | 5 g in 100 g |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| 1 | NDC:72934-1126- | 30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination | 05/01/2019 | |

| | | | | |
|---|---|---|---|---|
| 2 | Product | | 05/01/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 05/01/2019 | |

## Labeler - Sincerus Florida, LLC (080105003)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Sincerus Florida, LLC | | 080105003 | manufacture(72934-1126) |

Revised: 4/2019 Sincerus Florida, LLC